

|                                                                                         |            |                  |   |
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| <b>DOC. TITLE:</b> Declaration of Conformity MDR Kendall Calcium Alginate Dressings CAH |            |                  |   |
| <b>DOCUMENT NO:</b>                                                                     | RE00205881 | <b>REVISION:</b> | 2 |
|                                                                                         |            |                  |   |

## DECLARATION OF CONFORMITY



**CardinalHealth**

We, Cardinal Health 200 LLC, declare that the products covered in this EU Declaration of Conformity meet the provision of the Medical Device Regulation (EU) 2017/745.

|                                                       |                                                                                                                                                      |
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| <b>Declaration of Conformity Number</b>               | RE00205881                                                                                                                                           |
| <b>Technical Documentation Number</b>                 | RE00249263                                                                                                                                           |
| <b>Manufacturer's Name</b>                            | Cardinal Health 200, LLC                                                                                                                             |
| <b>Manufacturer's Address</b>                         | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                          |
| <b>Single Registration Number</b>                     | US-MF-000006765                                                                                                                                      |
| <b>Authorized Representative's Name and Address</b>   | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                      |
| <b>Notified body's Name and Identification Number</b> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Identification Number: 2797                           |
| <b>CE Certificate Number</b>                          | MDR 784266                                                                                                                                           |
| <b>Product Category</b>                               | Alginate Dressings, Combined with other substances                                                                                                   |
| <b>Basic UDI-DI</b>                                   | Refer to Attachment 1                                                                                                                                |
| <b>EMDN</b>                                           | Refer to Attachment 1                                                                                                                                |
| <b>Product Code, Trade Name and Description</b>       | Refer to Attachment 1                                                                                                                                |
| <b>Intended Purpose</b>                               | Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from contamination. |
| <b>Classification and Rule</b>                        | Refer to Attachment 1                                                                                                                                |
| <b>Common Specifications</b>                          | Not Applicable                                                                                                                                       |
| <b>Where appropriate, add applicable</b>              | Not Applicable                                                                                                                                       |

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| DECLARATION OF CONFORMITY    |                             |
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| <b>Union legislation</b>     |                             |
| <b>Conformity Assessment</b> | Annex IX Chapters I and III |

| SIGNATURE SECTION                                                                                                                              |                                                                                                                            |
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| This EU Declaration of Conformity is issued for and on behalf of and under the sole responsibility of the Legal Manufacturer identified above. |                                                                                                                            |
| <b>Place of Issue</b>                                                                                                                          | Waukegan, IL 60085 USA                                                                                                     |
| <b>Signature/ Date</b>                                                                                                                         | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Name and Function</b>                                                                                                                       | Yuan Zhou<br>Regulatory Affairs                                                                                            |

| Product Code List |                                                                  |                          |           |                         |
|-------------------|------------------------------------------------------------------|--------------------------|-----------|-------------------------|
| Product Code      | Trade Name and Description                                       | Basic UDI-DI             | EMDN      | Classification and Rule |
| 9233              | Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm)  | 06301400000000000002556P | M04040202 | Class: IIb<br>Rule: 4   |
| 9232              | Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)    | 06301400000000000002556P | M04040202 | Class: IIb<br>Rule: 4   |
| 9238              | Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)  | 06301400000000000002556P | M04040202 | Class: IIb<br>Rule: 4   |
| 9242              | Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)  | 06301400000000000002556P | M04040202 | Class: IIb<br>Rule: 4   |
| 9239              | Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm) | 06301400000000000002556P | M04040202 | Class: IIb<br>Rule: 4   |
| 9235              | Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)    | 06301400000000000002556P | M04040202 | Class: IIb<br>Rule: 4   |
| 9240              | Kendall™ Calcium Alginate Dressing,                              | 06301400000000000002556P | M04040202 | Class: IIb              |

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| Product Code List |                                                                      |                           |           |                       |
|-------------------|----------------------------------------------------------------------|---------------------------|-----------|-----------------------|
|                   | 4" x 5-1/2" (10.2 cm x 14 cm)                                        |                           |           | Rule: 4               |
| 9236              | Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm) | 063014000000000000002556P | M04040202 | Class: IIb<br>Rule: 4 |
| 9231              | Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)              | 063014000000000000002556P | M04040202 | Class: IIb<br>Rule: 4 |
| 9243              | Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)                 | 063014000000000000002556P | M04040202 | Class: IIb<br>Rule: 4 |
| 9244              | Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)               | 063014000000000000002556P | M04040202 | Class: IIb<br>Rule: 4 |

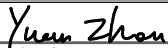
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## CROATIAN

| <b>IZJAVA O SUKLADNOSTI</b><br><b>DECLARATION OF CONFORMITY</b>                                                   |                                                                                                                                                                                                                                                                                                                    |
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| <br><b>CardinalHealth</b>         | <b>MDR:</b> Mi, Cardinal Health 200 LLC, izjavljujemo da proizvodi na koje se odnosi ova Izjava o sukladnosti EU ispunjavaju odredbe Uredbe o medicinskim proizvodima (EU) 2017/745.                                                                                                                               |
| <b>Broj izjave o sukladnosti</b><br><i>Declaration of Conformity Number</i>                                       | RE00205881                                                                                                                                                                                                                                                                                                         |
| <b>Broj tehničke dokumentacije</b><br><i>Technical Documentation Number</i>                                       | RE00249263                                                                                                                                                                                                                                                                                                         |
| <b>Naziv proizvođača</b><br><i>Manufacturer's Name</i>                                                            | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                                           |
| <b>Adresa proizvođača</b><br><i>Manufacturer's Address</i>                                                        | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                                        |
| <b>Jedinstveni registracijski broj</b><br><i>Single Registration Number</i>                                       | US-MF-000006765                                                                                                                                                                                                                                                                                                    |
| <b>Naziv i adresa ovlaštenog predstavnika</b><br><i>Authorized Representative's Name and Address</i>              | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                                    |
| <b>Naziv i identifikacijski broj prijavljenog tijela</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Identifikacijski broj: 2797                                                                                                                                                                                         |
| <b>Broj certifikata CE</b><br><i>CE Certificate Number</i>                                                        | MDR 784266                                                                                                                                                                                                                                                                                                         |
| <b>Kategorija proizvoda</b><br><i>Product Category</i>                                                            | Alginatne obloge, u kombinaciji s drugim tvarima<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                                             |
| <b>Osnovni UDI-DI</b><br><i>Basic UDI-DI</i>                                                                      | Pogledajte Prilog I/ Refer to Attachment 1                                                                                                                                                                                                                                                                         |
| <b>EMDN</b>                                                                                                       | Pogledajte Prilog I/ Refer to Attachment 1                                                                                                                                                                                                                                                                         |
| <b>Kôd, trgovački naziv i opis proizvoda</b><br><i>Product Code, Trade Name and Description</i>                   | Pogledajte Prilog I/ Refer to Attachment 1                                                                                                                                                                                                                                                                         |
| <b>Namjena</b><br><i>Intended Purpose</i>                                                                         | <p>Obloge za rane od kalcijevog alginata Kendall™ Calcium vanjske su obloge za rane namijenjene upijanju eksudata i zaštiti rane od kontaminacije.</p> <p>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from contamination.</p> |
| <b>Klasifikacija i pravilo</b><br><i>Classification and Rule</i>                                                  | Pogledajte Prilog I/ Refer to Attachment 1                                                                                                                                                                                                                                                                         |

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| <b>IZJAVA O SUKLADNOSTI</b><br><i>DECLARATION OF CONFORMITY</i>                                                                                       |                                                             |
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| <b>Zajedničke specifikacije</b><br><i>Common Specifications</i>                                                                                       | Nije primjenjivo (N/A)                                      |
| <b>Dodajte primjenjivo zakonodavstvo</b><br><b>Europske unije, gdje je to prikladno</b><br><i>Where appropriate, add applicable Union legislation</i> | Nije primjenjivo (N/A)                                      |
| <b>Ocjena sukladnosti</b><br><i>Conformity Assessment</i>                                                                                             | Prilog IX. Poglavlja I. i III./ Annex IX Chapters I and III |

| <b>ODJELJAK S POTPISIMA</b><br><i>SIGNATURE SECTION</i>                                                                         |                                                                                                                            |
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| <b>Ova Izjava o sukladnosti EU izdaje se za i u ime te na isključivu odgovornost prethodno navedenog zakonitog proizvođača.</b> |                                                                                                                            |
| <b>Mjesto izdavanja</b><br><i>Place of Issue</i>                                                                                | Waukegan, IL 60085 USA                                                                                                     |
| <b>Potpis/ Datum</b><br><i>Signature/ Date</i>                                                                                  | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Ime i funkcija</b><br><i>Name and Function</i>                                                                               | Yuan Zhou<br>Regulatory Affairs<br>Odjel za regulatorna pitanja                                                            |

**PRILOG I**  
*ATTACHMENT I*

| <b>Popis kodova proizvoda</b><br><i>Product Code List</i> |                                                                                                                                            |                                              |             |                                                                  |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|-------------|------------------------------------------------------------------|
| <b>Kôd proizvoda</b><br><i>Product Code</i>               | <b>Trgovački naziv i opis</b><br><i>Trade Name and Description</i>                                                                         | <b>Osnovni UDI-DI</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Klasifikacija i pravilo</b><br><i>Classification and Rule</i> |
| 9233                                                      | Obloga od kalcijevog alginata Kendall™, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm) | 06301400000000000002556P                     | M04040202   | Klasa/ Class: IIb<br>Pravilo/ Rule: 4                            |
| 9232                                                      | Obloga od kalcijevog alginata Kendall™, 2" x 2" (5,1 cm x 5,1 cm)                                                                          | 06301400000000000002556P                     | M04040202   | Klasa/ Class: IIb<br>Pravilo/ Rule: 4                            |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Popis kodova proizvoda</b><br><i>Product Code List</i> |                                                                                                                                                      |                          |           |                                       |
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|                                                           | Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)                                                                                        |                          |           |                                       |
| 9238                                                      | Obloga od kalcijevog alginata Kendall™, 8" x 4" (20,3 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)           | 06301400000000000002556P | M04040202 | Klasa/ Class: IIb<br>Pravilo/ Rule: 4 |
| 9242                                                      | Obloga od kalcijevog alginata Kendall™, 12" x 24" (30,5 cm x 61 cm)<br><br>Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)           | 06301400000000000002556P | M04040202 | Klasa/ Class: IIb<br>Pravilo/ Rule: 4 |
| 9239                                                      | Obloga od kalcijevog alginata Kendall™, 6" x 10" (15,2 cm x 25,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)         | 06301400000000000002556P | M04040202 | Klasa/ Class: IIb<br>Pravilo/ Rule: 4 |
| 9235                                                      | Obloga od kalcijevog alginata Kendall™, 2" x 1" (5,1 cm x 2,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)               | 06301400000000000002556P | M04040202 | Klasa/ Class: IIb<br>Pravilo/ Rule: 4 |
| 9240                                                      | Obloga od kalcijevog alginata Kendall™, 4" x 5 1/2" (10,2 cm x 14 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)       | 06301400000000000002556P | M04040202 | Klasa/ Class: IIb<br>Pravilo/ Rule: 4 |
| 9236                                                      | Obloga od kalcijevog alginata Kendall™ Plus, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm) | 06301400000000000002556P | M04040202 | Klasa/ Class: IIb<br>Pravilo/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Popis kodova proizvoda</b><br><i>Product Code List</i> |                                                                                                                                |                          |           |                                          |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|------------------------------------------|
| 9231                                                      | Obloga od kalcijevog alginata<br>Kendall™, uže 12" (30,5 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope, 12" (30.5 cm) | 06301400000000000002556P | M04040202 | Klasa/ Class:<br>IIb<br>Pravilo/ Rule: 4 |
| 9243                                                      | Obloga od kalcijevog alginata<br>Kendall™, uže 24" (61 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 24" (61 cm)      | 06301400000000000002556P | M04040202 | Klasa/ Class:<br>IIb<br>Pravilo/ Rule: 4 |
| 9244                                                      | Obloga od kalcijevog alginata<br>Kendall™, uže 36" (91,4 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 36" (91.4 cm)  | 06301400000000000002556P | M04040202 | Klasa/ Class:<br>IIb<br>Pravilo/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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## CZECH

| <b>PROHLÁŠENÍ O SHODĚ</b><br><b>DECLARATION OF CONFORMITY</b>                                                   |                                                                                                                                                                                                                                                                                                           |
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|                                 | <b>MDR:</b> Naše společnost, Cardinal Health 200 LLC, prohlašuje, že výrobky uvedené v tomto EU prohlášení o shodě splňují ustanovení nařízení (EU) 2017/745 o zdravotnických prostředcích.                                                                                                               |
| <b>Číslo prohlášení o shodě</b><br><i>Declaration of Conformity Number</i>                                      | RE00205881                                                                                                                                                                                                                                                                                                |
| <b>Číslo technické dokumentace</b><br><i>Technical Documentation Number</i>                                     | RE00249263                                                                                                                                                                                                                                                                                                |
| <b>Název výrobce</b><br><i>Manufacturer's Name</i>                                                              | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                                  |
| <b>Adresa výrobce</b><br><i>Manufacturer's Address</i>                                                          | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                               |
| <b>Jediné registrační číslo</b><br><i>Single Registration Number</i>                                            | US-MF-000006765                                                                                                                                                                                                                                                                                           |
| <b>Název a adresa autorizovaného zástupce</b><br><i>Authorized Representative's Name and Address</i>            | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                           |
| <b>Název a identifikační číslo oznámeného subjektu</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Identifikační číslo: 2797                                                                                                                                                                                  |
| <b>Číslo certifikátu CE</b><br><i>CE Certificate Number</i>                                                     | MDR 784266                                                                                                                                                                                                                                                                                                |
| <b>Kategorie výrobku</b><br><i>Product Category</i>                                                             | Alginátová krytí, v kombinaci s jinými látkami<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                                      |
| <b>Základní UDI-DI</b><br><i>Basic UDI-DI</i>                                                                   | Viz Příloha I / Refer to Attachment 1                                                                                                                                                                                                                                                                     |
| <b>EMDN</b>                                                                                                     | Viz Příloha I / Refer to Attachment 1                                                                                                                                                                                                                                                                     |
| <b>Kód, obchodní název a popis výrobku</b><br><i>Product Code, Trade Name and Description</i>                   | Viz Příloha I / Refer to Attachment 1                                                                                                                                                                                                                                                                     |
| <b>Účel použití</b><br><i>Intended Purpose</i>                                                                  | <p>Alginátová krytí s vápníkem Kendall™ jsou vnější krytí na rány určená pro použití k absorpci exsudátu a ochraně rány před kontaminací.</p> <p>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from contamination.</p> |
| <b>Klasifikace a pravidlo</b><br><i>Classification and Rule</i>                                                 | Viz Příloha I / Refer to Attachment 1                                                                                                                                                                                                                                                                     |

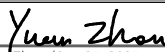
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**PROHLÁŠENÍ O SHODĚ**  
**DECLARATION OF CONFORMITY**

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| <b>Obecná specifikace</b><br><i>Common Specifications</i>                                                       | Nelze uplatnit (N/A)                                      |
| <b>Dle potřeby doplňte příslušný předpis Unie</b><br><i>Where appropriate, add applicable Union legislation</i> | Nelze uplatnit (N/A)                                      |
| <b>Posouzení shody</b><br><i>Conformity Assessment</i>                                                          | Příloha IX, kapitoly I a III/ Annex IX Chapters I and III |

**PODPISOVÁ ČÁST**  
**SIGNATURE SECTION**

**Toto EU prohlášení o shodě se vydává jménem a na výhradní odpovědnost oprávněného výrobce uvedeného výše.**

|                                                   |                                                                                                                            |
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| <b>Místo vydání</b><br><i>Place of Issue</i>      | Waukegan, IL 60085 USA                                                                                                     |
| <b>Podpis / Datum</b><br><i>Signature/ Date</i>   | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Jméno a funkce</b><br><i>Name and Function</i> | Yuan Zhou<br>Regulatory Affairs<br>Oddělení regulačních záležitostí                                                        |

**PŘÍLOHA I**  
**ATTACHMENT I**

**Seznam kódů výrobků**  
**Product Code List**

| <b>Kód výrobku</b><br><i>Product Code</i> | <b>Obchodní název a popis</b><br><i>Trade Name and Description</i>                                                                       | <b>Základní UDI-DI</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Klasifikace a pravidlo</b><br><i>Classification and Rule</i> |
|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|-------------|-----------------------------------------------------------------|
| 9233                                      | Alginátové krytí s vápníkem Kendall™, 10,2 cm x 10,2 cm (4" x 4")<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm) | 063014000000000000002556P                     | M04040202   | Třída/ Class: IIb<br>Pravidlo/ Rule: 4                          |
| 9232                                      | Alginátové krytí s vápníkem Kendall™, 5,1 cm x 5,1 cm (2" x 2")                                                                          | 063014000000000000002556P                     | M04040202   | Třída/ Class: IIb<br>Pravidlo/ Rule: 4                          |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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| Seznam kódů výrobků<br>Product Code List |                                                                                                                                                    |                          |           |                                        |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|----------------------------------------|
|                                          | Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)                                                                                      |                          |           |                                        |
| 9238                                     | Alginátové krytí s vápníkem Kendall™, 20,3 cm x 10,2 cm (8" x 4")<br><br>Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)           | 06301400000000000002556P | M04040202 | Třída/ Class: IIb<br>Pravidlo/ Rule: 4 |
| 9242                                     | Alginátové krytí s vápníkem Kendall™, 30,5 cm x 61 cm (12" x 24")<br><br>Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)           | 06301400000000000002556P | M04040202 | Třída/ Class: IIb<br>Pravidlo/ Rule: 4 |
| 9239                                     | Alginátové krytí s vápníkem Kendall™, 15,2 cm x 25,4 cm (6" x 10")<br><br>Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)         | 06301400000000000002556P | M04040202 | Třída/ Class: IIb<br>Pravidlo/ Rule: 4 |
| 9235                                     | Alginátové krytí s vápníkem Kendall™, 5,1 cm x 2,5 cm (2" x 1")<br><br>Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)               | 06301400000000000002556P | M04040202 | Třída/ Class: IIb<br>Pravidlo/ Rule: 4 |
| 9240                                     | Alginátové krytí s vápníkem Kendall™, 10,2 cm x 14 cm (4" x 5 1/2")<br><br>Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)       | 06301400000000000002556P | M04040202 | Třída/ Class: IIb<br>Pravidlo/ Rule: 4 |
| 9236                                     | Alginátové krytí s vápníkem Kendall™ Plus, 10,2 cm x 10,2 cm (4" x 4")<br><br>Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm) | 06301400000000000002556P | M04040202 | Třída/ Class: IIb<br>Pravidlo/ Rule: 4 |

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| <b>Seznam kódů výrobků</b><br><i>Product Code List</i> |                                                                                                                               |                           |           |                                           |
|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------|-------------------------------------------|
| 9231                                                   | Alginátové krytí s vápníkem<br>Kendall™, pás, 30,5 cm (12")<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope, 12" (30.5 cm) | 063014000000000000002556P | M04040202 | Třída/ Class: IIb<br>Pravidlo/ Rule:<br>4 |
| 9243                                                   | Alginátové krytí s vápníkem<br>Kendall™, pás, 61 cm (24")<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 24" (61 cm)      | 063014000000000000002556P | M04040202 | Třída/ Class: IIb<br>Pravidlo/ Rule:<br>4 |
| 9244                                                   | Alginátové krytí s vápníkem<br>Kendall™, pás, 91,4 cm (36")<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 36" (91.4 cm)  | 063014000000000000002556P | M04040202 | Třída/ Class: IIb<br>Pravidlo/ Rule:<br>4 |

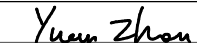
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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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## DANISH

| <b>PROHLÁŠENÍ O SHODĚ</b><br><b>DECLARATION OF CONFORMITY</b>                                                     |                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <b>CardinalHealth</b>            | <b>MDR:</b> Vi, Cardinal Health 200 LLC, erklærer, at produkterne dækket af denne EU-overensstemmelseserklæring overholder kravene i Forordning (EU) 2017/745 om medicinsk udstyr.                                                                                                                     |
| <b>Overensstemmelseserklæringsnummer</b><br><i>Declaration of Conformity Number</i>                               | RE00205881                                                                                                                                                                                                                                                                                             |
| <b>Teknisk dokumentationsnummer</b><br><i>Technical Documentation Number</i>                                      | RE00249263                                                                                                                                                                                                                                                                                             |
| <b>Producentens navn</b><br><i>Manufacturer's Name</i>                                                            | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                               |
| <b>Producentens adresse</b><br><i>Manufacturer's Address</i>                                                      | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                            |
| <b>Enkelt registreringsnummer</b><br><i>Single Registration Number</i>                                            | US-MF-000006765                                                                                                                                                                                                                                                                                        |
| <b>Navn og adresse på godkendt repræsentant</b><br><i>Authorized Representative's Name and Address</i>            | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                        |
| <b>Navn og identifikationsnummer på bemyndiget organ</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Identifikationsnummer: 2797                                                                                                                                                                             |
| <b>CE-certifikationsnummer</b><br><i>CE Certificate Number</i>                                                    | MDR 784266                                                                                                                                                                                                                                                                                             |
| <b>Produktkategori</b><br><i>Product Category</i>                                                                 | Alginatforbindinger, kombineret med andre stoffer<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                                |
| <b>Grundlæggende UDI-DI</b><br><i>Basic UDI-DI</i>                                                                | Se bilag I / Refer to Attachment 1                                                                                                                                                                                                                                                                     |
| <b>EMDN</b>                                                                                                       | Se bilag I / Refer to Attachment 1                                                                                                                                                                                                                                                                     |
| <b>Produktkode(r), handelsnavn og beskrivelse</b><br><i>Product Code, Trade Name and Description</i>              | Se bilag I / Refer to Attachment 1                                                                                                                                                                                                                                                                     |
| <b>Tiltænkt formål</b><br><i>Intended Purpose</i>                                                                 | <p>Kendall™ calciumalginat sårforbindinger er eksterne sårforbindinger beregnet til brug for at absorbere eksudater og beskytte såret mod forurening.</p> <p>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from</p> |

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| <b>PROHLÁŠENÍ O SHODĚ</b><br><i>DECLARATION OF CONFORMITY</i>                                                        |                                                         |
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|                                                                                                                      | contamination.                                          |
| <b>Klassificering og regel</b><br><i>Classification and Rule</i>                                                     | Se bilag I / Refer to Attachment 1                      |
| <b>Fælles specifikationer</b><br><i>Common Specifications</i>                                                        | Ikke relevant (N/A)                                     |
| <b>Hvor relevant, tilføj gældende union-lovgivning</b><br><i>Where appropriate, add applicable Union legislation</i> | Ikke relevant (N/A)                                     |
| <b>Overensstemmelsesvurdering</b><br><i>Conformity Assessment</i>                                                    | Bilag IX, kapitel I og III/ Annex IX Chapters I and III |

| <b>SIGNATURAFSNIT</b><br><i>SIGNATURE SECTION</i>                                                                                               |                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Denne EU-overensstemmelseserklæring er udstedt for og på vegne af og under eneansvar for den juridiske producent, der er identificeret ovenfor. |                                                                                                                              |
| <b>Udstedelsessted</b><br><i>Place of Issue</i>                                                                                                 | Waukegan, IL 60085 USA                                                                                                       |
| <b>Underskrift / Dato</b><br><i>Signature/ Date</i>                                                                                             | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Navn og function</b><br><i>Name and Function</i>                                                                                             | Yuan Zhou<br>Regulatory Affairs<br>Lovgivningsanliggender                                                                    |

**BILAG I**  
*ATTACHMENT 1*

| <b>Produktkodeliste</b><br><i>Product Code List</i> |                                                                                                                                          |                                                    |             |                                                                  |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|-------------|------------------------------------------------------------------|
| <b>Produktkode</b><br><i>Product Code</i>           | <b>Handelsnavn og beskrivelse</b><br><i>Trade Name and Description</i>                                                                   | <b>Grundlæggende UDI-DI</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Klassificering og regel</b><br><i>Classification and Rule</i> |
| 9233                                                | Kendall™<br>calciumalginatforbinding, 10,2 cm x 10,2 cm (4" x 4")<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm) | 06301400000000000002556P                           | M04040202   | Klasse /Class:<br>IIb<br>Regel/ Rule: 4                          |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Produktkodeliste</b><br><i>Product Code List</i> |                                                                                                                                                       |                          |           |                                         |
|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-----------------------------------------|
| 9232                                                | Kendall™<br>calciumalginatforbinding, 5,1 cm<br>x 5,1 cm (2" x 2")<br><br>Kendall™ Calcium Alginate<br>Dressing, 2" x 2" (5.1 cm x 5.1<br>cm)         | 06301400000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9238                                                | Kendall™<br>calciumalginatforbinding, 20,3<br>cm x 10,2 cm (8" x 4")<br><br>Kendall™ Calcium Alginate<br>Dressing, 8" x 4" (20.3 cm x 10.2<br>cm)     | 06301400000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9242                                                | Kendall™<br>calciumalginatforbinding, 30,5<br>cm x 61 cm (12" x 24")<br><br>Kendall™ Calcium Alginate<br>Dressing, 12" x 24" (30.5 cm x 61<br>cm)     | 06301400000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9239                                                | Kendall™<br>calciumalginatforbinding, 15,2<br>cm x 25,4 cm (6" x 10")<br><br>Kendall™ Calcium Alginate<br>Dressing, 6" x 10" (15.2 cm x<br>25.4 cm)   | 06301400000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9235                                                | Kendall™<br>calciumalginatforbinding, 5,1 cm<br>x 2,5 cm (2" x 1")<br><br>Kendall™ Calcium Alginate<br>Dressing, 2" x 1" (5.1 cm x 2.5<br>cm)         | 06301400000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9240                                                | Kendall™<br>calciumalginatforbinding, 10,2<br>cm x 14 cm (4" x 5-1/2")<br><br>Kendall™ Calcium Alginate<br>Dressing, 4" x 5-1/2" (10.2 cm x<br>14 cm) | 06301400000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9236                                                | Kendall™<br>calciumalginatforbinding Plus                                                                                                             | 06301400000000000002556P | M04040202 | Klasse /Class:<br>IIb                   |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Produktkodeliste</b><br><i>Product Code List</i> |                                                                                                                      |                          |           |                                      |
|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|--------------------------------------|
|                                                     | 10,2 cm x 10,2 cm (4" x 4")<br><br>Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)              |                          |           | Regel/ Rule: 4                       |
| 9231                                                | Kendall™ calciumalginatforbinding, Rope 30,5 cm (12")<br><br>Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm) | 06301400000000000002556P | M04040202 | Klasse /Class: IIb<br>Regel/ Rule: 4 |
| 9243                                                | Kendall™ calciumalginatforbinding, Rope 61 cm (24")<br><br>Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)      | 06301400000000000002556P | M04040202 | Klasse /Class: IIb<br>Regel/ Rule: 4 |
| 9244                                                | Kendall™ calciumalginatforbinding, Rope 91,4 cm (36")<br><br>Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)  | 06301400000000000002556P | M04040202 | Klasse /Class: IIb<br>Regel/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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## DUTCH

| <b>CONFORMITEITSVERKLARING</b><br><b>DECLARATION OF CONFORMITY</b>                                                      |                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <b>CardinalHealth</b>                  | <b>MDR:</b> Wij, Cardinal Health 200 LLC, verklaren dat de producten die onder deze EU-conformiteitsverklaring vallen, voldoen aan Verordening (EU) 2017/745 betreffende medische hulpmiddelen.                                                                                                                           |
| <b>Nummer conformiteitsverklaring</b><br><i>Declaration of Conformity Number</i>                                        | RE00205881                                                                                                                                                                                                                                                                                                                |
| <b>Nummer technische documentatie</b><br><i>Technical Documentation Number</i>                                          | RE00249263                                                                                                                                                                                                                                                                                                                |
| <b>Naam fabrikant</b><br><i>Manufacturer's Name</i>                                                                     | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                                                  |
| <b>Adres van de fabrikant</b><br><i>Manufacturer's Address</i>                                                          | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                                               |
| <b>Enkel registratienummer</b><br><i>Single Registration Number</i>                                                     | US-MF-000006765                                                                                                                                                                                                                                                                                                           |
| <b>Naam en adres van de erkende vertegenwoordiger</b><br><i>Authorized Representative's Name and Address</i>            | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                                           |
| <b>Naam en identificatienummer van de aangemelde instantie</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Identificatienummer: 2797                                                                                                                                                                                                  |
| <b>Nummer CE-markering</b><br><i>CE Certificate Number</i>                                                              | MDR 784266                                                                                                                                                                                                                                                                                                                |
| <b>Productcategorie</b><br><i>Product Category</i>                                                                      | Alginaatpleisters, gecombineerd met andere stoffen<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                                                  |
| <b>Basis UDI-DI</b><br><i>Basic UDI-DI</i>                                                                              | Zie Bijlage I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                      |
| <b>EMDN</b>                                                                                                             | Zie Bijlage I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                      |
| <b>Productcode, handelsnaam en beschrijving</b><br><i>Product Code, Trade Name and Description</i>                      | Zie Bijlage I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                      |
| <b>Beoogd doel</b><br><i>Intended Purpose</i>                                                                           | Kendall™-wondpleisters met calciumalginaat zijn externe wondverbanden die zijn bedoeld voor het absorberen van exsudaat en het beschermen van de wond tegen verontreiniging.<br><br>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from |

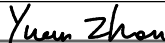
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**CONFORMITEITSVERKLARING**  
*DECLARATION OF CONFORMITY*

|                                                                                                                                              |                                                            |
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|                                                                                                                                              | contamination.                                             |
| <b>Classificatie en regel</b><br><i>Classification and Rule</i>                                                                              | Zie Bijlage I/ Refer to Attachment 1                       |
| <b>Algemene specificities</b><br><i>Common Specifications</i>                                                                                | Niet van toepassing (N/A)                                  |
| <b>Voeg, indien van toepassing, de toepasselijke wetgeving van de Unie toe</b><br><i>Where appropriate, add applicable Union legislation</i> | Niet van toepassing (N/A)                                  |
| <b>Conformiteitsbeoordeling</b><br><i>Conformity Assessment</i>                                                                              | Bijlage IX Hoofdstuk I en III/ Annex IX Chapters I and III |

**HANDTEKENINGGEDEELTE**  
*SIGNATURE SECTION*

**Deze EU-conformiteitsverklaring wordt voor en namens en uitsluitend onder de verantwoordelijkheid van de fabrikant afgegeven.**

|                                                     |                                                                                                                              |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| <b>Plaats van afgifte</b><br><i>Place of Issue</i>  | Waukegan, IL 60085 USA                                                                                                       |
| <b>Handtekening/Datum</b><br><i>Signature/ Date</i> | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Naam en functie</b><br><i>Name and Function</i>  | Yuan Zhou<br>Regulatory Affairs<br>Regelgevingszaken                                                                         |

**BIJLAGE I**  
*ATTACHMENT 1*

**Produktkodeliste**  
*Product Code List*

| <b>Productcode</b><br><i>Product Code</i> | <b>Handelsnaam en beschrijving</b><br><i>Trade Name and Description</i>                                                                           | <b>Basis UDI-DI</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Classificatie en regel</b><br><i>Classification and Rule</i> |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|-------------|-----------------------------------------------------------------|
| 9233                                      | Kendall™-<br>calciumalginaatpleister, 4" x 4"<br>(10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 4" x 4" (10.2 cm x 10.2<br>cm) | 063014000000000000002556P                  | M04040202   | Klasse /Class:<br>IIb<br>Regel/ Rule: 4                         |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Produktkodeliste</b><br><i>Product Code List</i> |                                                                                                                                                        |                           |           |                                         |
|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------|-----------------------------------------|
| 9232                                                | Kendall™-<br>calciumalginaatpleister, 2" x 2"<br>(5,1 cm x 5,1 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 2" x 2" (5.1 cm x 5.1<br>cm)          | 063014000000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9238                                                | Kendall™-<br>calciumalginaatpleister, 8" x 4"<br>(20,3 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 8" x 4" (20.3 cm x 10.2<br>cm)      | 063014000000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9242                                                | Kendall™-<br>calciumalginaatpleister, 12" x 24"<br>(30,5 cm x 61 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 12" x 24" (30.5 cm x 61<br>cm)      | 063014000000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9239                                                | Kendall™-<br>calciumalginaatpleister, 6" x 10"<br>(15,2 cm x 25,4 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 6" x 10" (15.2 cm x<br>25.4 cm)    | 063014000000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9235                                                | Kendall™-<br>calciumalginaatpleister, 2" x 1"<br>(5,1 cm x 2,5 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 2" x 1" (5.1 cm x 2.5<br>cm)          | 063014000000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9240                                                | Kendall™-<br>calciumalginaatpleister, 4" x 5-<br>1/2" (10,2 cm x 14 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 4" x 5-1/2" (10.2 cm x<br>14 cm) | 063014000000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9236                                                | Kendall™-calciumalginaatpleister<br>Plus, 4" x 4" (10,2 cm x 10,2 cm)                                                                                  | 063014000000000000002556P | M04040202 | Klasse /Class:<br>IIb                   |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Produktkodeliste</b><br><i>Product Code List</i> |                                                                                                                               |                          |           |                                         |
|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-----------------------------------------|
|                                                     | Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)                                                          |                          |           | Regel/ Rule: 4                          |
| 9231                                                | Kendall™-<br>calciumalginaatpleister, streng,<br>12" (30,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm) | 06301400000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9243                                                | Kendall™-<br>calciumalginaatpleister, streng,<br>24" (61 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)      | 06301400000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |
| 9244                                                | Kendall™-<br>calciumalginaatpleister, streng,<br>36" (91,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)  | 06301400000000000002556P | M04040202 | Klasse /Class:<br>IIb<br>Regel/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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## FINNISH

### VAATIMUSTENMUKAISUUSVAKUUTUS DECLARATION OF CONFORMITY



**CardinalHealth**

**MDR:** Me, Cardinal Health 200 LLC, vakuutamme, että tässä EU-vaatimustenmukaisuusvakuutuksessa kuvatut tuotteet täyttävät lääkintälaitteasetuksen (EU) 2017/745 vaatimukset.

|                                                                                                           |                                                                                                                                                                                                                                                                                                                                  |
|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>VAATIMUSTENMUKAISUUSVAKUUTUS</b><br><i>Declaration of Conformity Number</i>                            | RE00205881                                                                                                                                                                                                                                                                                                                       |
| <b>Teknisen dokumentin numero</b><br><i>Technical Documentation Number</i>                                | RE00249263                                                                                                                                                                                                                                                                                                                       |
| <b>Valmistajan nimi</b><br><i>Manufacturer's Name</i>                                                     | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                                                         |
| <b>Valmistajan osoite</b><br><i>Manufacturer's Address</i>                                                | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                                                      |
| <b>Yksittäinen rekisterinumero</b><br><i>Single Registration Number</i>                                   | US-MF-000006765                                                                                                                                                                                                                                                                                                                  |
| <b>Valtuutetun edustajan nimi ja osoite</b><br><i>Authorized Representative's Name and Address</i>        | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                                                  |
| <b>Ilmoitetun laitoksen nimi ja tunnusnumero</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Tunnusnumero: 2797                                                                                                                                                                                                                |
| <b>CE-sertifikaatin numero</b><br><i>CE Certificate Number</i>                                            | MDR 784266                                                                                                                                                                                                                                                                                                                       |
| <b>Tuotekategoria</b><br><i>Product Category</i>                                                          | Alginaattisidokset, yhdessä muiden aineiden kanssa<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                                                         |
| <b>Yksilöllinen laitemallin tunniste (Basic UDI-DI)</b><br><i>Basic UDI-DI</i>                            | Katso liite I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                             |
| <b>EMDN</b>                                                                                               | Katso liite I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                             |
| <b>Tuotekoodi, kaupp nimi ja kuvaus</b><br><i>Product Code, Trade Name and Description</i>                | Katso liite I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                             |
| <b>Käyttötarkoitus</b><br><i>Intended Purpose</i>                                                         | Kendall™-kalsium-alginaattihaavasidokset ovat ulkoisia haavasidoksia, jotka on tarkoitettu imemään itseensä haavaeritteitä ja suojaamaan haavaa kontaminoitumiselta.<br><br>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from contamination. |
| <b>Luokittelu ja sääntö</b><br><i>Classification and Rule</i>                                             | Katso liite I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                             |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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**VAATIMUSTENMUKAISUUSVAKUUTUS**  
**DECLARATION OF CONFORMITY**

|                                                                                                                        |                                                          |
|------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| <b>Yleiset tekniset tiedot</b><br><i>Common Specifications</i>                                                         | Ei sovellu (N/A)                                         |
| <b>Lisää tarvittaessa soveltuva unionin lainsäädäntö</b><br><i>Where appropriate, add applicable Union legislation</i> | Ei sovellu (N/A)                                         |
| <b>Vaatimustenmukaisuuden arviointi</b><br><i>Conformity Assessment</i>                                                | Liite IX kappaleet I ja III/ Annex IX Chapters I and III |

**ALLEKIRJOITUSOSIO**  
**SIGNATURE SECTION**

**Tämä EU-vaatimustenmukaisuusvakuutus on annettu edellä mainitun laillisen valmistajan puolesta ja sen omalla, yksinomaisella vastuulla.**

|                                                                |                                                                                                                            |
|----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| <b>Paikka</b><br><i>Place of Issue</i>                         | Waukegan, IL 60085 USA                                                                                                     |
| <b>Allekirjoitus/<br/>Päivämäärä</b><br><i>Signature/ Date</i> | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Nimi ja asema</b><br><i>Name and Function</i>               | Yuan Zhou<br>Regulatory Affairs<br>Sääntelyasiat                                                                           |

**LIITE I**  
**ATTACHMENT I**

**Tuotekoodiluettelo**  
**Product Code List**

| <b>Tuotekoodi</b><br><i>Product Code</i> | <b>Kauppanimi ja kuvaus</b><br><i>Trade Name and Description</i>                                                                     | <b>Yksilöllinen laitemallin tunnistus (Basic UDI-DI)</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Luokittelu ja sääntö</b><br><i>Classification and Rule</i> |
|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-------------|---------------------------------------------------------------|
| 9233                                     | Kendall™-kalsium-alginaattisidos, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm) | 063014000000000000002556P                                                       | M04040202   | Luokka/<br>Classification:<br>Iib<br>Sääntö/ Rule: 4          |
| 9232                                     | Kendall™-kalsium-alginaattisidos, 2" x 2" (5,1 cm x 5,1 cm)<br><br>Kendall™ Calcium Alginate                                         | 063014000000000000002556P                                                       | M04040202   | Luokka/<br>Classification:<br>Iib<br>Sääntö/ Rule: 4          |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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| <b>Tuotekoodiluettelo</b><br><i>Product Code List</i> |                                                                                                                                                |                           |           |                                                      |
|-------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------|------------------------------------------------------|
|                                                       | Dressing, 2" x 2" (5.1 cm x 5.1 cm)                                                                                                            |                           |           |                                                      |
| 9238                                                  | Kendall™-kalsium-alginaattisidos, 8" x 4" (20,3 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)           | 063014000000000000002556P | M04040202 | Luokka/<br>Classification:<br>IIb<br>Sääntö/ Rule: 4 |
| 9242                                                  | Kendall™-kalsium-alginaattisidos, 12" x 24" (30,5 cm x 61 cm)<br><br>Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)           | 063014000000000000002556P | M04040202 | Luokka/<br>Classification:<br>IIb<br>Sääntö/ Rule: 4 |
| 9239                                                  | Kendall™-kalsium-alginaattisidos, 6" x 10" (15,2 cm x 25,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)         | 063014000000000000002556P | M04040202 | Luokka/<br>Classification:<br>IIb<br>Sääntö/ Rule: 4 |
| 9235                                                  | Kendall™-kalsium-alginaattisidos, 2" x 1" (5,1 cm x 2,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)               | 063014000000000000002556P | M04040202 | Luokka/<br>Classification:<br>IIb<br>Sääntö/ Rule: 4 |
| 9240                                                  | Kendall™-kalsium-alginaattisidos, 4" x 5-1/2" (10,2 cm x 14 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)       | 063014000000000000002556P | M04040202 | Luokka/<br>Classification:<br>IIb<br>Sääntö/ Rule: 4 |
| 9236                                                  | Kendall™-kalsium-alginaattisidos Plus, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm) | 063014000000000000002556P | M04040202 | Luokka/<br>Classification:<br>IIb<br>Sääntö/ Rule: 4 |
| 9231                                                  | Kendall™-kalsium-                                                                                                                              | 063014000000000000002556P | M04040202 | Luokka/                                              |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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| <b>Tuotekoodiluettelo</b><br><i>Product Code List</i> |                                                                                                                          |                           |           |                                                      |
|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------|------------------------------------------------------|
|                                                       | alginaattisidos, nuora, 12" (30,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)                     |                           |           | Classification:<br>IIb<br>Sääntö/ Rule: 4            |
| 9243                                                  | Kendall™-kalsium-<br>alginaattisidos, nuora, 24" (61 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)     | 063014000000000000002556P | M04040202 | Luokka/<br>Classification:<br>IIb<br>Sääntö/ Rule: 4 |
| 9244                                                  | Kendall™-kalsium-<br>alginaattisidos, nuora, 36" (91,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm) | 063014000000000000002556P | M04040202 | Luokka/<br>Classification:<br>IIb<br>Sääntö/ Rule: 4 |

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## FRENCH

| <b>DÉCLARATION DE CONFORMITÉ</b><br><b>DECLARATION OF CONFORMITY</b>                                                  |                                                                                                                                                                                                                                                                                                                       |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                       | <b>MDR:</b> Nous, Cardinal Health 200 LLC, déclarons que les produits couverts par la présente déclaration de conformité de l'Union européenne satisfont à la disposition du règlement (UE) 2017/745 sur les dispositifs médicaux.                                                                                    |
| <b>Numéro de la déclaration de conformité</b><br><i>Declaration of Conformity Number</i>                              | RE00205881                                                                                                                                                                                                                                                                                                            |
| <b>Numéro de la documentation technique</b><br><i>Technical Documentation Number</i>                                  | RE00249263                                                                                                                                                                                                                                                                                                            |
| <b>Nom du fabricant</b><br><i>Manufacturer's Name</i>                                                                 | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                                              |
| <b>Adresse du fabricant</b><br><i>Manufacturer's Address</i>                                                          | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                                           |
| <b>Numéro d'enregistrement unique</b><br><i>Single Registration Number</i>                                            | US-MF-000006765                                                                                                                                                                                                                                                                                                       |
| <b>Nom et adresse du représentant agréé</b><br><i>Authorized Representative's Name and Address</i>                    | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                                       |
| <b>Nom et numéro d'identification de l'organisme notifié</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Numéro d'identification: 2797                                                                                                                                                                                          |
| <b>Numéro de certificat CE</b><br><i>CE Certificate Number</i>                                                        | MDR 784266                                                                                                                                                                                                                                                                                                            |
| <b>Catégorie de produit</b><br><i>Product Category</i>                                                                | Pansements alginate, combinés à d'autres substances<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                                             |
| <b>UDI-DI de base</b><br><i>Basic UDI-DI</i>                                                                          | Voir PJ I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                      |
| <b>EMDN</b>                                                                                                           | Voir PJ I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                      |
| <b>Code, nom commercial et description du produit</b><br><i>Product Code, Trade Name and Description</i>              | Voir PJ I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                      |
| <b>Usage prévu</b><br><i>Intended Purpose</i>                                                                         | <p>Les pansements alginate de calcium Kendall™ sont des pansements externes pour plaies destinés à absorber les exsudats et à protéger la plaie de la contamination.</p> <p>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from</p> |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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| <b>DÉCLARATION DE CONFORMITÉ</b><br><i>DECLARATION OF CONFORMITY</i>                                                                         |                                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
|                                                                                                                                              | contamination.                                             |
| <b>Classification et règle</b><br><i>Classification and Rule</i>                                                                             | Voir PJ I/ Refer to Attachment 1                           |
| <b>Caractéristiques communes</b><br><i>Common Specifications</i>                                                                             | Sans objet (N/A)                                           |
| <b>Le cas échéant, ajouter la législation de l'Union européenne en vigueur</b><br><i>Where appropriate, add applicable Union legislation</i> | Sans objet (N/A)                                           |
| <b>Évaluation de la conformité</b><br><i>Conformity Assessment</i>                                                                           | Annexe IX, Chapitres I et III/ Annex IX Chapters I and III |

| <b>SECTION SIGNATURE</b><br><i>SIGNATURE SECTION</i>                                                                                                                   |                                                                                                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| <b>La présente déclaration de conformité de l'Union européenne est établie pour, au nom de et sous la seule responsabilité du fabricant légal identifié plus haut.</b> |                                                                                                                              |
| <b>Lieu de délivrance</b><br><i>Place of Issue</i>                                                                                                                     | Waukegan, IL 60085 USA                                                                                                       |
| <b>Signature/Date</b><br><i>Signature/Date</i>                                                                                                                         | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Nom et fonction</b><br><i>Name and Function</i>                                                                                                                     | Yuan Zhou<br>Regulatory Affairs<br>Affaires réglementaires                                                                   |

**PJ I**  
*ATTACHMENT 1*

| <b>Liste de référence produit</b><br><i>Product Code List</i> |                                                                                                                                        |                                              |             |                                                                  |
|---------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|-------------|------------------------------------------------------------------|
| <b>Code du produit</b><br><i>Product Code</i>                 | <b>Nom commercial et description du produit</b><br><i>Trade Name and Description</i>                                                   | <b>UDI-DI de base</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Classification et règle</b><br><i>Classification and Rule</i> |
| 9233                                                          | Pansement alginate de calcium Kendall™, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 | 06301400000000000002556P                     | M04040202   | Classification/<br>Classification:<br>IIb<br>Règle/ Rule: 4      |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Liste de référence produit</b><br><i>Product Code List</i> |                                                                                                                                                |                          |           |                                                              |
|---------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|--------------------------------------------------------------|
|                                                               | cm)                                                                                                                                            |                          |           |                                                              |
| 9232                                                          | Pansement alginate de calcium Kendall™, 2" x 2" (5,1 cm x 5,1 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)         | 06301400000000000002556P | M04040202 | Classification/<br>Classification:<br>I Ib<br>Règle/ Rule: 4 |
| 9238                                                          | Pansement alginate de calcium Kendall™, 8" x 4" (20,3 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)     | 06301400000000000002556P | M04040202 | Classification/<br>Classification:<br>I Ib<br>Règle/ Rule: 4 |
| 9242                                                          | Pansement alginate de calcium Kendall™, 12" x 24" (30,5 cm x 61 cm)<br><br>Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)     | 06301400000000000002556P | M04040202 | Classification/<br>Classification:<br>I Ib<br>Règle/ Rule: 4 |
| 9239                                                          | Pansement alginate de calcium Kendall™, 6" x 10" (15,2 cm x 25,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)   | 06301400000000000002556P | M04040202 | Classification/<br>Classification:<br>I Ib<br>Règle/ Rule: 4 |
| 9235                                                          | Pansement alginate de calcium Kendall™, 2" x 1" (5,1 cm x 2,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)         | 06301400000000000002556P | M04040202 | Classification/<br>Classification:<br>I Ib<br>Règle/ Rule: 4 |
| 9240                                                          | Pansement alginate de calcium Kendall™, 4" x 5-1/2" (10,2 cm x 14 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm) | 06301400000000000002556P | M04040202 | Classification/<br>Classification:<br>I Ib<br>Règle/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Liste de référence produit</b><br><i>Product Code List</i> |                                                                                                                                                            |                           |           |                                                             |
|---------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------|-------------------------------------------------------------|
| 9236                                                          | Pansement alginaté de calcium<br>Kendall™ Plus, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm) | 063014000000000000002556P | M04040202 | Classification/<br>Classification:<br>IIb<br>Règle/ Rule: 4 |
| 9231                                                          | Pansement alginaté de calcium<br>Kendall™, mèche, 12" (30,5 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope, 12" (30.5 cm)                          | 063014000000000000002556P | M04040202 | Classification/<br>Classification:<br>IIb<br>Règle/ Rule: 4 |
| 9243                                                          | Pansement alginaté de calcium<br>Kendall™, mèche, 24" (61 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 24" (61 cm)                               | 063014000000000000002556P | M04040202 | Classification/<br>Classification:<br>IIb<br>Règle/ Rule: 4 |
| 9244                                                          | Pansement alginaté de calcium<br>Kendall™, mèche, 36" (91,4 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 36" (91.4 cm)                           | 063014000000000000002556P | M04040202 | Classification/<br>Classification:<br>IIb<br>Règle/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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## GERMAN

| <b>KONFORMITÄTSERKLÄRUNG</b><br><b>DECLARATION OF CONFORMITY</b>                                                    |                                                                                                                                                                                                                                                                                                       |
|---------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <br><b>CardinalHealth</b>           | <b>MDR:</b> Wir, Cardinal Health 200 LLC, erklären, dass die Produkte, die in dieser EU-Konformitätserklärung behandelt werden, den Bestimmungen der Medizinprodukteverordnung (EU) 2017/745 entsprechen.                                                                                             |
| <b>Nummer der Konformitätserklärung</b><br><i>Declaration of Conformity Number</i>                                  | RE00205881                                                                                                                                                                                                                                                                                            |
| <b>Technische Dokumentennummer</b><br><i>Technical Documentation Number</i>                                         | RE00249263                                                                                                                                                                                                                                                                                            |
| <b>Name des Herstellers</b><br><i>Manufacturer's Name</i>                                                           | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                              |
| <b>Adresse des Herstellers</b><br><i>Manufacturer's Address</i>                                                     | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                           |
| <b>Einzel-Registrierungsnummer</b><br><i>Single Registration Number</i>                                             | US-MF-000006765                                                                                                                                                                                                                                                                                       |
| <b>Name und Adresse des bevollmächtigten Vertreters</b><br><i>Authorized Representative's Name and Address</i>      | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                       |
| <b>Name und Identifikationsnummer der benannten Stelle</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Identifikationsnummer: 2797                                                                                                                                                                            |
| <b>CE-Zertifikat-Nummer</b><br><i>CE Certificate Number</i>                                                         | MDR 784266                                                                                                                                                                                                                                                                                            |
| <b>Produktkategorie</b><br><i>Product Category</i>                                                                  | Alginat-Verbände, kombiniert mit anderen Substanzen<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                             |
| <b>Grundlegende UDI-DI</b><br><i>Basic UDI-DI</i>                                                                   | Siehe Anhang I/ Refer to Attachment 1                                                                                                                                                                                                                                                                 |
| <b>EMDN</b>                                                                                                         | Siehe Anhang I/ Refer to Attachment 1                                                                                                                                                                                                                                                                 |
| <b>Produktcode, Handelsname und Beschreibung</b><br><i>Product Code, Trade Name and Description</i>                 | Siehe Anhang I/ Refer to Attachment 1                                                                                                                                                                                                                                                                 |
| <b>Verwendungszweck</b><br><i>Intended Purpose</i>                                                                  | Kalziumalginat-Wundverbände von Kendall™ sind externe Wundverbände zur Aufnahme von Exsudat und zum Schutz der Wunde vor Kontaminationen.<br><br>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from contamination. |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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| <b>KONFORMITÄTSERKLÄRUNG</b><br><i>DECLARATION OF CONFORMITY</i>                                                                              |                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| <b>Klassifizierung und Richtlinie</b><br><i>Classification and Rule</i>                                                                       | Siehe Anhang I/ Refer to Attachment 1                    |
| <b>Allgemeine Spezifikationen</b><br><i>Common Specifications</i>                                                                             | Nicht zutreffend (N/A)                                   |
| <b>Gegebenenfalls anwendbare Rechtsvorschriften der Gewerkschaft hinzufügen</b><br><i>Where appropriate, add applicable Union legislation</i> | Nicht zutreffend (N/A)                                   |
| <b>Konformitätsbewertung</b><br><i>Conformity Assessment</i>                                                                                  | Anhang IX Kapitel I und III/ Annex IX Chapters I and III |

| <b>UNTERSCHRIFTSABSCHNITT</b><br><i>SIGNATURE SECTION</i>                                                                                                     |                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| <b>Diese EU-Konformitätserklärung wird für und im Namen und unter der alleinigen Verantwortung des oben angegebenen rechtmäßigen Herstellers ausgestellt.</b> |                                                              |
| <b>Ausstellungsort</b><br><i>Place of Issue</i>                                                                                                               | Waukegan, IL 60085 USA                                       |
| <b>Unterschrift /Datum</b><br><i>Signature/Date</i>                                                                                                           | <u>Yuan Zhou</u><br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT)    |
| <b>Name und Funktion</b><br><i>Name and Function</i>                                                                                                          | Yuan Zhou<br>Regulatory Affairs<br>Zulassungsangelegenheiten |

**ANHANG I**  
*ATTACHMENT I*

| <b>Produktcodeliste</b><br><i>Product Code List</i> |                                                                                                                                      |                                                   |             |                                                                         |
|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|-------------|-------------------------------------------------------------------------|
| <b>Produktcode</b><br><i>Product Code</i>           | <b>Handelsname und Beschreibung</b><br><i>Trade Name and Description</i>                                                             | <b>Grundlegende UDI-DI</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Klassifizierung und Richtlinie</b><br><i>Classification and Rule</i> |
| 9233                                                | Kendall™ Calcium-Alginat-Verband, 10,2 cm x 10,2 cm (4" x 4")<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm) | 06301400000000000002556P                          | M04040202   | Klasse/<br>Classification:<br>IIb<br>Richtlinie/ Rule:<br>4             |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Produktcodeliste</b><br><i>Product Code List</i> |                                                                                                                                          |                          |           |                                                             |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-------------------------------------------------------------|
| 9232                                                | Kendall™ Calzium-Alginat-Verband, 5,1 cm x 5,1 cm (2" x 2")<br><br>Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)         | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Richtlinie/ Rule:<br>4 |
| 9238                                                | Kendall™ Calzium-Alginat-Verband, 20,3 cm x 10,2 cm (8" x 4")<br><br>Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)     | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Richtlinie/ Rule:<br>4 |
| 9242                                                | Kendall™ Kalziumalginat-Verband, 30,5 cm x 61 cm (12" x 24")<br><br>Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)      | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Richtlinie/ Rule:<br>4 |
| 9239                                                | Kendall™ Kalzium-Alginat-Verband, 15,2 cm x 25,4 cm (6" x 10")<br><br>Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)   | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Richtlinie/ Rule:<br>4 |
| 9235                                                | Kendall™ Calzium-Alginat-Verband, 5,1 cm x 2,5 cm (2" x 1")<br><br>Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)         | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Richtlinie/ Rule:<br>4 |
| 9240                                                | Kendall™ Kalzium-Alginat-Verband, 10,2 cm x 14 cm (4" x 5-1/2")<br><br>Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm) | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Richtlinie/ Rule:<br>4 |
| 9236                                                | Kendall™ Calzium-Alginat-Verband Plus, 10,2 cm x 10,2 cm                                                                                 | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:                                  |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Produktcodeliste</b><br><i>Product Code List</i> |                                                                                                                      |                          |           |                                                             |
|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-------------------------------------------------------------|
|                                                     | (4" x 4")<br><br>Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)                                |                          |           | IIb<br>Richtlinie/ Rule:<br>4                               |
| 9231                                                | Kendall™ Kalzium-Alginat-Verband, Seil, 30,5 cm (12")<br><br>Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm) | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Richtlinie/ Rule:<br>4 |
| 9243                                                | Kendall™ Kalzium-Alginat-Verband, Seil 61 cm (24")<br><br>Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)       | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Richtlinie/ Rule:<br>4 |
| 9244                                                | Kendall™ Kalzium-Alginat-Verband, Seil 91,4 cm (36")<br><br>Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)   | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Richtlinie/ Rule:<br>4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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## GREEK

| ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ<br>DECLARATION OF CONFORMITY                                                                         |                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <br><b>CardinalHealth</b>               | <b>MDR:</b> Εμείς, η Cardinal Health 200 LLC, δηλώνουμε ότι τα προϊόντα που καλύπτονται στην παρούσα Δήλωση συμμόρφωσης ΕΕ πληρούν τις διατάξεις του Κανονισμού (ΕΕ) 2017/745 για τα ιατροτεχνολογικά προϊόντα.                                                                                                                                 |
| <b>Αριθμός δήλωσης συμμόρφωσης</b><br><i>Declaration of Conformity Number</i>                                           | RE00205881                                                                                                                                                                                                                                                                                                                                      |
| <b>Αριθμός τεχνικού φακέλου</b><br><i>Technical Documentation Number</i>                                                | RE00249263                                                                                                                                                                                                                                                                                                                                      |
| <b>Όνομα κατασκευαστή</b><br><i>Manufacturer's Name</i>                                                                 | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                                                                        |
| <b>Διεύθυνση κατασκευαστή</b><br><i>Manufacturer's Address</i>                                                          | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                                                                     |
| <b>Ενιαίος αριθμός καταχώρισης</b><br><i>Single Registration Number</i>                                                 | US-MF-000006765                                                                                                                                                                                                                                                                                                                                 |
| <b>Όνομα και διεύθυνση εξουσιοδοτημένου αντιπροσώπου</b><br><i>Authorized Representative's Name and Address</i>         | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                                                                 |
| <b>Όνομα και αριθμός αναγνώρισης κοινοποιημένου οργανισμού</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Αριθμός αναγνώρισης: 2797                                                                                                                                                                                                                        |
| <b>Αριθμός πιστοποιητικού CE</b><br><i>CE Certificate Number</i>                                                        | MDR 784266                                                                                                                                                                                                                                                                                                                                      |
| <b>Κατηγορία προϊόντος</b><br><i>Product Category</i>                                                                   | Αλγινικοί επίδεσμοι, σε συνδυασμό με άλλες ουσίες<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                                                                         |
| <b>Βασικό UDI-DI</b><br><i>Basic UDI-DI</i>                                                                             | Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                               |
| <b>EMDN</b>                                                                                                             | Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                               |
| <b>Κωδικός προϊόντος, εμπορική επωνυμία και περιγραφή</b><br><i>Product Code, Trade Name and Description</i>            | Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                               |
| <b>Προοριζόμενος σκοπός</b><br><i>Intended Purpose</i>                                                                  | Τα επιθέματα τραυμάτων αλγινικού ασβεστίου Kendall™ είναι εξωτερικά επιθέματα τραυμάτων που προορίζονται για χρήση για την απορρόφηση των εξιδρωμάτων και την προστασία του τραύματος από μόλυνση.<br><br>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from |

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| <b>ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ</b><br><i>DECLARATION OF CONFORMITY</i>                                                                    |                                                              |
|----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
|                                                                                                                                  | contamination.                                               |
| <b>Ταξινόμηση και κανόνας</b><br><i>Classification and Rule</i>                                                                  | Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1            |
| <b>Κοινές προδιαγραφές</b><br><i>Common Specifications</i>                                                                       | Δεν ισχύει (N/A)                                             |
| <b>Όπου αρμόζει, προσθέστε την εφαρμοστέα νομοθεσία της Ένωσης</b><br><i>Where appropriate, add applicable Union legislation</i> | Δεν ισχύει (N/A)                                             |
| <b>Αξιολόγηση της συμμόρφωσης</b><br><i>Conformity Assessment</i>                                                                | Παράρτημα IX Κεφάλαια I και III/ Annex IX Chapters I and III |

| <b>ΕΝΟΤΗΤΑ ΥΠΟΓΡΑΦΗΣ</b><br><i>SIGNATURE SECTION</i>                                                                                                       |                                                           |
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| Η παρούσα Δήλωση συμμόρφωσης ΕΕ εκδίδεται στο όνομα και για λογαριασμό και με την αποκλειστική ευθύνη του Νόμιμου κατασκευαστή που ταυτοποιείται παραπάνω. |                                                           |
| <b>Τόπος έκδοσης</b><br><i>Place of Issue</i>                                                                                                              | Waukegan, IL 60085 USA                                    |
| <b>Υπογραφή/Ημερομηνία</b><br><i>Signature/Date</i>                                                                                                        | <u>Yuan Zhou</u><br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Όνομα και λειτουργία</b><br><i>Name and Function</i>                                                                                                    | Yuan Zhou<br>Regulatory Affairs<br>Ρυθμιστικές υποθέσεις  |

**ΠΡΟΣΑΡΤΗΜΑ I**  
*ATTACHMENT I*

| <b>Κατάλογος κωδικών προϊόντος</b><br><i>Product Code List</i> |                                                                                                                                        |                                             |             |                                                                 |
|----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|-------------|-----------------------------------------------------------------|
| <b>Κωδικός προϊόντος</b><br><i>Product Code</i>                | <b>Εμπορική επωνυμία και περιγραφή</b><br><i>Trade Name and Description</i>                                                            | <b>Βασικό UDI-DI</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Ταξινόμηση και κανόνας</b><br><i>Classification and Rule</i> |
| 9233                                                           | Επίδεσμος αλγινικού ασβεστίου Kendall™, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 | 06301400000000000002556P                    | M04040202   | Κατηγορία/<br>Classification:<br>IIb<br>Κανόνας/ Rule:<br>4     |

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| <b>Κατάλογος κωδικών προϊόντος</b><br><i>Product Code List</i> |                                                                                                                                                   |                          |           |                                                             |
|----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-------------------------------------------------------------|
|                                                                | cm)                                                                                                                                               |                          |           |                                                             |
| 9232                                                           | Επίδεσμος αλγινικού ασβεστίου<br>Kendall™, 2" x 2" (5,1 cm x 5,1 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)         | 06301400000000000002556P | M04040202 | Κατηγορία/<br>Classification:<br>IIb<br>Κανόνας/ Rule:<br>4 |
| 9238                                                           | Επίδεσμος αλγινικού ασβεστίου<br>Kendall™, 8" x 4" (20,3 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)     | 06301400000000000002556P | M04040202 | Κατηγορία/<br>Classification:<br>IIb<br>Κανόνας/ Rule:<br>4 |
| 9242                                                           | Επίδεσμος αλγινικού ασβεστίου<br>Kendall™, 12" x 24" (30,5 cm x 61 cm)<br><br>Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)     | 06301400000000000002556P | M04040202 | Κατηγορία/<br>Classification:<br>IIb<br>Κανόνας/ Rule:<br>4 |
| 9239                                                           | Επίδεσμος αλγινικού ασβεστίου<br>Kendall™, 6" x 10" (15,2 cm x 25,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)   | 06301400000000000002556P | M04040202 | Κατηγορία/<br>Classification:<br>IIb<br>Κανόνας/ Rule:<br>4 |
| 9235                                                           | Επίδεσμος αλγινικού ασβεστίου<br>Kendall™, 2" x 1" (5,1 cm x 2,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)         | 06301400000000000002556P | M04040202 | Κατηγορία/<br>Classification:<br>IIb<br>Κανόνας/ Rule:<br>4 |
| 9240                                                           | Επίδεσμος αλγινικού ασβεστίου<br>Kendall™, 4" x 5-1/2" (10,2 cm x 14 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm) | 06301400000000000002556P | M04040202 | Κατηγορία/<br>Classification:<br>IIb<br>Κανόνας/ Rule:<br>4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Κατάλογος κωδικών προϊόντος</b><br><i>Product Code List</i> |                                                                                                                                                         |                          |           |                                                             |
|----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-------------------------------------------------------------|
| 9236                                                           | Επίδεσμος αλγινικού ασβεστίου<br>Kendall™ Plus, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm) | 06301400000000000002556P | M04040202 | Κατηγορία/<br>Classification:<br>IIb<br>Κανόνας/ Rule:<br>4 |
| 9231                                                           | Επίδεσμος αλγινικού ασβεστίου<br>Kendall™, σχοινί, 12" (30,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)                         | 06301400000000000002556P | M04040202 | Κατηγορία/<br>Classification:<br>IIb<br>Κανόνας/ Rule:<br>4 |
| 9243                                                           | Επίδεσμος αλγινικού ασβεστίου<br>Kendall™, σχοινί, 24" (61 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)                              | 06301400000000000002556P | M04040202 | Κατηγορία/<br>Classification:<br>IIb<br>Κανόνας/ Rule:<br>4 |
| 9244                                                           | Επίδεσμος αλγινικού ασβεστίου<br>Kendall™, σχοινί, 36" (91,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)                          | 06301400000000000002556P | M04040202 | Κατηγορία/<br>Classification:<br>IIb<br>Κανόνας/ Rule:<br>4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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## ITALIAN

### DICHIARAZIONE DI CONFORMITÀ DECLARATION OF CONFORMITY



**CardinalHealth**

**MDR:** Noi sottoscritti, Cardinal Health 200 LLC, dichiariamo che i prodotti relativi alla presente Dichiarazione di conformità UE sono conformi alle disposizioni del Regolamento sui dispositivi medici (UE) 2017/745.

|                                                                                                                            |                                                                                                                                                                                                                                                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Numero della dichiarazione di conformità</b><br><i>Declaration of Conformity Number</i>                                 | RE00205881                                                                                                                                                                                                                                                                                                              |
| <b>Numero di documentazione tecnica</b><br><i>Technical Documentation Number</i>                                           | RE00249263                                                                                                                                                                                                                                                                                                              |
| <b>Nome del fabbricante</b><br><i>Manufacturer's Name</i>                                                                  | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                                                |
| <b>Indirizzo del fabbricante</b><br><i>Manufacturer's Address</i>                                                          | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                                             |
| <b>Numero di registrazione unico</b><br><i>Single Registration Number</i>                                                  | US-MF-000006765                                                                                                                                                                                                                                                                                                         |
| <b>Nome e indirizzo del mandatario</b><br><i>Authorized Representative's Name and Address</i>                              | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                                         |
| <b>Nome e numero di identificazione dell'organismo notificato</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Numero di identificazione: 2797                                                                                                                                                                                          |
| <b>Numero di certificato CE</b><br><i>CE Certificate Number</i>                                                            | MDR 784266                                                                                                                                                                                                                                                                                                              |
| <b>Categoria di prodotto</b><br><i>Product Category</i>                                                                    | Medicazioni a base di alginato, combinate con altre sostanze<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                                      |
| <b>UDI-DI di base</b><br><i>Basic UDI-DI</i>                                                                               | Consultare l'Allegato I/ Refer to Attachment 1                                                                                                                                                                                                                                                                          |
| <b>EMDN</b>                                                                                                                | Consultare l'Allegato I/ Refer to Attachment 1                                                                                                                                                                                                                                                                          |
| <b>Codice prodotto, denominazione commerciale e descrizione</b><br><i>Product Code, Trade Name and Description</i>         | Consultare l'Allegato I/ Refer to Attachment 1                                                                                                                                                                                                                                                                          |
| <b>Destinazione d'uso</b><br><i>Intended Purpose</i>                                                                       | Le medicazioni per ferite con alginato di calcio Kendall™ sono medicazioni per ferite esterne indicate per assorbire essudati e proteggere la ferita dalla contaminazione.<br><br>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from |

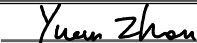
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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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**DICHIARAZIONE DI CONFORMITÀ**  
**DECLARATION OF CONFORMITY**

|                                                                                                                                        |                                                            |
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|                                                                                                                                        | contamination.                                             |
| <b>Classificazione e regola</b><br><i>Classification and Rule</i>                                                                      | Consultare l'Allegato I/ Refer to Attachment 1             |
| <b>Specifiche comuni</b><br><i>Common Specifications</i>                                                                               | Non applicabile (N/A)                                      |
| <b>Ove necessario, aggiungere la legislazione pertinente dell'Unione</b><br><i>Where appropriate, add applicable Union legislation</i> | Non applicabile (N/A)                                      |
| <b>Valutazione della conformità</b><br><i>Conformity Assessment</i>                                                                    | Allegato IX, Capitoli I e III/ Annex IX Chapters I and III |

**SEZIONE FIRMA**  
**SIGNATURE SECTION**

**La presente Dichiarazione di conformità UE è stata prodotta per, a nome e sotto esclusiva responsabilità del fabbricante legale sopra indicato.**

|                                                   |                                                                                                                              |
|---------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| <b>Luogo di rilascio</b><br><i>Place of Issue</i> | Waukegan, IL 60085 USA                                                                                                       |
| <b>Firma/Data</b><br><i>Signature/Date</i>        | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Nome e mansion</b><br><i>Name and Function</i> | Yuan Zhou<br>Regulatory Affairs<br>Affari regolatori                                                                         |

**ALLEGATO I**  
**ATTACHMENT 1**

**Elenco codice prodotto**  
**Product Code List**

| <b>Codice prodotto</b><br><i>Product Code</i> | <b>Denominazione commerciale e descrizione</b><br><i>Trade Name and Description</i>                                                   | <b>UDI-DI di base</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Classificazione e regola</b><br><i>Classification and Rule</i> |
|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|-------------|-------------------------------------------------------------------|
| 9233                                          | Medicazione con alginato di calcio Kendall™, 10,2 cm x 10,2 cm<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm) | 063014000000000000002556P                    | M04040202   | Classe/<br>Classification:<br>IIb<br>Regola/ Rule: 4              |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Elenco codice prodotto</b><br><i>Product Code List</i> |                                                                                                                                                       |                          |           |                                                      |
|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|------------------------------------------------------|
| 9232                                                      | Medicazione con alginato di calcio<br>Kendall™, 5,1 cm x 5,1 cm<br><br>Kendall™ Calcium Alginate<br>Dressing, 2" x 2" (5.1 cm x 5.1 cm)               | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regola/ Rule: 4 |
| 9238                                                      | Medicazione con alginato di calcio<br>Kendall™, 20,3 cm x 10,2 cm<br><br>Kendall™ Calcium Alginate<br>Dressing, 8" x 4" (20.3 cm x 10.2 cm)           | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regola/ Rule: 4 |
| 9242                                                      | Medicazione con alginato di calcio<br>Kendall™, 30,5 cm x 61 cm<br><br>Kendall™ Calcium Alginate<br>Dressing, 12" x 24" (30.5 cm x 61 cm)             | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regola/ Rule: 4 |
| 9239                                                      | Medicazione con alginato di calcio<br>Kendall™, 15,2 cm x 25,4 cm<br><br>Kendall™ Calcium Alginate<br>Dressing, 6" x 10" (15.2 cm x 25.4 cm)          | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regola/ Rule: 4 |
| 9235                                                      | Medicazione con alginato di calcio<br>Kendall™, 5,1 cm x 2,5 cm<br><br>Kendall™ Calcium Alginate<br>Dressing, 2" x 1" (5.1 cm x 2.5 cm)               | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regola/ Rule: 4 |
| 9240                                                      | Medicazione con alginato di calcio<br>Kendall™, 10,2 cm x 14 cm<br><br>Kendall™ Calcium Alginate<br>Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)           | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regola/ Rule: 4 |
| 9236                                                      | Medicazione con alginato di calcio<br>Kendall™ Plus, 10,2 cm x 10,2 cm<br><br>Kendall™ Calcium Alginate<br>Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm) | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regola/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Elenco codice prodotto</b><br><i>Product Code List</i> |                                                                                                                                   |                          |           |                                                      |
|-----------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|------------------------------------------------------|
| 9231                                                      | Medicazione con alginato di calcio<br>Kendall™, Filo, (30,5 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope, 12" (30.5 cm) | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regola/ Rule: 4 |
| 9243                                                      | Medicazione con alginato di calcio<br>Kendall™, Filo, 61 cm<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 24" (61 cm)        | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regola/ Rule: 4 |
| 9244                                                      | Medicazione con alginato di calcio<br>Kendall™, Filo, 91,4 cm<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 36" (91.4 cm)    | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regola/ Rule: 4 |

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## NORWEGIAN

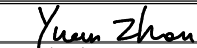
| <b>SAMSVARSERKLÆRING</b><br><b>DECLARATION OF CONFORMITY</b>                                                         |                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <br><b>CardinalHealth</b>            | <b>MDR:</b> Vi, Cardinal Health 200 LLC, erklærer at produktene som dekkes i denne EU-samsvarserklæringen oppfyller bestemmelsene i forordningen om medisinsk utstyr (EU) 2017/745.                                                                                                                                 |
| <b>Samsvarserklæringsnummer</b><br><i>Declaration of Conformity Number</i>                                           | RE00205881                                                                                                                                                                                                                                                                                                          |
| <b>Teknisk dokumentasjonsnummer</b><br><i>Technical Documentation Number</i>                                         | RE00249263                                                                                                                                                                                                                                                                                                          |
| <b>Produsentens navn</b><br><i>Manufacturer's Name</i>                                                               | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                                            |
| <b>Produsentens adresse</b><br><i>Manufacturer's Address</i>                                                         | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                                         |
| <b>Enkeltregistreringsnummer</b><br><i>Single Registration Number</i>                                                | US-MF-000006765                                                                                                                                                                                                                                                                                                     |
| <b>Autorisert representants navn og adresse</b><br><i>Authorized Representative's Name and Address</i>               | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                                     |
| <b>Teknisk kontrollorgans navn og identifikasjonsnummer</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Identifikasjonsnummer: 2797                                                                                                                                                                                          |
| <b>CE-sertifikatnummer</b><br><i>CE Certificate Number</i>                                                           | MDR 784266                                                                                                                                                                                                                                                                                                          |
| <b>Produktkategori</b><br><i>Product Category</i>                                                                    | Alginatbandasjer tilsatt med andre stoffer<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                                                    |
| <b>Grunnleggende UDI-DI</b><br><i>Basic UDI-DI</i>                                                                   | Se Tillegg I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                 |
| <b>EMDN</b>                                                                                                          | Se Tillegg I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                 |
| <b>Produktkode, handelsnavn og beskrivelse</b><br><i>Product Code, Trade Name and Description</i>                    | Se Tillegg I/ Refer to Attachment 1                                                                                                                                                                                                                                                                                 |
| <b>Tiltenkt formal</b><br><i>Intended Purpose</i>                                                                    | Kendall™ kalsium-alginatbandasjer for sår er bandasjer til utvortes bruk, som er beregnet for å absorbere sårveske og beskytte såret mot kontaminering.<br><br>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from contamination. |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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**SAMSVARSERKLÆRING**  
*DECLARATION OF CONFORMITY*

|                                                                                                                           |                                                            |
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| <b>Klassifisering og regel</b><br><i>Classification and Rule</i>                                                          | Se Tillegg I/ Refer to Attachment 1                        |
| <b>Vanlige spesifikasjoner</b><br><i>Common Specifications</i>                                                            | Ikke relevant (N/A)                                        |
| <b>Legg til gjeldende EU-lovgivning der det er relevant</b><br><i>Where appropriate, add applicable Union legislation</i> | Ikke relevant (N/A)                                        |
| <b>Samsvarsvurdering</b><br><i>Conformity Assessment</i>                                                                  | Tillegg IX, kapittel I og III/ Annex IX Chapters I and III |

**SIGNATURDEL**  
*SIGNATURE SECTION*

|                                                                                                                                                      |                                                                                                                              |
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| <b>Denne EU-samsvarserklæringen utstedes for og på vegne av den ovenfor identifiserte lomessige produsenten, og utelukkende under dennes ansvar.</b> |                                                                                                                              |
| <b>Utstedelsessted</b><br><i>Place of Issue</i>                                                                                                      | Waukegan, IL 60085 USA                                                                                                       |
| <b>Signatur/Dato</b><br><i>Signature/Date</i>                                                                                                        | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Navn og funksjon</b><br><i>Name and Function</i>                                                                                                  | Yuan Zhou<br>Regulatory Affairs<br>Juridisk avdeling                                                                         |

**TILLEGG I**  
*ATTACHMENT I*

| <b>Produktkodeliste</b><br><i>Product Code List</i> |                                                                                                                                      |                                                    |             |                                                                  |
|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|-------------|------------------------------------------------------------------|
| <b>Produktkode</b><br><i>Product Code</i>           | <b>Handelsnavn og beskrivelse</b><br><i>Trade Name and Description</i>                                                               | <b>Grunnleggende UDI-DI</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Klassifisering og regel</b><br><i>Classification and Rule</i> |
| 9233                                                | Kendall™ kalsium-alginatbandasje, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm) | 063014000000000000002556P                          | M04040202   | Klasse/<br>Classification:<br>IIb<br>Regel/ Rule: 4              |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Produktkodeliste</b><br><i>Product Code List</i> |                                                                                                                                          |                          |           |                                                     |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-----------------------------------------------------|
| 9232                                                | Kendall™ kalsium-alginatbandasje, 2" x 2" (5,1 cm x 5,1 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)         | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Regel/ Rule: 4 |
| 9238                                                | Kendall™ kalsium-alginatbandasje, 8" x 4" (20,3 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)     | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Regel/ Rule: 4 |
| 9242                                                | Kendall™ kalsium-alginatbandasje, 12" x 24" (30,5 cm x 61 cm)<br><br>Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)     | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Regel/ Rule: 4 |
| 9239                                                | Kendall™ kalsium-alginatbandasje, 6" x 10" (15,2 cm x 25,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)   | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Regel/ Rule: 4 |
| 9235                                                | Kendall™ kalsium-alginatbandasje, 2" x 1" (5,1 cm x 2,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)         | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Regel/ Rule: 4 |
| 9240                                                | Kendall™ kalsium-alginatbandasje, 4" x 5-1/2" (10,2 cm x 14 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm) | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Regel/ Rule: 4 |
| 9236                                                | Kendall™ kalsium-alginatbandasje Plus, 4" x 4"                                                                                           | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:                          |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Produktkodeliste</b><br><i>Product Code List</i> |                                                                                                                      |                          |           |                                                     |
|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-----------------------------------------------------|
|                                                     | (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)                      |                          |           | IIb<br>Regel/ Rule: 4                               |
| 9231                                                | Kendall™ kalsium-alginatbandasje, bånd, 12" (30,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm) | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Regel/ Rule: 4 |
| 9243                                                | Kendall™ kalsium-alginatbandasje, bånd, 24" (61 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)      | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Regel/ Rule: 4 |
| 9244                                                | Kendall™ kalsium-alginatbandasje, bånd, 36" (91,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)  | 06301400000000000002556P | M04040202 | Klasse/<br>Classification:<br>IIb<br>Regel/ Rule: 4 |

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## POLISH

| <b>DEKLARACJA ZGODNOŚCI</b><br><b>DECLARATION OF CONFORMITY</b>                                                       |                                                                                                                                                                                                                                                                                                        |
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|  <b>CardinalHealth</b>                | <b>MDR:</b> My, Cardinal Health 200 LLC, oświadczamy, że produkty objęte Deklaracją zgodności UE spełniają wymagania rozporządzenia w sprawie wyrobów medycznych (EU) 2017/745.                                                                                                                        |
| <b>Numer Deklaracji zgodności</b><br><i>Declaration of Conformity Number</i>                                          | RE00205881                                                                                                                                                                                                                                                                                             |
| <b>Numer dokumentacji technicznej</b><br><i>Technical Documentation Number</i>                                        | RE00249263                                                                                                                                                                                                                                                                                             |
| <b>Nazwa producenta</b><br><i>Manufacturer's Name</i>                                                                 | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                               |
| <b>Adres producenta</b><br><i>Manufacturer's Address</i>                                                              | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                            |
| <b>Pojedynczy numer rejestracyjny</b><br><i>Single Registration Number</i>                                            | US-MF-000006765                                                                                                                                                                                                                                                                                        |
| <b>Nazwa i adres autoryzowanego przedstawiciela</b><br><i>Authorized Representative's Name and Address</i>            | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                        |
| <b>Nazwa i numer identyfikacyjny jednostki notyfikowanej</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Numer identyfikacyjny: 2797                                                                                                                                                                             |
| <b>Numer certyfikatu CE</b><br><i>CE Certificate Number</i>                                                           | MDR 784266                                                                                                                                                                                                                                                                                             |
| <b>Kategoria produktuc</b><br><i>Product Category</i>                                                                 | Opatrunki z alginianem wapnia w połączeniu z innymi substancjami<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                 |
| <b>Podstawowy unikalny identyfikator urządzenia UDI-DI</b><br><i>Basic UDI-DI</i>                                     | Patrz Załącznik I/ Refer to Attachment 1                                                                                                                                                                                                                                                               |
| <b>EMDN</b>                                                                                                           | Patrz Załącznik I/ Refer to Attachment 1                                                                                                                                                                                                                                                               |
| <b>Kod produktu, nazwa handlowa i opis</b><br><i>Product Code, Trade Name and Description</i>                         | Patrz Załącznik I/ Refer to Attachment 1                                                                                                                                                                                                                                                               |
| <b>Przeznaczenie</b><br><i>Intended Purpose</i>                                                                       | <p>Opatrunki Kendall™ z alginianem wapnia to zewnętrzne opatrunki na rany przeznaczone do chłonięcia wysięków i ochrony rany przed zanieczyszczeniem.</p> <p>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from</p> |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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| <b>DEKLARACJA ZGODNOŚCI</b><br><i>DECLARATION OF CONFORMITY</i>                                                                  |                                                              |
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|                                                                                                                                  | contamination.                                               |
| <b>Klasyfikacja i reguła</b><br><i>Classification and Rule</i>                                                                   | Patrz Załącznik I/ Refer to Attachment 1                     |
| <b>Wspólne specyfikacje</b><br><i>Common Specifications</i>                                                                      | Nie dotyczy (N/A)                                            |
| <b>W stosownych przypadkach dodać obowiązujące przepisy unijne</b><br><i>Where appropriate, add applicable Union legislation</i> | Nie dotyczy (N/A)                                            |
| <b>Ocena zgodności</b><br><i>Conformity Assessment</i>                                                                           | Załącznik IX, rozdziały I i III/ Annex IX Chapters I and III |

| <b>SEKCJA PODPISÓW</b><br><i>SIGNATURE SECTION</i>                                                                                  |                                                                                                                              |
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| Niniejsza deklaracja zgodności UE została wydana w imieniu i na wyłączną odpowiedzialność legalnego producenta określonego powyżej. |                                                                                                                              |
| <b>Miejsce wydania</b><br><i>Place of Issue</i>                                                                                     | Waukegan, IL 60085 USA                                                                                                       |
| <b>Podpis/Data</b><br><i>Signature/Date</i>                                                                                         | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Imię i nazwisko oraz stanowisko</b><br><i>Name and Function</i>                                                                  | Yuan Zhou<br>Regulatory Affairs<br>Dział spraw regulacyjnych                                                                 |

**ZAŁĄCZNIK 1**  
*ATTACHMENT 1*

| <b>Lista kodów produktu</b><br><i>Product Code List</i> |                                                                                                                                       |                                                                                             |             |                                                                |
|---------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|-------------|----------------------------------------------------------------|
| <b>Kod produktu</b><br><i>Product Code</i>              | <b>Nazwa handlowa i opis</b><br><i>Trade Name and Description</i>                                                                     | <b>Podstawowy unikalny identyfikator urządzenia</b><br><b>UDI-DI</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Klasyfikacja i reguła</b><br><i>Classification and Rule</i> |
| 9233                                                    | Opatrunek Kendall™ z alginianem wapnia, 4"x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 | 063014000000000000002556P                                                                   | M04040202   | Klasa/<br>Classification:<br>IIb<br>Reguła/ Rule: 4            |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Lista kodów produktu</b><br><i>Product Code List</i> |                                                                                                                                               |                          |           |                                                      |
|---------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|------------------------------------------------------|
|                                                         | cm)                                                                                                                                           |                          |           |                                                      |
| 9232                                                    | Opatrunek Kendall™ z alginianem wapnia, 2"x 2" (5,1 cm x 5,1 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)         | 06301400000000000002556P | M04040202 | Klasa./<br>Classification:<br>IIb<br>Reguła/ Rule: 4 |
| 9238                                                    | Opatrunek Kendall™ z alginianem wapnia, 8"x 4" (20,3 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)     | 06301400000000000002556P | M04040202 | Klasa./<br>Classification:<br>IIb<br>Reguła/ Rule: 4 |
| 9242                                                    | Opatrunek Kendall™ z alginianem wapnia, 12"x 24" (30,5 cm x 61 cm)<br><br>Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)     | 06301400000000000002556P | M04040202 | Klasa./<br>Classification:<br>IIb<br>Reguła/ Rule: 4 |
| 9239                                                    | Opatrunek Kendall™ z alginianem wapnia, 6"x 10" (15,2 cm x 25,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)   | 06301400000000000002556P | M04040202 | Klasa./<br>Classification:<br>IIb<br>Reguła/ Rule: 4 |
| 9235                                                    | Opatrunek Kendall™ z alginianem wapnia, 2"x 1" (5,1 cm x 2,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)         | 06301400000000000002556P | M04040202 | Klasa./<br>Classification:<br>IIb<br>Reguła/ Rule: 4 |
| 9240                                                    | Opatrunek Kendall™ z alginianem wapnia, 4"x 5-1/2" (10,2 cm x 14 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm) | 06301400000000000002556P | M04040202 | Klasa./<br>Classification:<br>IIb<br>Reguła/ Rule: 4 |
| 9236                                                    | Opatrunek Kendall™ z alginianem wapnia Plus, 4"x 4" (10,2 cm x                                                                                | 06301400000000000002556P | M04040202 | Klasa./<br>Classification:                           |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Lista kodów produktu</b><br><i>Product Code List</i> |                                                                                                                             |                          |           |                                                 |
|---------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-------------------------------------------------|
|                                                         | 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)                                        |                          |           | I Ib<br>Reguła/ Rule: 4                         |
| 9231                                                    | Opatrunek Kendall™ z alginianem wapnia, linka, 12" (30,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm) | 06301400000000000002556P | M04040202 | Klasa,/ Classification: I Ib<br>Reguła/ Rule: 4 |
| 9243                                                    | Opatrunek Kendall™ z alginianem wapnia, linka, 24" (61 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)      | 06301400000000000002556P | M04040202 | Klasa,/ Classification: I Ib<br>Reguła/ Rule: 4 |
| 9244                                                    | Opatrunek Kendall™ z alginianem wapnia, linka, 36" (91,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)  | 06301400000000000002556P | M04040202 | Klasa,/ Classification: I Ib<br>Reguła/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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## PORTUGUESE

### **DECLARAÇÃO DE CONFORMIDADE** **DECLARATION OF CONFORMITY**



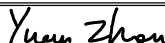
**CardinalHealth**

**MDR:** Nos, Cardinal Health 200 LLC, declaramos que os produtos abrangidos por esta Declaração de Conformidade da UE cumprem a disposição do Regulamento relativo a dispositivos médicos (UE) 2017/745.

|                                                                                                                        |                                                                                                                                                                                                                              |
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| <b>Número de Declaração de Conformidade</b><br><i>Declaration of Conformity Number</i>                                 | RE00205881                                                                                                                                                                                                                   |
| <b>Número de documentação técnica</b><br><i>Technical Documentation Number</i>                                         | RE00249263                                                                                                                                                                                                                   |
| <b>Nome do fabricante</b><br><i>Manufacturer's Name</i>                                                                | Cardinal Health 200, LLC                                                                                                                                                                                                     |
| <b>Endereço do fabricante</b><br><i>Manufacturer's Address</i>                                                         | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                  |
| <b>Número único de registo</b><br><i>Single Registration Number</i>                                                    | US-MF-000006765                                                                                                                                                                                                              |
| <b>Nome e endereço do representante autorizado</b><br><i>Authorized Representative's Name and Address</i>              | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                              |
| <b>Nome e número de identificação do organismo notificado</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Número de identificação: 2797                                                                                                 |
| <b>Número do certificado CE</b><br><i>CE Certificate Number</i>                                                        | MDR 784266                                                                                                                                                                                                                   |
| <b>Categoria do produto</b><br><i>Product Category</i>                                                                 | Curativos de alginato, combinados com outras substâncias<br>Alginate Dressings, Combined with other substances                                                                                                               |
| <b>UDI-DI básico</b><br><i>Basic UDI-DI</i>                                                                            | Consultar o Anexo I/ Refer to Attachment 1                                                                                                                                                                                   |
| <b>EMDN</b>                                                                                                            | Consultar o Anexo I/ Refer to Attachment 1                                                                                                                                                                                   |
| <b>Código, nome comercial e descrição do produto</b><br><i>Product Code, Trade Name and Description</i>                | Consultar o Anexo I/ Refer to Attachment 1                                                                                                                                                                                   |
| <b>Finalidade</b><br><i>Intended Purpose</i>                                                                           | Os curativos de alginato de cálcio Kendall™ são curativos externos para feridas destinados a absorver exsudatos e proteger a ferida contra contaminação.<br><br>Kendall™ Calcium Alginate Wound Dressings are external wound |

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| <b>DECLARAÇÃO DE CONFORMIDADE</b><br><i>DECLARATION OF CONFORMITY</i>                                                                 |                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
|                                                                                                                                       | dressings intended for use to absorb exudates and protect the wound from contamination. |
| <b>Classificação e regra</b><br><i>Classification and Rule</i>                                                                        | Consultar o Anexo I/ Refer to Attachment 1                                              |
| <b>Especificações comuns</b><br><i>Common Specifications</i>                                                                          | Não aplicável (N/A)                                                                     |
| <b>Se for o caso, adicione a legislação aplicável ao nível da União</b><br><i>Where appropriate, add applicable Union legislation</i> | Não aplicável (N/A)                                                                     |
| <b>Avaliação de conformidade</b><br><i>Conformity Assessment</i>                                                                      | Anexo IX, Capítulos I e III / Annex IX Chapters I and III                               |

| <b>SECÇÃO DE ASSINATURA</b><br><i>SIGNATURE SECTION</i>                                                                                   |                                                                                                                              |
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| <b>Esta Declaração de Conformidade da UE é emitida em nome e sob a responsabilidade exclusiva do Fabricante legal identificado acima.</b> |                                                                                                                              |
| <b>Local de emissão</b><br><i>Place of Issue</i>                                                                                          | Waukegan, IL 60085 USA                                                                                                       |
| <b>Assinatura/Data</b><br><i>Signature/Date</i>                                                                                           | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Nome e cargo</b><br><i>Name and Function</i>                                                                                           | Yuan Zhou<br>Regulatory Affairs<br>Assuntos Regulamentares                                                                   |

**ANEXO I**  
*ATTACHMENT 1*

| <b>Lista de códigos dos produtos</b><br><i>Product Code List</i> |                                                                                                                                                |                                             |             |                                                                |
|------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|-------------|----------------------------------------------------------------|
| <b>Código do produto</b><br><i>Product Code</i>                  | <b>Nome comercial e descrição</b><br><i>Trade Name and Description</i>                                                                         | <b>UDI-DI básico</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Classificação e regra</b><br><i>Classification and Rule</i> |
| 9233                                                             | Curativo de alginato de cálcio Kendall™ 10,2 cm x 10,2 cm (4 pol. x 4 pol.)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 | 06301400000000000002556P                    | M04040202   | Classe/<br>Classification:<br>IIb<br>Regra/ Rule: 4            |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Lista de códigos dos produtos</b><br><i>Product Code List</i> |                                                                                                                                                                    |                          |           |                                                      |
|------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|------------------------------------------------------|
|                                                                  | cm)                                                                                                                                                                |                          |           |                                                      |
| 9232                                                             | Curativo de alginato de cálcio<br>Kendall™ 5,1 cm x 5,1 cm (2 pol.<br>x 2 pol.)<br><br>Kendall™ Calcium Alginate<br>Dressing, 2" x 2" (5.1 cm x 5.1<br>cm)         | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>I Ib<br>Regra/ Rule: 4 |
| 9238                                                             | Curativo de alginato de cálcio<br>Kendall™ 20,3 cm x 10,2 cm (8<br>pol. x 4 pol.)<br><br>Kendall™ Calcium Alginate<br>Dressing, 8" x 4" (20.3 cm x 10.2<br>cm)     | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>I Ib<br>Regra/ Rule: 4 |
| 9242                                                             | Curativo de alginato de cálcio<br>Kendall™ 30,5 cm x 61 cm (12<br>pol. x 24 pol.)<br><br>Kendall™ Calcium Alginate<br>Dressing, 12" x 24" (30.5 cm x 61<br>cm)     | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>I Ib<br>Regra/ Rule: 4 |
| 9239                                                             | Curativo de alginato de cálcio<br>Kendall™ 15,2 cm x 25,4 cm (6<br>pol. x 10 pol.)<br><br>Kendall™ Calcium Alginate<br>Dressing, 6" x 10" (15.2 cm x 25.4<br>cm)   | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>I Ib<br>Regra/ Rule: 4 |
| 9235                                                             | Curativo de alginato de cálcio<br>Kendall™ 5,1 cm x 2,5 cm (2 pol.<br>x 1 pol.)<br><br>Kendall™ Calcium Alginate<br>Dressing, 2" x 1" (5.1 cm x 2.5<br>cm)         | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>I Ib<br>Regra/ Rule: 4 |
| 9240                                                             | Curativo de alginato de cálcio<br>Kendall™ 10,2 cm x 14 cm (4 pol.<br>x 5-1/2 pol.)<br><br>Kendall™ Calcium Alginate<br>Dressing, 4" x 5-1/2" (10.2 cm x<br>14 cm) | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>I Ib<br>Regra/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Lista de códigos dos produtos</b><br><i>Product Code List</i> |                                                                                                                                                                          |                          |           |                                                     |
|------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-----------------------------------------------------|
| 9236                                                             | Curativo de alginato de cálcio<br>Kendall™ Plus 10,2 cm x 10,2 cm<br>(4 pol. x 4 pol.)<br><br>Kendall™ Calcium Alginate<br>Dressing Plus, 4" x 4" (10.2 cm x<br>10.2 cm) | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regra/ Rule: 4 |
| 9231                                                             | Curativo de alginato de cálcio<br>Kendall™, tipo corda, 30,5 cm (12<br>pol.)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope, 12" (30.5 cm)                           | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regra/ Rule: 4 |
| 9243                                                             | Curativo de alginato de cálcio<br>Kendall™, tipo corda, 61 cm (24<br>pol.)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 24" (61 cm)                                | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regra/ Rule: 4 |
| 9244                                                             | Curativo de alginato de cálcio<br>Kendall™, tipo corda, 91,4 cm (36<br>pol.)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 36" (91.4 cm)                            | 06301400000000000002556P | M04040202 | Classe/<br>Classification:<br>IIb<br>Regra/ Rule: 4 |

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## ROMANIAN

| DECLARAȚIE DE CONFORMITATE<br>DECLARATION OF CONFORMITY                                                                     |                                                                                                                                                                                                                                                                                                                       |
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|  <b>CardinalHealth</b>                      | <b>MDR:</b> Noi, Cardinal Health 200 LLC, declarăm că produsele acoperite în această Declarație de conformitate UE respectă prevederile Regulamentului privind dispozitivele medicale (UE) 2017/745.                                                                                                                  |
| <b>Număr declarație de conformitate</b><br><i>Declaration of Conformity Number</i>                                          | RE00205881                                                                                                                                                                                                                                                                                                            |
| <b>Număr documentație tehnică</b><br><i>Technical Documentation Number</i>                                                  | RE00249263                                                                                                                                                                                                                                                                                                            |
| <b>Numele producătorului</b><br><i>Manufacturer's Name</i>                                                                  | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                                              |
| <b>Adresa producătorului</b><br><i>Manufacturer's Address</i>                                                               | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                                           |
| <b>Număr unic de înregistrare</b><br><i>Single Registration Number</i>                                                      | US-MF-000006765                                                                                                                                                                                                                                                                                                       |
| <b>Numele și adresa reprezentantului autorizat</b><br><i>Authorized Representative's Name and Address</i>                   | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                                       |
| <b>Numele și numărul de identificare al Organismului notificat</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Număr de identificare: 2797                                                                                                                                                                                            |
| <b>Numărul certificatului CE</b><br><i>CE Certificate Number</i>                                                            | MDR 784266                                                                                                                                                                                                                                                                                                            |
| <b>Categoria de produs</b><br><i>Product Category</i>                                                                       | Pansamente cu alginat, combinate cu alte substanțe<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                                              |
| <b>UDI-DI de bază</b><br><i>Basic UDI-DI</i>                                                                                | Consultați Anexa I/ Refer to Attachment 1                                                                                                                                                                                                                                                                             |
| <b>EMDN</b>                                                                                                                 | Consultați Anexa I/ Refer to Attachment 1                                                                                                                                                                                                                                                                             |
| <b>Cod produs, Nume comercial și Descriere</b><br><i>Product Code, Trade Name and Description</i>                           | Consultați Anexa I/ Refer to Attachment 1                                                                                                                                                                                                                                                                             |
| <b>Destinația utilizării</b><br><i>Intended Purpose</i>                                                                     | <p>Pansamentele cu alginat de calciu Kendall™ sunt pansamente externe destinate utilizării pentru absorbția exsudatelor și protejarea plăgii împotriva contaminării.</p> <p>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from</p> |

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| <b>DECLARAȚIE DE CONFORMITATE</b><br><i>DECLARATION OF CONFORMITY</i>                                                           |                                                            |
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|                                                                                                                                 | contamination.                                             |
| <b>Clasificare și regulă</b><br><i>Classification and Rule</i>                                                                  | Consultați Anexa I/ Refer to Attachment 1                  |
| <b>Specificații comune</b><br><i>Common Specifications</i>                                                                      | Nu este cazul (N/A)                                        |
| <b>Când este cazul, adăugați legislația aplicabilă din Uniune</b><br><i>Where appropriate, add applicable Union legislation</i> | Nu este cazul (N/A)                                        |
| <b>Evaluarea de conformitate</b><br><i>Conformity Assessment</i>                                                                | Anexa IX, Capitolele I și III/ Annex IX Chapters I and III |

| <b>SECȚIUNEA DE SEMNĂTURI</b><br><i>SIGNATURE SECTION</i>                                                                                 |                                                                                                                              |
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| Această Declarație de conformitate UE este emisă în numele și sub responsabilitatea exclusivă a Producătorului Legal identificat mai sus. |                                                                                                                              |
| <b>Locul emiterii</b><br><i>Place of Issue</i>                                                                                            | Waukegan, IL 60085 USA                                                                                                       |
| <b>Semnătura/Data</b><br><i>Signature/Date</i>                                                                                            | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Nume și funcție</b><br><i>Name and Function</i>                                                                                        | Yuan Zhou<br>Regulatory Affairs<br>Afaceri de reglementare                                                                   |

**ANEXA I**  
*ATTACHMENT I*

| <b>Listă cu Coduri de produse</b><br><i>Product Code List</i> |                                                                                                                                         |                                              |             |                                                                |
|---------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|-------------|----------------------------------------------------------------|
| <b>Cod produs</b><br><i>Product Code</i>                      | <b>Nume comercial și descriere</b><br><i>Trade Name and Description</i>                                                                 | <b>UDI-DI de bază</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Clasificare și regulă</b><br><i>Classification and Rule</i> |
| 9233                                                          | Pansament cu alginat de calciu Kendall™, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 | 06301400000000000002556P                     | M04040202   | Clasă/ Class: IIb<br>Regulă/ Rule: 4                           |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Listă cu Coduri de produse</b><br><i>Product Code List</i> |                                                                                                                                                       |                          |           |                                      |
|---------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|--------------------------------------|
|                                                               | cm)                                                                                                                                                   |                          |           |                                      |
| 9232                                                          | Pansament cu alginat de calciu<br>Kendall™, 2" x 2" (5,1 cm x 5,1 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 2" x 2" (5.1 cm x 5.1 cm)         | 06301400000000000002556P | M04040202 | Clasă/ Class: IIb<br>Regulă/ Rule: 4 |
| 9238                                                          | Pansament cu alginat de calciu<br>Kendall™, 8" x 4" (20,3 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 8" x 4" (20.3 cm x 10.2 cm)     | 06301400000000000002556P | M04040202 | Clasă/ Class: IIb<br>Regulă/ Rule: 4 |
| 9242                                                          | Pansament cu alginat de calciu<br>Kendall™, 12" x 24" (30,5 cm x 61 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 12" x 24" (30.5 cm x 61 cm)     | 06301400000000000002556P | M04040202 | Clasă/ Class: IIb<br>Regulă/ Rule: 4 |
| 9239                                                          | Pansament cu alginat de calciu<br>Kendall™, 6" x 10" (15,2 cm x 25,4 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 6" x 10" (15.2 cm x 25.4 cm)   | 06301400000000000002556P | M04040202 | Clasă/ Class: IIb<br>Regulă/ Rule: 4 |
| 9235                                                          | Pansament cu alginat de calciu<br>Kendall™, 2" x 1" (5,1 cm x 2,5 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 2" x 1" (5.1 cm x 2.5 cm)         | 06301400000000000002556P | M04040202 | Clasă/ Class: IIb<br>Regulă/ Rule: 4 |
| 9240                                                          | Pansament cu alginat de calciu<br>Kendall™, 4" x 5-1/2" (10,2 cm x 14 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 4" x 5-1/2" (10.2 cm x 14 cm) | 06301400000000000002556P | M04040202 | Clasă/ Class: IIb<br>Regulă/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Listă cu Coduri de produse</b><br><i>Product Code List</i> |                                                                                                                                                          |                           |           |                                      |
|---------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------|--------------------------------------|
| 9236                                                          | Pansament cu alginat de calciu<br>Kendall™ Plus, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm) | 063014000000000000002556P | M04040202 | Clasă/ Class: IIb<br>Regulă/ Rule: 4 |
| 9231                                                          | Pansament cu alginat de calciu<br>Kendall™, șnur, 12" (30,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)                           | 063014000000000000002556P | M04040202 | Clasă/ Class: IIb<br>Regulă/ Rule: 4 |
| 9243                                                          | Pansament cu alginat de calciu<br>Kendall™, șnur, 24" (61 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)                                | 063014000000000000002556P | M04040202 | Clasă/ Class: IIb<br>Regulă/ Rule: 4 |
| 9244                                                          | Pansament cu alginat de calciu<br>Kendall™, șnur, 36" (91,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)                            | 063014000000000000002556P | M04040202 | Clasă/ Class: IIb<br>Regulă/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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## SLOVAK

| <b>VYHLÁSENIE O ZHODE</b><br><b>DECLARATION OF CONFORMITY</b>                                                   |                                                                                                                                                                                                                                                                                                                       |
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|                                 | <b>MDR:</b> Vyhlasujeme, Cardinal Health 200 LLC, že produkty uvedené v tomto vyhlásení o zhode EÚ spĺňajú ustanovenia nariadenia o zdravotníckych pomôckach (EÚ) 2017/745.                                                                                                                                           |
| <b>Číslo vyhlásenia o zhode</b><br><i>Declaration of Conformity Number</i>                                      | RE00205881                                                                                                                                                                                                                                                                                                            |
| <b>Číslo technickej dokumentácie</b><br><i>Technical Documentation Number</i>                                   | RE00249263                                                                                                                                                                                                                                                                                                            |
| <b>Názov výrobcu</b><br><i>Manufacturer's Name</i>                                                              | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                                              |
| <b>Adresa výrobcu</b><br><i>Manufacturer's Address</i>                                                          | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                                           |
| <b>Jednotné registračné číslo</b><br><i>Single Registration Number</i>                                          | US-MF-000006765                                                                                                                                                                                                                                                                                                       |
| <b>Meno a adresa oprávneného zástupcu</b><br><i>Authorized Representative's Name and Address</i>                | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                                       |
| <b>Meno a identifikačné číslo informovaného orgánu</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Identifikačné číslo: 2797                                                                                                                                                                                              |
| <b>Číslo certifikátu CE</b><br><i>CE Certificate Number</i>                                                     | MDR 784266                                                                                                                                                                                                                                                                                                            |
| <b>Kategória výrobku</b><br><i>Product Category</i>                                                             | Krytie na rany s obsahom alginátu, kombinované s inými látkami<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                                  |
| <b>Základné UDI-DI</b><br><i>Basic UDI-DI</i>                                                                   | Pozrite si Prílohu I/ Refer to Attachment 1                                                                                                                                                                                                                                                                           |
| <b>EMDN</b>                                                                                                     | Pozrite si Prílohu I/ Refer to Attachment 1                                                                                                                                                                                                                                                                           |
| <b>Kód výrobku, obchodný názov a popis</b><br><i>Product Code, Trade Name and Description</i>                   | Pozrite si Prílohu I/ Refer to Attachment 1                                                                                                                                                                                                                                                                           |
| <b>Zamýšľaný účel</b><br><i>Intended Purpose</i>                                                                | <p>Krytie na rany s obsahom alginátu vápenatého Kendall™ sú vonkajšie obvazy na rany určené na absorpciu exsudátov a ochranu rany pred kontamináciou.</p> <p>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from contamination.</p> |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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**VYHLÁSENIE O ZHODE**  
**DECLARATION OF CONFORMITY**

|                                                                                                                               |                                                           |
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| <b>Klasifikácia a pravidlo</b><br><i>Classification and Rule</i>                                                              | Pozrite si Prílohu I/ Refer to Attachment 1               |
| <b>Bežné špecifikácie</b><br><i>Common Specifications</i>                                                                     | Nevzťahuje sa (N/A)                                       |
| <b>V prípade potreby doplňte príslušné právne predpisy Únie</b><br><i>Where appropriate, add applicable Union legislation</i> | Nevzťahuje sa (N/A)                                       |
| <b>Posúdenie zhody</b><br><i>Conformity Assessment</i>                                                                        | Príloha IX, kapitoly I a III/ Annex IX Chapters I and III |

**PODPISOVÁ SEKCIA**  
**SIGNATURE SECTION**

**Toto vyhlásenie o zhode EÚ sa vydáva pre zákonného výrobcu, v jeho mene a na jeho výhradnú zodpovednosť.**

|                                                   |                                                                                                                              |
|---------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| <b>Miesto vydania</b><br><i>Place of Issue</i>    | Waukegan, IL 60085 USA                                                                                                       |
| <b>Podpis/ Dátum</b><br><i>Signature/Date</i>     | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Meno a pozícia</b><br><i>Name and Function</i> | Yuan Zhou<br>Regulatory Affairs<br>Regulačné záležitosti                                                                     |

**PRÍLOHU I**  
**ATTACHMENT I**

**Zoznam kódov výrobkov**  
**Product Code List**

| <b>Kód výrobku</b><br><i>Product Code</i> | <b>Obchodný názov a popis</b><br><i>Trade Name and Description</i>                                                                                        | <b>Základné UDI-DI</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Klasifikácia a pravidlo</b><br><i>Classification and Rule</i> |
|-------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|-------------|------------------------------------------------------------------|
| 9233                                      | Krytie na rany Kendall™ s obsahom alginátu vápenatého, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm) | 063014000000000000002556P                     | M04040202   | Trieda/ Class:<br>IIb<br>Pravidlo/ Rule:<br>4                    |
| 9232                                      | Krytie na rany Kendall™ s obsahom alginátu vápenatého, 2" x                                                                                               | 063014000000000000002556P                     | M04040202   | Trieda/ Class:<br>IIb                                            |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Zoznam kódov výrobkov</b><br><i>Product Code List</i> |                                                                                                                                                               |                          |           |                                               |
|----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-----------------------------------------------|
|                                                          | 2" (5,1 cm x 5,1 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)                                                                     |                          |           | Pravidlo/ Rule:<br>4                          |
| 9238                                                     | Krytie na rany Kendall™ s obsahom alginátu vápenatého, 8" x 4" (20,3 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)     | 06301400000000000002556P | M04040202 | Trieda/ Class:<br>IIb<br>Pravidlo/ Rule:<br>4 |
| 9242                                                     | Krytie na rany Kendall™ s obsahom alginátu vápenatého, 12" x 24" (30,5 cm x 61 cm)<br><br>Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)     | 06301400000000000002556P | M04040202 | Trieda/ Class:<br>IIb<br>Pravidlo/ Rule:<br>4 |
| 9239                                                     | Krytie na rany Kendall™ s obsahom alginátu vápenatého, 6" x 10" (15,2 cm x 25,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)   | 06301400000000000002556P | M04040202 | Trieda/ Class:<br>IIb<br>Pravidlo/ Rule:<br>4 |
| 9235                                                     | Krytie na rany Kendall™ s obsahom alginátu vápenatého, 2" x 1" (5,1 cm x 2,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)         | 06301400000000000002556P | M04040202 | Trieda/ Class:<br>IIb<br>Pravidlo/ Rule:<br>4 |
| 9240                                                     | Krytie na rany Kendall™ s obsahom alginátu vápenatého, 4" x 5-1/2" (10,2 cm x 14 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm) | 06301400000000000002556P | M04040202 | Trieda/ Class:<br>IIb<br>Pravidlo/ Rule:<br>4 |
| 9236                                                     | Krytie na rany Kendall™ Plus s obsahom alginátu vápenatého, 4" x 4" (10,2 cm x 10,2 cm)                                                                       | 06301400000000000002556P | M04040202 | Trieda/ Class:<br>IIb<br>Pravidlo/ Rule:<br>4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Zoznam kódov výrobkov</b><br><i>Product Code List</i> |                                                                                                                                          |                           |           |                                         |
|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------|-----------------------------------------|
|                                                          | Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)                                                                     |                           |           |                                         |
| 9231                                                     | Krytie na rany Kendall™ Rope s obsahom alginátu vápenatého, 12" (30,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm) | 063014000000000000002556P | M04040202 | Trieda/ Class: IIb<br>Pravidlo/ Rule: 4 |
| 9243                                                     | Krytie na rany Kendall™ Rope s obsahom alginátu vápenatého, 24" (61 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)      | 063014000000000000002556P | M04040202 | Trieda/ Class: IIb<br>Pravidlo/ Rule: 4 |
| 9244                                                     | Krytie na rany Kendall™ Rope s obsahom alginátu vápenatého, 36" (91,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)  | 063014000000000000002556P | M04040202 | Trieda/ Class: IIb<br>Pravidlo/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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## SPANISH

### **DECLARACIÓN DE CONFORMIDAD** **DECLARATION OF CONFORMITY**



**CardinalHealth**

**MDR:** Nosotros, Cardinal Health 200 LLC, declaramos que los productos contemplados en la presente Declaración de conformidad de la UE cumplen con la disposición del Reglamento sobre productos sanitarios (UE) 2017/745.

|                                                                                                                            |                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Número de declaración de conformidad</b><br><i>Declaration of Conformity Number</i>                                     | RE00205881                                                                                                                                                                                                                                                                                                          |
| <b>Número de documentación técnica</b><br><i>Technical Documentation Number</i>                                            | RE00249263                                                                                                                                                                                                                                                                                                          |
| <b>Nombre del fabricante</b><br><i>Manufacturer's Name</i>                                                                 | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                                            |
| <b>Dirección del fabricante</b><br><i>Manufacturer's Address</i>                                                           | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                                                         |
| <b>Número de registro único</b><br><i>Single Registration Number</i>                                                       | US-MF-000006765                                                                                                                                                                                                                                                                                                     |
| <b>Nombre y dirección del representante autorizado</b><br><i>Authorized Representative's Name and Address</i>              | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                                                     |
| <b>Nombre y número de identificación del organismo notificado</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Número de identificación: 2797                                                                                                                                                                                       |
| <b>Número de certificado CE</b><br><i>CE Certificate Number</i>                                                            | MDR 784266                                                                                                                                                                                                                                                                                                          |
| <b>Categoría del product</b><br><i>Product Category</i>                                                                    | Apósitos de alginato combinados con otras sustancias<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                                          |
| <b>UDI-DI básico</b><br><i>Basic UDI-DI</i>                                                                                | Consulte el Archivo adjunto I/ Refer to Attachment 1                                                                                                                                                                                                                                                                |
| <b>EMDN</b>                                                                                                                | Consulte el Archivo adjunto I/ Refer to Attachment 1                                                                                                                                                                                                                                                                |
| <b>Código del producto, nombre comercial y descripción</b><br><i>Product Code, Trade Name and Description</i>              | Consulte el Archivo adjunto I/ Refer to Attachment 1                                                                                                                                                                                                                                                                |
| <b>Propósito</b><br><i>Intended Purpose</i>                                                                                | Los apósitos de alginato de calcio para heridas Kendall™ son apósitos externos para heridas diseñados para absorber exudados y proteger la herida de la contaminación.<br><br>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from |

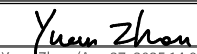
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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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**DECLARACIÓN DE CONFORMIDAD**  
*DECLARATION OF CONFORMITY*

|                                                                                                                                          |                                                         |
|------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
|                                                                                                                                          | contamination.                                          |
| <b>Clasificación y regla</b><br><i>Classification and Rule</i>                                                                           | Consulte el Archivo adjunto I/ Refer to Attachment 1    |
| <b>Especificaciones communes</b><br><i>Common Specifications</i>                                                                         | No corresponde (N/A)                                    |
| <b>Cuando proceda, añada la legislación de la Unión Europea applicable</b><br><i>Where appropriate, add applicable Union legislation</i> | No corresponde (N/A)                                    |
| <b>Evaluación de conformidad</b><br><i>Conformity Assessment</i>                                                                         | Anexo IX capítulos I y III/ Annex IX Chapters I and III |

**SECCIÓN DE FIRMA**  
*SIGNATURE SECTION*

**La presente Declaración de conformidad de la UE se emite para y en nombre de y bajo la responsabilidad exclusiva del fabricante que se identificó anteriormente.**

|                                                     |                                                                                                                              |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| <b>Lugar de emission</b><br><i>Place of Issue</i>   | Waukegan, IL 60085 USA                                                                                                       |
| <b>Firma / Fecha</b><br><i>Signature/Date</i>       | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Nombre y función</b><br><i>Name and Function</i> | Yuan Zhou<br>Regulatory Affairs<br>Asuntos normativos                                                                        |

**ARCHIVO ADJUNTO I**  
*ATTACHMENT 1*

**Lista de códigos del product**  
*Product Code List*

| <b>Código del product</b><br><i>Product Code</i> | <b>Nombre comercial y descripción</b><br><i>Trade Name and Description</i>                                                             | <b>UDI-DI básico</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Clasificación y regla</b><br><i>Classification and Rule</i> |
|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|-------------|----------------------------------------------------------------|
| 9233                                             | Apósito de alginato de calcio Kendall™, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 | 063014000000000000002556P                   | M04040202   | Clase/ Class: IIb<br>Regla/ Rule: 4                            |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Lista de códigos del product</b><br><i>Product Code List</i> |                                                                                                                                                   |                          |           |                                     |
|-----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-------------------------------------|
|                                                                 | cm)                                                                                                                                               |                          |           |                                     |
| 9232                                                            | Apósito de alginato de calcio<br>Kendall™, 2" x 2" (5,1 cm x 5,1 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)         | 06301400000000000002556P | M04040202 | Clase/ Class: IIb<br>Regla/ Rule: 4 |
| 9238                                                            | Apósito de alginato de calcio<br>Kendall™, 8" x 4" (20,3 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)     | 06301400000000000002556P | M04040202 | Clase/ Class: IIb<br>Regla/ Rule: 4 |
| 9242                                                            | Apósito de alginato de calcio<br>Kendall™, 12" x 24" (30,5 cm x 61 cm)<br><br>Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)     | 06301400000000000002556P | M04040202 | Clase/ Class: IIb<br>Regla/ Rule: 4 |
| 9239                                                            | Apósito de alginato de calcio<br>Kendall™, 6" x 10" (15,2 cm x 25,4 cm)<br><br>Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)   | 06301400000000000002556P | M04040202 | Clase/ Class: IIb<br>Regla/ Rule: 4 |
| 9235                                                            | Apósito de alginato de calcio<br>Kendall™, 2" x 1" (5,1 cm x 2,5 cm)<br><br>Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)         | 06301400000000000002556P | M04040202 | Clase/ Class: IIb<br>Regla/ Rule: 4 |
| 9240                                                            | Apósito de alginato de calcio<br>Kendall™, 4" x 5-1/2" (10,2 cm x 14 cm)<br><br>Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm) | 06301400000000000002556P | M04040202 | Clase/ Class: IIb<br>Regla/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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| <b>Lista de códigos del product</b><br><i>Product Code List</i> |                                                                                                                                                            |                           |           |                                     |
|-----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------|-------------------------------------|
| 9236                                                            | Apósito de alginato de calcio<br>Kendall™ Plus, 4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm) | 063014000000000000002556P | M04040202 | Clase/ Class: IIb<br>Regla/ Rule: 4 |
| 9231                                                            | Apósito de alginato de calcio<br>Kendall™, cuerda, 12" (30,5 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope, 12" (30.5 cm)                         | 063014000000000000002556P | M04040202 | Clase/ Class: IIb<br>Regla/ Rule: 4 |
| 9243                                                            | Apósito de alginato de calcio<br>Kendall™, cuerda, 24" (61 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 24" (61 cm)                              | 063014000000000000002556P | M04040202 | Clase/ Class: IIb<br>Regla/ Rule: 4 |
| 9244                                                            | Apósito de alginato de calcio<br>Kendall™, cuerda, 36" (91,4 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 36" (91.4 cm)                          | 063014000000000000002556P | M04040202 | Clase/ Class: IIb<br>Regla/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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## SWEDISH

### **FÖRSÄKRAN OM ÖVERENSSTÄMMELSE** *DECLARATION OF CONFORMITY*



**CardinalHealth**

**MDR:** Vi, Cardinal Health 200 LLC, försäkrar härmed att produkterna som omfattas av denna EU-försäkran om överensstämmelse uppfyller bestämmelserna om medicintekniska produkter i förordning (EU) 2017/745.

|                                                                                                                |                                                                                                                                                                                                                                                                                          |
|----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Nummer på försäkran om överensstämmelse</b><br><i>Declaration of Conformity Number</i>                      | RE00205881                                                                                                                                                                                                                                                                               |
| <b>Nummer på teknisk documentation</b><br><i>Technical Documentation Number</i>                                | RE00249263                                                                                                                                                                                                                                                                               |
| <b>Tillverkarens namn</b><br><i>Manufacturer's Name</i>                                                        | Cardinal Health 200, LLC                                                                                                                                                                                                                                                                 |
| <b>Tillverkarens address</b><br><i>Manufacturer's Address</i>                                                  | 3651 Birchwood Drive Waukegan, IL 60085 USA                                                                                                                                                                                                                                              |
| <b>Unikt registreringsnummer</b><br><i>Single Registration Number</i>                                          | US-MF-000006765                                                                                                                                                                                                                                                                          |
| <b>Namn på auktoriserad representant och address</b><br><i>Authorized Representative's Name and Address</i>    | Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland                                                                                                                                                          |
| <b>Namn på anmält organ och identifikationsnummer</b><br><i>Notified body's Name and Identification Number</i> | BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam<br>Identifikationsnummer: 2797                                                                                                                                                               |
| <b>Nummer på CE-certifikat</b><br><i>CE Certificate Number</i>                                                 | MDR 784266                                                                                                                                                                                                                                                                               |
| <b>Produktkategori</b><br><i>Product Category</i>                                                              | Alginatförband i kombination med andra ämnen<br>Alginate Dressings, Combined with other substances                                                                                                                                                                                       |
| <b>Grundläggande UDI-DI</b><br><i>Basic UDI-DI</i>                                                             | Medföljande dokument I/ Refer to Attachment 1                                                                                                                                                                                                                                            |
| <b>EMDN</b>                                                                                                    | Medföljande dokument I/ Refer to Attachment 1                                                                                                                                                                                                                                            |
| <b>Produktkod, handelsnamn och beskrivning</b><br><i>Product Code, Trade Name and Description</i>              | Medföljande dokument I/ Refer to Attachment 1                                                                                                                                                                                                                                            |
| <b>Avsedd användning</b><br><i>Intended Purpose</i>                                                            | Kendall™ kalciumalginatförband är utvändiga sårförband avsedda att absorbera sårvätskor och skydda såret från kontaminering.<br><br>Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from contamination. |

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**FÖRSÄKRAN OM ÖVERENSSTÄMMELSE**  
*DECLARATION OF CONFORMITY*

|                                                                                                           |                                                          |
|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| <b>Klassificering och regel</b><br><i>Classification and Rule</i>                                         | Medföljande dokument I/ Refer to Attachment 1            |
| <b>Gemensamma specifikationer</b><br><i>Common Specifications</i>                                         | Ej tillämpligt (N/A)                                     |
| <b>Lägg till tillämplig EU-lagstiftning</b><br><i>Where appropriate, add applicable Union legislation</i> | Ej tillämpligt (N/A)                                     |
| <b>Bedömning av överensstämmelse</b><br><i>Conformity Assessment</i>                                      | Bilaga IX kapitel I och III/ Annex IX Chapters I and III |

**SEKTION FÖR UNDERSKRIFT**  
*SIGNATURE SECTION*

|                                                                                                                                                  |                                                                                                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| <b>Denna EU-försäkran om överensstämmelse utfärdas för och på uppdrag av och under eget ansvar av den juridiska tillverkaren som anges ovan.</b> |                                                                                                                              |
| <b>Plats för utfärdande</b><br><i>Place of Issue</i>                                                                                             | Waukegan, IL 60085 USA                                                                                                       |
| <b>Underskrift/ Datum</b><br><i>Signature/Date</i>                                                                                               | <br>Yuan Zhou (Aug 27, 2025 14:09:47 EDT) |
| <b>Namn och function</b><br><i>Name and Function</i>                                                                                             | Yuan Zhou<br>Regulatory Affairs<br>Myndighetsärenden                                                                         |

**DOKUMENT I**  
*ATTACHMENT I*

**Lista de códigos del product**  
*Product Code List*

| <b>Produktkod</b><br><i>Product Code</i> | <b>Handelsnamn och beskrivning</b><br><i>Trade Name and Description</i>                                                                     | <b>Grundläggande UDI-DI</b><br><i>Basic UDI-DI</i> | <b>EMDN</b> | <b>Klassificering och regel</b><br><i>Classification and Rule</i> |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|-------------|-------------------------------------------------------------------|
| 9233                                     | Kendall™ kalciumalginatförband,<br>4" x 4" (10,2 cm x 10,2 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, 4" x 4" (10.2 cm x 10.2<br>cm) | 063014000000000000002556P                          | M04040202   | Klass/ Class: IIb<br>Regel/ Rule: 4                               |
| 9232                                     | Kendall™ kalciumalginatförband,<br>2" x 2" (5,1 cm x 5,1 cm)                                                                                | 063014000000000000002556P                          | M04040202   | Klass/ Class: IIb<br>Regel/ Rule: 4                               |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | 2 |
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| <b>Lista de códigos del product</b><br><i>Product Code List</i> |                                                                                                                                          |                          |           |                                     |
|-----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-------------------------------------|
|                                                                 | Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)                                                                            |                          |           |                                     |
| 9238                                                            | Kendall™ kalciumalginatförband, 8" x 4" (20,3 cm x 10,2 cm)<br>Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)           | 06301400000000000002556P | M04040202 | Klass/ Class: IIb<br>Regel/ Rule: 4 |
| 9242                                                            | Kendall™ kalciumalginatförband, 12" x 24" (30,5 cm x 61 cm)<br>Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)           | 06301400000000000002556P | M04040202 | Klass/ Class: IIb<br>Regel/ Rule: 4 |
| 9239                                                            | Kendall™ kalciumalginatförband, 6" x 10" (15,2 cm x 25,4 cm)<br>Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)         | 06301400000000000002556P | M04040202 | Klass/ Class: IIb<br>Regel/ Rule: 4 |
| 9235                                                            | Kendall™ kalciumalginatförband, 2" x 1" (5,1 cm x 2,5 cm)<br>Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)               | 06301400000000000002556P | M04040202 | Klass/ Class: IIb<br>Regel/ Rule: 4 |
| 9240                                                            | Kendall™ kalciumalginatförband, 4" x 5-1/2" (10,2 cm x 14 cm)<br>Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)       | 06301400000000000002556P | M04040202 | Klass/ Class: IIb<br>Regel/ Rule: 4 |
| 9236                                                            | Kendall™ kalciumalginatförband Plus, 4" x 4" (10,2 cm x 10,2 cm)<br>Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm) | 06301400000000000002556P | M04040202 | Klass/ Class: IIb<br>Regel/ Rule: 4 |
| 9231                                                            | Kendall™ kalciumalginatförband, rep, 12" (30,5 cm)<br>Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)                            | 06301400000000000002556P | M04040202 | Klass/ Class: IIb<br>Regel/ Rule: 4 |

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| <b>DOCUMENT NO:</b> | RE00205881 | <b>REVISION:</b> | <b>2</b> |
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**Lista de códigos del product**  
*Product Code List*

|      |                                                                                                                       |                          |           |                                     |
|------|-----------------------------------------------------------------------------------------------------------------------|--------------------------|-----------|-------------------------------------|
| 9243 | Kendall™ kalciumalginatförband,<br>rep 24" (61 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 24" (61 cm)     | 06301400000000000002556P | M04040202 | Klass/ Class: IIb<br>Regel/ Rule: 4 |
| 9244 | Kendall™ kalciumalginatförband,<br>rep 36" (91,4 cm)<br><br>Kendall™ Calcium Alginate<br>Dressing, Rope 36" (91.4 cm) | 06301400000000000002556P | M04040202 | Klass/ Class: IIb<br>Regel/ Rule: 4 |

# RE00205881

Final Audit Report

2025-08-27

|                 |                                              |
|-----------------|----------------------------------------------|
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