

DOC. TITLE: Declaration of Conformity MDR Kendall Calcium Alginate Dressings CAH			
DOCUMENT NO:	RE00205881	REVISION:	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.

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

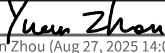
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DECLARATION OF CONFORMITY

Union legislation	
Conformity Assessment	Annex IX Chapters I and III

SIGNATURE SECTION

This EU Declaration of Conformity is issued for and on behalf of and under the sole responsibility of the Legal Manufacturer identified above.

Place of Issue	Waukegan, IL 60085 USA
Signature/ Date	 Yuan Zhou (Aug 27, 2025 14:09:47 EDT)
Name and Function	Yuan Zhou 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 Rule: 4
9232	Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000002556P	M04040202	Class: IIb Rule: 4
9238	Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Class: IIb Rule: 4
9242	Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Class: IIb Rule: 4
9239	Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Class: IIb Rule: 4
9235	Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Class: IIb 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)	06301400000000000002556P	M04040202	Class: IIb Rule: 4
9231	Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Class: IIb Rule: 4
9243	Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Class: IIb Rule: 4
9244	Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Class: IIb Rule: 4

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**IZJAVA O SUKLADNOSTI
DECLARATION OF CONFORMITY**



MDR: 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.

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

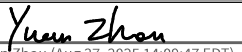
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IZJAVA O SUKLADNOSTI
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Zajedničke specifikacije <i>Common Specifications</i>	Nije primjenjivo (N/A)
Dodajte primjenjivo zakonodavstvo Europske unije, gdje je to prikladno <i>Where appropriate, add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

ODJELJAK S POTPISIMA
SIGNATURE SECTION

Ova Izjava o sukladnosti EU izdaje se za i u ime te na isključivu odgovornost prethodno navedenog zakonitog proizvođača.

Mjesto izdavanja <i>Place of Issue</i>	Waukegan, IL 60085 USA
Potpis/ Datum <i>Signature/ Date</i>	 Yuan Zhou (Aug 27, 2025 14:09:47 EDT)
Ime i funkcija <i>Name and Function</i>	Yuan Zhou Regulatory Affairs Odjel za regulatorna pitanja

PRILOG I
ATTACHMENT I

Popis kodova proizvoda
Product Code List

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

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Popis kodova proizvoda

Product Code List

	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) Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Klasa/ Class: IIb Pravilo/ Rule: 4
9242	Obloga od kalcijevog alginata Kendall™, 12" x 24" (30,5 cm x 61 cm) Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Klasa/ Class: IIb Pravilo/ Rule: 4
9239	Obloga od kalcijevog alginata Kendall™, 6" x 10" (15,2 cm x 25,4 cm) Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Klasa/ Class: IIb Pravilo/ Rule: 4
9235	Obloga od kalcijevog alginata Kendall™, 2" x 1" (5,1 cm x 2,5 cm) Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Klasa/ Class: IIb Pravilo/ Rule: 4
9240	Obloga od kalcijevog alginata Kendall™, 4" x 5 1/2" (10,2 cm x 14 cm) Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Klasa/ Class: IIb Pravilo/ Rule: 4
9236	Obloga od kalcijevog alginata Kendall™ Plus, 4" x 4" (10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Klasa/ Class: IIb Pravilo/ Rule: 4

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Popis kodova proizvoda


Product Code List

9231	Obloga od kalcijeveg alginata Kendall™, uže 12" (30,5 cm) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Klasa/ Class: IIb Pravilo/ Rule: 4
9243	Obloga od kalcijeveg alginata Kendall™, uže 24" (61 cm) Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Klasa/ Class: IIb Pravilo/ Rule: 4
9244	Obloga od kalcijeveg alginata Kendall™, uže 36" (91,4 cm) Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Klasa/ Class: IIb Pravilo/ Rule: 4

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CZECH

PROHLÁŠENÍ O SHODĚ
DECLARATION OF CONFORMITY

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

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PROHLÁŠENÍ O SHODĚ
DECLARATION OF CONFORMITY

Obecná specifikace <i>Common Specifications</i>	Nelze uplatnit (N/A)
Dle potřeby doplňte příslušný předpis Unie <i>Where appropriate, add applicable Union legislation</i>	Nelze uplatnit (N/A)
Posouzení shody <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.

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

PŘÍLOHA I
ATTACHMENT I

Seznam kódů výrobků
Product Code List

Kód výrobku <i>Product Code</i>	Obchodní název a popis <i>Trade Name and Description</i>	Základní UDI-DI <i>Basic UDI-DI</i>	EMDN	Klasifikace a pravidlo <i>Classification and Rule</i>
9233	Alginátové krytí s vápníkem Kendall™, 10,2 cm x 10,2 cm (4" x 4") Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Třída/ Class: IIb Pravidlo/ Rule: 4
9232	Alginátové krytí s vápníkem Kendall™, 5,1 cm x 5,1 cm (2" x 2")	06301400000000000002556P	M04040202	Třída/ Class: IIb Pravidlo/ Rule: 4

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Seznam kódů výrobků
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") Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Třída/ Class: Iib Pravidlo/ Rule: 4
9242	Alginátové krytí s vápníkem Kendall™, 30,5 cm x 61 cm (12" x 24") Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Třída/ Class: Iib Pravidlo/ Rule: 4
9239	Alginátové krytí s vápníkem Kendall™, 15,2 cm x 25,4 cm (6" x 10") Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Třída/ Class: Iib Pravidlo/ Rule: 4
9235	Alginátové krytí s vápníkem Kendall™, 5,1 cm x 2,5 cm (2" x 1") Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Třída/ Class: Iib Pravidlo/ Rule: 4
9240	Alginátové krytí s vápníkem Kendall™, 10,2 cm x 14 cm (4" x 5 1/2") Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Třída/ Class: Iib Pravidlo/ Rule: 4
9236	Alginátové krytí s vápníkem Kendall™ Plus, 10,2 cm x 10,2 cm (4" x 4") Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Třída/ Class: Iib Pravidlo/ Rule: 4

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Seznam kódů výrobků
Product Code List

9231	Alginátové krytí s vápníkem Kendall™, pás, 30,5 cm (12") Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Třída/ Class: IIb Pravidlo/ Rule: 4
9243	Alginátové krytí s vápníkem Kendall™, pás, 61 cm (24") Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Třída/ Class: IIb Pravidlo/ Rule: 4
9244	Alginátové krytí s vápníkem Kendall™, pás, 91,4 cm (36") Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Třída/ Class: IIb Pravidlo/ Rule: 4

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DANISH

PROHLÁŠENÍ O SHODĚ
DECLARATION OF CONFORMITY

	<p>MDR: Vi, Cardinal Health 200 LLC, erklærer, at produkterne dækket af denne EU-overensstemmelseserklæring overholder kravene i Forordning (EU) 2017/745 om medicinsk udstyr.</p>
Overensstemmelseserklæringsnummer <i>Declaration of Conformity Number</i>	RE00205881
Teknisk dokumentationsnummer <i>Technical Documentation Number</i>	RE00249263
Producentens navn <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Producentens adresse <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Enkelt registreringsnummer <i>Single Registration Number</i>	US-MF-000006765
Navn og adresse på godkendt repræsentant <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Navn og identifikationsnummer på bemyndiget organ <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identifikationsnummer: 2797
CE-certifikationsnummer <i>CE Certificate Number</i>	MDR 784266
Produktkategori <i>Product Category</i>	Alginatforbindinger, kombineret med andre stoffer Alginate Dressings, Combined with other substances
Grundlæggende UDI-DI <i>Basic UDI-DI</i>	Se bilag I / Refer to Attachment 1
EMDN	Se bilag I / Refer to Attachment 1
Produktkode(r), handelsnavn og beskrivelse <i>Product Code, Trade Name and Description</i>	Se bilag I / Refer to Attachment 1
Tiltænkt formål <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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PROHLÁŠENÍ O SHODĚ
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	contamination.
Klassificering og regel <i>Classification and Rule</i>	Se bilag I / Refer to Attachment 1
Fælles specifikationer <i>Common Specifications</i>	Ikke relevant (N/A)
Hvor relevant, tilføj gældende union-lovgivning <i>Where appropriate, add applicable Union legislation</i>	Ikke relevant (N/A)
Overensstemmelsesvurdering <i>Conformity Assessment</i>	Bilag IX, kapitel I og III/ Annex IX Chapters I and III

SIGNATURAFSNIT
SIGNATURE SECTION

Denne EU-overensstemmelseserklæring er udstedt for og på vegne af og under eneansvar for den juridiske producent, der er identificeret ovenfor.

Udstedelsessted <i>Place of Issue</i>	Waukegan, IL 60085 USA
Underskrift / Dato <i>Signature/ Date</i>	 Yuan Zhou (Aug 27, 2025 14:09:47 EDT)
Navn og funktion <i>Name and Function</i>	Yuan Zhou Regulatory Affairs Lovgivningsanliggender

BILAG I
ATTACHMENT 1

Produktkodeliste
Product Code List

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

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Produktkodeliste
Product Code List

9232	Kendall™ calciumalginatforbinding, 5,1 cm x 5,1 cm (2" x 2") Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9238	Kendall™ calciumalginatforbinding, 20,3 cm x 10,2 cm (8" x 4") Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9242	Kendall™ calciumalginatforbinding, 30,5 cm x 61 cm (12" x 24") Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9239	Kendall™ calciumalginatforbinding, 15,2 cm x 25,4 cm (6" x 10") Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9235	Kendall™ calciumalginatforbinding, 5,1 cm x 2,5 cm (2" x 1") Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9240	Kendall™ calciumalginatforbinding, 10,2 cm x 14 cm (4" x 5-1/2") Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9236	Kendall™ calciumalginatforbinding Plus	06301400000000000002556P	M04040202	Klasse /Class: IIb

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Produktkodeliste
Product Code List

	10,2 cm x 10,2 cm (4" x 4") 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") Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9243	Kendall™ calciumalginatforbinding, Rope 61 cm (24") Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9244	Kendall™ calciumalginatforbinding, Rope 91,4 cm (36") Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4

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DUTCH

**CONFORMITEITSVERKLARING
DECLARATION OF CONFORMITY**



MDR: Wij, Cardinal Health 200 LLC, verklaren dat de producten die onder deze EU-conformiteitsverklaring vallen, voldoen aan Verordening (EU) 2017/745 betreffende medische hulpmiddelen.

Nummer conformiteitsverklaring <i>Declaration of Conformity Number</i>	RE00205881
Nummer technische documentatie <i>Technical Documentation Number</i>	RE00249263
Naam fabrikant <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Adres van de fabrikant <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Enkel registratienummer <i>Single Registration Number</i>	US-MF-000006765
Naam en adres van de erkende vertegenwoordiger <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Naam en identificatienummer van de aangemelde instantie <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identificatienummer: 2797
Nummer CE-markering <i>CE Certificate Number</i>	MDR 784266
Productcategorie <i>Product Category</i>	Alginaatpleisters, gecombineerd met andere stoffen Alginate Dressings, Combined with other substances
Basis UDI-DI <i>Basic UDI-DI</i>	Zie Bijlage I/ Refer to Attachment 1
EMDN	Zie Bijlage I/ Refer to Attachment 1
Productcode, handelsnaam en beschrijving <i>Product Code, Trade Name and Description</i>	Zie Bijlage I/ Refer to Attachment 1
Beoogd doel <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. 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

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

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

BIJLAGE I
ATTACHMENT 1

Produktkodeliste
Product Code List

Productcode <i>Product Code</i>	Handelsnaam en beschrijving <i>Trade Name and Description</i>	Basis UDI-DI <i>Basic UDI-DI</i>	EMDN	Classificatie en regel <i>Classification and Rule</i>
9233	Kendall™- calciumalginaatpleister, 4" x 4" (10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4

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Produktkodeliste
Product Code List

9232	Kendall™- calciumalginaatpleister, 2" x 2" (5,1 cm x 5,1 cm) Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9238	Kendall™- calciumalginaatpleister, 8" x 4" (20,3 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9242	Kendall™- calciumalginaatpleister, 12" x 24" (30,5 cm x 61 cm) Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9239	Kendall™- calciumalginaatpleister, 6" x 10" (15,2 cm x 25,4 cm) Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9235	Kendall™- calciumalginaatpleister, 2" x 1" (5,1 cm x 2,5 cm) Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9240	Kendall™- calciumalginaatpleister, 4" x 5- 1/2" (10,2 cm x 14 cm) Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9236	Kendall™-calciumalginaatpleister Plus, 4" x 4" (10,2 cm x 10,2 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb

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Produktkodeliste
Product Code List

	Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)			Regel/ Rule: 4
9231	Kendall™- calciumalginaatpleister, streng, 12" (30,5 cm) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9243	Kendall™- calciumalginaatpleister, streng, 24" (61 cm) Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4
9244	Kendall™- calciumalginaatpleister, streng, 36" (91,4 cm) Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Klasse /Class: IIb Regel/ Rule: 4

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FINNISH

**VAATIMUSTENMUKAISUUSVAKUUTUS
DECLARATION OF CONFORMITY**

	MDR: Me, Cardinal Health 200 LLC, vakuutamme, että tässä EU-vaatimustenmukaisuusvakuutuksessa kuvatut tuotteet täyttävät lääkintälaitteasetuksen (EU) 2017/745 vaatimukset.
VAATIMUSTENMUKAISUUSVAKUUTUS <i>Declaration of Conformity Number</i>	RE00205881
Teknisen dokumentin numero <i>Technical Documentation Number</i>	RE00249263
Valmistajan nimi <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Valmistajan osoite <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Yksittäinen rekisterinumero <i>Single Registration Number</i>	US-MF-000006765
Valtuutetun edustajan nimi ja osoite <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Ilmoitetun laitoksen nimi ja tunnusnumero <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Tunnusnumero: 2797
CE-sertifikaatin numero <i>CE Certificate Number</i>	MDR 784266
Tuotekategoria <i>Product Category</i>	Alginaattisidokset, yhdessä muiden aineiden kanssa Alginate Dressings, Combined with other substances
Yksilöllinen laitemallin tunniste (Basic UDI-DI) <i>Basic UDI-DI</i>	Katso liite I/ Refer to Attachment 1
EMDN	Katso liite I/ Refer to Attachment 1
Tuotekoodi, kaupan nimi ja kuvaus <i>Product Code, Trade Name and Description</i>	Katso liite I/ Refer to Attachment 1
Käyttötarkoitus <i>Intended Purpose</i>	Kendall™-kalsium-alginaattihaavasidokset ovat ulkoisia haavasidoksia, jotka on tarkoitettu imemään itseensä haavaeritteitä ja suojaamaan haavaa kontaminoitumiselta. Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from contamination.
Luokittelu ja sääntö <i>Classification and Rule</i>	Katso liite I/ Refer to Attachment 1

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VAATIMUSTENMUKAISUUSVAKUUTUS
DECLARATION OF CONFORMITY

Yleiset tekniset tiedot <i>Common Specifications</i>	Ei sovellu (N/A)
Lisää tarvittaessa soveltuva unionin lainsäädäntö <i>Where appropriate, add applicable Union legislation</i>	Ei sovellu (N/A)
Vaatimustenmukaisuuden arviointi <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.

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

LIITE I
ATTACHMENT I

Tuotekoodiluettelo
Product Code List

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

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Tuotekoodiluettelo

Product Code List

	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) Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Luokka/ Classification: IIb Sääntö/ Rule: 4
9242	Kendall™-kalsium-alginaattisidos, 12" x 24" (30,5 cm x 61 cm) Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Luokka/ Classification: IIb Sääntö/ Rule: 4
9239	Kendall™-kalsium-alginaattisidos, 6" x 10" (15,2 cm x 25,4 cm) Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Luokka/ Classification: IIb Sääntö/ Rule: 4
9235	Kendall™-kalsium-alginaattisidos, 2" x 1" (5,1 cm x 2,5 cm) Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Luokka/ Classification: IIb Sääntö/ Rule: 4
9240	Kendall™-kalsium-alginaattisidos, 4" x 5-1/2" (10,2 cm x 14 cm) Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Luokka/ Classification: IIb Sääntö/ Rule: 4
9236	Kendall™-kalsium-alginaattisidos Plus, 4" x 4" (10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Luokka/ Classification: IIb Sääntö/ Rule: 4
9231	Kendall™-kalsium-	06301400000000000002556P	M04040202	Luokka/

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Tuotekoodiluettelo


Product Code List

	alginaattisidos, nuora, 12" (30,5 cm) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)			Classification: IIb Sääntö/ Rule: 4
9243	Kendall™-kalsium- alginaattisidos, nuora, 24" (61 cm) Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Luokka/ Classification: IIb Sääntö/ Rule: 4
9244	Kendall™-kalsium- alginaattisidos, nuora, 36" (91,4 cm) Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Luokka/ Classification: IIb Sääntö/ Rule: 4

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FRENCH

DÉCLARATION DE CONFORMITÉ
DECLARATION OF CONFORMITY

	<p>MDR: 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.</p>
Numéro de la déclaration de conformité <i>Declaration of Conformity Number</i>	RE00205881
Numéro de la documentation technique <i>Technical Documentation Number</i>	RE00249263
Nom du fabricant <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Adresse du fabricant <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Numéro d'enregistrement unique <i>Single Registration Number</i>	US-MF-000006765
Nom et adresse du représentant agréé <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Nom et numéro d'identification de l'organisme notifié <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Numéro d'identification: 2797
Numéro de certificat CE <i>CE Certificate Number</i>	MDR 784266
Catégorie de produit <i>Product Category</i>	Pansements alginate, combinés à d'autres substances Alginate Dressings, Combined with other substances
UDI-DI de base <i>Basic UDI-DI</i>	Voir PJ I/ Refer to Attachment 1
EMDN	Voir PJ I/ Refer to Attachment 1
Code, nom commercial et description du produit <i>Product Code, Trade Name and Description</i>	Voir PJ I/ Refer to Attachment 1
Usage prévu <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>

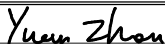
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DÉCLARATION DE CONFORMITÉ
DECLARATION OF CONFORMITY

	contamination.
Classification et règle <i>Classification and Rule</i>	Voir PJ I/ Refer to Attachment 1
Caractéristiques communes <i>Common Specifications</i>	Sans objet (N/A)
Le cas échéant, ajouter la législation de l'Union européenne en vigueur <i>Where appropriate, add applicable Union legislation</i>	Sans objet (N/A)
Évaluation de la conformité <i>Conformity Assessment</i>	Annexe IX, Chapitres I et III/ Annex IX Chapters I and III

SECTION SIGNATURE
SIGNATURE SECTION

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.

Lieu de délivrance <i>Place of Issue</i>	Waukegan, IL 60085 USA
Signature/Date <i>Signature/Date</i>	 Yuan Zhou (Aug 27, 2025 14:09:47 EDT)
Nom et fonction <i>Name and Function</i>	Yuan Zhou Regulatory Affairs Affaires réglementaires

PJ I

ATTACHMENT 1

Liste de référence produit
Product Code List

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

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Liste de référence produit
Product Code List

	cm)			
9232	Pansement alginate de calcium Kendall™, 2" x 2" (5,1 cm x 5,1 cm) Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000002556P	M04040202	Classification/ Classification: Iib Règle/ Rule: 4
9238	Pansement alginate de calcium Kendall™, 8" x 4" (20,3 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Classification/ Classification: Iib Règle/ Rule: 4
9242	Pansement alginate de calcium Kendall™, 12" x 24" (30,5 cm x 61 cm) Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Classification/ Classification: Iib Règle/ Rule: 4
9239	Pansement alginate de calcium Kendall™, 6" x 10" (15,2 cm x 25,4 cm) Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Classification/ Classification: Iib Règle/ Rule: 4
9235	Pansement alginate de calcium Kendall™, 2" x 1" (5,1 cm x 2,5 cm) Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Classification/ Classification: Iib Règle/ Rule: 4
9240	Pansement alginate de calcium Kendall™, 4" x 5-1/2" (10,2 cm x 14 cm) Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Classification/ Classification: Iib Règle/ Rule: 4

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Liste de référence produit
Product Code List

9236	Pansement alginate de calcium Kendall™ Plus, 4" x 4" (10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Classification/ Classification: IIb Règle/ Rule: 4
9231	Pansement alginate de calcium Kendall™, mèche, 12" (30,5 cm) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Classification/ Classification: IIb Règle/ Rule: 4
9243	Pansement alginate de calcium Kendall™, mèche, 24" (61 cm) Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Classification/ Classification: IIb Règle/ Rule: 4
9244	Pansement alginate de calcium Kendall™, mèche, 36" (91,4 cm) Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Classification/ Classification: IIb Règle/ Rule: 4

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GERMAN

**KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY**



CardinalHealth

MDR: Wir, Cardinal Health 200 LLC, erklären, dass die Produkte, die in dieser EU-Konformitätserklärung behandelt werden, den Bestimmungen der Medizinprodukteverordnung (EU) 2017/745 entsprechen.

Numer der Konformitätserklärung <i>Declaration of Conformity Number</i>	RE00205881
Technische Dokumentennummer <i>Technical Documentation Number</i>	RE00249263
Name des Herstellers <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Adresse des Herstellers <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Einzel-Registrierungsnummer <i>Single Registration Number</i>	US-MF-000006765
Name und Adresse des bevollmächtigten Vertreters <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Name und Identifikationsnummer der benannten Stelle <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identifikationsnummer: 2797
CE-Zertifikat-Nummer <i>CE Certificate Number</i>	MDR 784266
Produktkategorie <i>Product Category</i>	Alginat-Verbände, kombiniert mit anderen Substanzen Alginate Dressings, Combined with other substances
Grundlegende UDI-DI <i>Basic UDI-DI</i>	Siehe Anhang I/ Refer to Attachment 1
EMDN	Siehe Anhang I/ Refer to Attachment 1
Produktcode, Handelsname und Beschreibung <i>Product Code, Trade Name and Description</i>	Siehe Anhang I/ Refer to Attachment 1
Verwendungszweck <i>Intended Purpose</i>	Kalziumalginat-Wundverbände von Kendall™ sind externe Wundverbände zur Aufnahme von Exsudat und zum Schutz der Wunde vor Kontaminationen. 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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**KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY**

Klassifizierung und Richtlinie <i>Classification and Rule</i>	Siehe Anhang I/ Refer to Attachment 1
Allgemeine Spezifikationen <i>Common Specifications</i>	Nicht zutreffend (N/A)
Gegebenenfalls anwendbare Rechtsvorschriften der Gewerkschaft hinzufügen <i>Where appropriate, add applicable Union legislation</i>	Nicht zutreffend (N/A)
Konformitätsbewertung <i>Conformity Assessment</i>	Anhang IX Kapitel I und III/ Annex IX Chapters I and III

**UNTERSCHRIFTSABSCHNITT
SIGNATURE SECTION**

Diese EU-Konformitätserklärung wird für und im Namen und unter der alleinigen Verantwortung des oben angegebenen rechtmäßigen Herstellers ausgestellt.

Ausstellungsort <i>Place of Issue</i>	Waukegan, IL 60085 USA
Unterschrift /Datum <i>Signature/Date</i>	 Yuan Zhou (Aug 27, 2025 14:09:47 EDT)
Name und Funktion <i>Name and Function</i>	Yuan Zhou Regulatory Affairs Zulassungsangelegenheiten

**ANHANG I
ATTACHMENT 1**

**Produktcodeliste
Product Code List**

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

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Produktcodeliste
Product Code List

9232	Kendall™ Calcium-Alginat-Verband, 5,1 cm x 5,1 cm (2" x 2") Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: IIb Richtlinie/ Rule: 4
9238	Kendall™ Calcium-Alginat-Verband, 20,3 cm x 10,2 cm (8" x 4") Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: IIb Richtlinie/ Rule: 4
9242	Kendall™ Kalziumalginat-Verband, 30,5 cm x 61 cm (12" x 24") Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: IIb Richtlinie/ Rule: 4
9239	Kendall™ Kalzium-Alginat-Verband, 15,2 cm x 25,4 cm (6" x 10") Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: IIb Richtlinie/ Rule: 4
9235	Kendall™ Calcium-Alginat-Verband, 5,1 cm x 2,5 cm (2" x 1") Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: IIb Richtlinie/ Rule: 4
9240	Kendall™ Kalzium-Alginat-Verband, 10,2 cm x 14 cm (4" x 5-1/2") Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: IIb Richtlinie/ Rule: 4
9236	Kendall™ Calcium-Alginat-Verband Plus, 10,2 cm x 10,2 cm	06301400000000000002556P	M04040202	Klasse/ Classification:

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Produktcodeliste
Product Code List

	(4" x 4") Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)			Iib Richtlinie/ Rule: 4
9231	Kendall™ Kalzium-Alginat-Verband, Seil, 30,5 cm (12") Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: Iib Richtlinie/ Rule: 4
9243	Kendall™ Kalzium-Alginat-Verband, Seil 61 cm (24") Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: Iib Richtlinie/ Rule: 4
9244	Kendall™ Kalzium-Alginat-Verband, Seil 91,4 cm (36") Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: Iib Richtlinie/ Rule: 4

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GREEK

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ
DECLARATION OF CONFORMITY



MDR: 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.

Αριθμός δήλωσης συμμόρφωσης <i>Declaration of Conformity Number</i>	RE00205881
Αριθμός τεχνικού φακέλου <i>Technical Documentation Number</i>	RE00249263
Όνομα κατασκευαστή <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Διεύθυνση κατασκευαστή <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Ενιαίος αριθμός καταχώρισης <i>Single Registration Number</i>	US-MF-000006765
Όνομα και διεύθυνση εξουσιοδοτημένου αντιπροσώπου <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Όνομα και αριθμός αναγνώρισης κοινοποιημένου οργανισμού <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Αριθμός αναγνώρισης: 2797
Αριθμός πιστοποιητικού CE <i>CE Certificate Number</i>	MDR 784266
Κατηγορία προϊόντος <i>Product Category</i>	Αλγινικοί επίδεσμοι, σε συνδυασμό με άλλες ουσίες Alginate Dressings, Combined with other substances
Βασικό UDI-DI <i>Basic UDI-DI</i>	Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1
EMDN	Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1
Κωδικός προϊόντος, εμπορική επωνυμία και περιγραφή <i>Product Code, Trade Name and Description</i>	Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1
Προοριζόμενος σκοπός <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. Kendall™ Calcium Alginate Wound Dressings are external wound dressings intended for use to absorb exudates and protect the wound from

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ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ
DECLARATION OF CONFORMITY

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

ΕΝΟΤΗΤΑ ΥΠΟΓΡΑΦΗΣ
SIGNATURE SECTION

Η παρούσα Δήλωση συμμόρφωσης ΕΕ εκδίδεται στο όνομα και για λογαριασμό και με την αποκλειστική ευθύνη του Νόμιμου κατασκευαστή που ταυτοποιείται παραπάνω.

Τόπος έκδοσης <i>Place of Issue</i>	Waukegan, IL 60085 USA
Υπογραφή/Ημερομηνία <i>Signature/Date</i>	<u>Yuan Zhou</u> Yuan Zhou (Aug 27, 2025 14:09:47 EDT)
Όνομα και λειτουργία <i>Name and Function</i>	Yuan Zhou Regulatory Affairs Ρυθμιστικές υποθέσεις

ΠΡΟΣΑΡΤΗΜΑ I
ATTACHMENT I

Κατάλογος κωδικών προϊόντος
Product Code List

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

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Κατάλογος κωδικών προϊόντος
Product Code List

	cm)			
9232	Επίδεσμος αλγινικού ασβεστίου Kendall™, 2" x 2" (5,1 cm x 5,1 cm) Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000002556P	M04040202	Κατηγορία/ Classification: Ib Κανόνας/ Rule: 4
9238	Επίδεσμος αλγινικού ασβεστίου Kendall™, 8" x 4" (20,3 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Κατηγορία/ Classification: Ib Κανόνας/ Rule: 4
9242	Επίδεσμος αλγινικού ασβεστίου Kendall™, 12" x 24" (30,5 cm x 61 cm) Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Κατηγορία/ Classification: Ib Κανόνας/ Rule: 4
9239	Επίδεσμος αλγινικού ασβεστίου Kendall™, 6" x 10" (15,2 cm x 25,4 cm) Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Κατηγορία/ Classification: Ib Κανόνας/ Rule: 4
9235	Επίδεσμος αλγινικού ασβεστίου Kendall™, 2" x 1" (5,1 cm x 2,5 cm) Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Κατηγορία/ Classification: Ib Κανόνας/ Rule: 4
9240	Επίδεσμος αλγινικού ασβεστίου Kendall™, 4" x 5-1/2" (10,2 cm x 14 cm) Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Κατηγορία/ Classification: Ib Κανόνας/ Rule: 4

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Κατάλογος κωδικών προϊόντος
Product Code List

9236	Επίδεσμος αλγινικού ασβεστίου Kendall™ Plus, 4" x 4" (10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Κατηγορία/ Classification: IIb Κανόνας/ Rule: 4
9231	Επίδεσμος αλγινικού ασβεστίου Kendall™, σχοινί, 12" (30,5 cm) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Κατηγορία/ Classification: IIb Κανόνας/ Rule: 4
9243	Επίδεσμος αλγινικού ασβεστίου Kendall™, σχοινί, 24" (61 cm) Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Κατηγορία/ Classification: IIb Κανόνας/ Rule: 4
9244	Επίδεσμος αλγινικού ασβεστίου Kendall™, σχοινί, 36" (91,4 cm) Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Κατηγορία/ Classification: IIb Κανόνας/ Rule: 4

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ITALIAN

**DICHIARAZIONE DI CONFORMITÀ
DECLARATION OF CONFORMITY**



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.

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


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DICHIARAZIONE DI CONFORMITÀ
DECLARATION OF CONFORMITY

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

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

ALLEGATO I
ATTACHMENT 1

Elenco codice prodotto
Product Code List

Codice prodotto <i>Product Code</i>	Denominazione commerciale e descrizione <i>Trade Name and Description</i>	UDI-DI di base <i>Basic UDI-DI</i>	EMDN	Classificazione e regola <i>Classification and Rule</i>
9233	Medicazione con alginato di calcio Kendall™, 10,2 cm x 10,2 cm Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regola/ Rule: 4

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Elenco codice prodotto
Product Code List

9232	Medicazione con alginato di calcio Kendall™, 5,1 cm x 5,1 cm Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regola/ Rule: 4
9238	Medicazione con alginato di calcio Kendall™, 20,3 cm x 10,2 cm Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regola/ Rule: 4
9242	Medicazione con alginato di calcio Kendall™, 30,5 cm x 61 cm Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regola/ Rule: 4
9239	Medicazione con alginato di calcio Kendall™, 15,2 cm x 25,4 cm Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regola/ Rule: 4
9235	Medicazione con alginato di calcio Kendall™, 5,1 cm x 2,5 cm Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regola/ Rule: 4
9240	Medicazione con alginato di calcio Kendall™, 10,2 cm x 14 cm Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regola/ Rule: 4
9236	Medicazione con alginato di calcio Kendall™ Plus, 10,2 cm x 10,2 cm Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regola/ Rule: 4

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Elenco codice prodotto

Product Code List

9231	Medicazione con alginato di calcio Kendall™, Filo, (30,5 cm) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regola/ Rule: 4
9243	Medicazione con alginato di calcio Kendall™, Filo, 61 cm Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regola/ Rule: 4
9244	Medicazione con alginato di calcio Kendall™, Filo, 91,4 cm Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regola/ Rule: 4

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NORWEGIAN

**SAMSVARERKLÆRING
DECLARATION OF CONFORMITY**



MDR: Vi, Cardinal Health 200 LLC, erklærer at produktene som dekkes i denne EU-samsvarserklæringen oppfyller bestemmelsene i forordningen om medisinsk utstyr (EU) 2017/745.

Samsvarserklæringsnummer <i>Declaration of Conformity Number</i>	RE00205881
Teknisk dokumentasjonsnummer <i>Technical Documentation Number</i>	RE00249263
Produsentens navn <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Produsentens adresse <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Enkeltregistreringsnummer <i>Single Registration Number</i>	US-MF-000006765
Autorisert representants navn og adresse <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Teknisk kontrollorgans navn og identifikasjonsnummer <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identifikasjonsnummer: 2797
CE-sertifikatnummer <i>CE Certificate Number</i>	MDR 784266
Produktkategori <i>Product Category</i>	Alginatbandasjer tilsatt med andre stoffer Alginate Dressings, Combined with other substances
Grunnleggende UDI-DI <i>Basic UDI-DI</i>	Se Tillegg I/ Refer to Attachment 1
EMDN	Se Tillegg I/ Refer to Attachment 1
Produktkode, handelsnavn og beskrivelse <i>Product Code, Trade Name and Description</i>	Se Tillegg I/ Refer to Attachment 1
Tiltenkt formal <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. 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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SAMSVARERKLÆRING
DECLARATION OF CONFORMITY

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

SIGNATURDEL
SIGNATURE SECTION

Denne EU-samsvarserklæringen utstedes for og på vegne av den ovenfor identifiserte lomessige produsenten, og utelukkende under dennes ansvar.

Utstedelsessted <i>Place of Issue</i>	Waukegan, IL 60085 USA
Signatur/Dato <i>Signature/Date</i>	 Yuan Zhou (Aug 27, 2025 14:09:47 EDT)
Navn og funksjon <i>Name and Function</i>	Yuan Zhou Regulatory Affairs Juridisk avdeling

TILLEGG I
ATTACHMENT 1

Produktkodeliste
Product Code List

Produktkode <i>Product Code</i>	Handelsnavn og beskrivelse <i>Trade Name and Description</i>	Grunnleggende UDI-DI <i>Basic UDI-DI</i>	EMDN	Klassifisering og regel <i>Classification and Rule</i>
9233	Kendall™ kalsium-alginatbandasje, 4" x 4" (10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: IIb Regel/ Rule: 4

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Produktkodeliste
Product Code List

9232	Kendall™ kalsium-alginatbandasje, 2" x 2" (5,1 cm x 5,1 cm) Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: I Ib Regel/ Rule: 4
9238	Kendall™ kalsium-alginatbandasje, 8" x 4" (20,3 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: I Ib Regel/ Rule: 4
9242	Kendall™ kalsium-alginatbandasje, 12" x 24" (30,5 cm x 61 cm) Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: I Ib Regel/ Rule: 4
9239	Kendall™ kalsium-alginatbandasje, 6" x 10" (15,2 cm x 25,4 cm) Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: I Ib Regel/ Rule: 4
9235	Kendall™ kalsium-alginatbandasje, 2" x 1" (5,1 cm x 2,5 cm) Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: I Ib Regel/ Rule: 4
9240	Kendall™ kalsium-alginatbandasje, 4" x 5-1/2" (10,2 cm x 14 cm) Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: I Ib Regel/ Rule: 4
9236	Kendall™ kalsium-alginatbandasje Plus, 4" x 4"	06301400000000000002556P	M04040202	Klasse/ Classification:

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Produktkodeliste
Product Code List

	(10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)			IIb Regel/ Rule: 4
9231	Kendall™ kalsium-alginatbandasje, bånd, 12" (30,5 cm) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: IIb Regel/ Rule: 4
9243	Kendall™ kalsium-alginatbandasje, bånd, 24" (61 cm) Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: IIb Regel/ Rule: 4
9244	Kendall™ kalsium-alginatbandasje, bånd, 36" (91,4 cm) Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Klasse/ Classification: IIb Regel/ Rule: 4

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POLISH

DEKLARACJA ZGODNOŚCI
DECLARATION OF CONFORMITY

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

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DEKLARACJA ZGODNOŚCI
DECLARATION OF CONFORMITY

	contamination.
Klasyfikacja i reguła <i>Classification and Rule</i>	Patrz Załącznik I/ Refer to Attachment 1
Wspólne specyfikacje <i>Common Specifications</i>	Nie dotyczy (N/A)
W stosownych przypadkach dodać obowiązujące przepisy unijne <i>Where appropriate, add applicable Union legislation</i>	Nie dotyczy (N/A)
Ocena zgodności <i>Conformity Assessment</i>	Załącznik IX, rozdziały I i III/ Annex IX Chapters I and III

SEKCJA PODPISÓW
SIGNATURE SECTION

Niniejsza deklaracja zgodności UE została wydana w imieniu i na wyłączną odpowiedzialność legalnego producenta określonego powyżej.

Miejsce wydania <i>Place of Issue</i>	Waukegan, IL 60085 USA
Podpis/Data <i>Signature/Date</i>	 Yuan Zhou (Aug 27, 2025 14:09:47 EDT)
Imię i nazwisko oraz stanowisko <i>Name and Function</i>	Yuan Zhou Regulatory Affairs Dział spraw regulacyjnych

ZAŁĄCZNIK 1
ATTACHMENT 1

Lista kodów produktu
Product Code List

Kod produktu <i>Product Code</i>	Nazwa handlowa i opis <i>Trade Name and Description</i>	Podstawowy unikalny identyfikator urządzenia UDI-DI <i>Basic UDI-DI</i>	EMDN	Klasyfikacja i reguła <i>Classification and Rule</i>
9233	Opatrunek Kendall™ z alginianem wapnia, 4" x 4" (10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2	06301400000000000002556P	M04040202	Klasa./ Classification: IIb Reguła/ Rule: 4

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Lista kodów produktu
Product Code List

	cm)			
9232	Opatrunek Kendall™ z alginianem wapnia, 2"x 2" (5,1 cm x 5,1 cm) Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000002556P	M04040202	Klasa, Classification: IIb Reguła/ Rule: 4
9238	Opatrunek Kendall™ z alginianem wapnia, 8"x 4" (20,3 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Klasa, Classification: IIb Reguła/ Rule: 4
9242	Opatrunek Kendall™ z alginianem wapnia, 12"x 24" (30,5 cm x 61 cm) Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Klasa, Classification: IIb Reguła/ Rule: 4
9239	Opatrunek Kendall™ z alginianem wapnia, 6"x 10" (15,2 cm x 25,4 cm) Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Klasa, Classification: IIb Reguła/ Rule: 4
9235	Opatrunek Kendall™ z alginianem wapnia, 2"x 1" (5,1 cm x 2,5 cm) Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Klasa, Classification: IIb Reguła/ Rule: 4
9240	Opatrunek Kendall™ z alginianem wapnia, 4"x 5-1/2" (10,2 cm x 14 cm) Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Klasa, Classification: IIb Reguła/ Rule: 4
9236	Opatrunek Kendall™ z alginianem wapnia Plus, 4"x 4" (10,2 cm x	06301400000000000002556P	M04040202	Klasa, Classification:

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Lista kodów produktu
Product Code List

	10,2 cm) Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)			IIb Reguła/ Rule: 4
9231	Opatrunek Kendall™ z alginianem wapnia, linka, 12" (30,5 cm) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Klasa./ Classification: IIb Reguła/ Rule: 4
9243	Opatrunek Kendall™ z alginianem wapnia, linka, 24" (61 cm) Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Klasa./ Classification: IIb Reguła/ Rule: 4
9244	Opatrunek Kendall™ z alginianem wapnia, linka, 36" (91,4 cm) Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Klasa./ Classification: IIb Reguła/ Rule: 4

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PORTUGUESE

DECLARAÇÃO DE CONFORMIDADE
DECLARATION OF CONFORMITY



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.

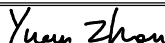
Número de Declaração de Conformidade <i>Declaration of Conformity Number</i>	RE00205881
Número de documentação técnica <i>Technical Documentation Number</i>	RE00249263
Nome do fabricante <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Endereço do fabricante <i>Manufacturer's Address</i>	3651 Birchwood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

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DECLARAÇÃO DE CONFORMIDADE
DECLARATION OF CONFORMITY

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

SECÇÃO DE ASSINATURA
SIGNATURE SECTION

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

ANEXO I
ATTACHMENT 1

Lista de códigos dos produtos
Product Code List

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

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Lista de códigos dos produtos
Product Code List

	cm)			
9232	Curativo de alginato de cálcio Kendall™ 5,1 cm x 5,1 cm (2 pol. x 2 pol.) Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000002556P	M04040202	Classe/ Classification: Ib Regra/ Rule: 4
9238	Curativo de alginato de cálcio Kendall™ 20,3 cm x 10,2 cm (8 pol. x 4 pol.) Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Classe/ Classification: Ib Regra/ Rule: 4
9242	Curativo de alginato de cálcio Kendall™ 30,5 cm x 61 cm (12 pol. x 24 pol.) Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Classe/ Classification: Ib Regra/ Rule: 4
9239	Curativo de alginato de cálcio Kendall™ 15,2 cm x 25,4 cm (6 pol. x 10 pol.) Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Classe/ Classification: Ib Regra/ Rule: 4
9235	Curativo de alginato de cálcio Kendall™ 5,1 cm x 2,5 cm (2 pol. x 1 pol.) Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Classe/ Classification: Ib Regra/ Rule: 4
9240	Curativo de alginato de cálcio Kendall™ 10,2 cm x 14 cm (4 pol. x 5-1/2 pol.) Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Classe/ Classification: Ib Regra/ Rule: 4

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Lista de códigos dos produtos
Product Code List

9236	Curativo de alginato de cálcio Kendall™ Plus 10,2 cm x 10,2 cm (4 pol. x 4 pol.) Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regra/ Rule: 4
9231	Curativo de alginato de cálcio Kendall™, tipo corda, 30,5 cm (12 pol.) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regra/ Rule: 4
9243	Curativo de alginato de cálcio Kendall™, tipo corda, 61 cm (24 pol.) Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regra/ Rule: 4
9244	Curativo de alginato de cálcio Kendall™, tipo corda, 91,4 cm (36 pol.) Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Classe/ Classification: IIb Regra/ Rule: 4

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ROMANIAN

DECLARAȚIE DE CONFORMITATE
DECLARATION OF CONFORMITY



MDR: Noi, Cardinal Health 200 LLC, declarăm că produsele acoperite în această Declarație de conformitate UE respectă prevederile Regulamentului privind dispozitivele medicale (UE) 2017/745.

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

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DECLARAȚIE DE CONFORMITATE
DECLARATION OF CONFORMITY

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

SECȚIUNEA DE SEMNĂTURI
SIGNATURE SECTION

Această Declarație de conformitate UE este emisă în numele și sub responsabilitatea exclusivă a Producătorului Legal identificat mai sus.

Locul emiterii <i>Place of Issue</i>	Waukegan, IL 60085 USA
Semnătura/Data <i>Signature/Date</i>	 Yuan Zhou (Aug 27, 2025 14:09:47 EDT)
Nume și funcție <i>Name and Function</i>	Yuan Zhou Regulatory Affairs Afaceri de reglementare

ANEXA I
ATTACHMENT 1

Listă cu Coduri de produse
Product Code List

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

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Listă cu Coduri de produse
Product Code List

	cm)			
9232	Pansament cu alginat de calciu Kendall™, 2" x 2" (5,1 cm x 5,1 cm) Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000002556P	M04040202	Clasă/ Class: Iib Regulă/ Rule: 4
9238	Pansament cu alginat de calciu Kendall™, 8" x 4" (20,3 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Clasă/ Class: Iib Regulă/ Rule: 4
9242	Pansament cu alginat de calciu Kendall™, 12" x 24" (30,5 cm x 61 cm) Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Clasă/ Class: Iib Regulă/ Rule: 4
9239	Pansament cu alginat de calciu Kendall™, 6" x 10" (15,2 cm x 25,4 cm) Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Clasă/ Class: Iib Regulă/ Rule: 4
9235	Pansament cu alginat de calciu Kendall™, 2" x 1" (5,1 cm x 2,5 cm) Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Clasă/ Class: Iib Regulă/ Rule: 4
9240	Pansament cu alginat de calciu Kendall™, 4" x 5-1/2" (10,2 cm x 14 cm) Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Clasă/ Class: Iib Regulă/ Rule: 4

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Listă cu Coduri de produse
Product Code List

9236	Pansament cu alginat de calciu Kendall™ Plus, 4" x 4" (10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Clasă/ Class: Iib Regulă/ Rule: 4
9231	Pansament cu alginat de calciu Kendall™, șnur, 12" (30,5 cm) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Clasă/ Class: Iib Regulă/ Rule: 4
9243	Pansament cu alginat de calciu Kendall™, șnur, 24" (61 cm) Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Clasă/ Class: Iib Regulă/ Rule: 4
9244	Pansament cu alginat de calciu Kendall™, șnur, 36" (91,4 cm) Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Clasă/ Class: Iib Regulă/ Rule: 4

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SLOVAK

**VYHLÁSENIE O ZHODE
DECLARATION OF CONFORMITY**

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

Klasifikácia a pravidlo <i>Classification and Rule</i>	Pozrite si Prílohu I/ Refer to Attachment 1
Bežné špecifikácie <i>Common Specifications</i>	Nevzťahuje sa (N/A)
V prípade potreby doplňte príslušné právne predpisy Únie <i>Where appropriate, add applicable Union legislation</i>	Nevzťahuje sa (N/A)
Posúdenie zhody <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.

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

PRÍLOHU I
ATTACHMENT I

Zoznam kódov výrobkov
Product Code List

Kód výrobku <i>Product Code</i>	Obchodný názov a popis <i>Trade Name and Description</i>	Základné UDI-DI <i>Basic UDI-DI</i>	EMDN	Klasifikácia a pravidlo <i>Classification and Rule</i>
9233	Krytie na rany Kendall™ s obsahom alginátu vápenatého, 4" x 4" (10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Trieda/ Class: IIb Pravidlo/ Rule: 4
9232	Krytie na rany Kendall™ s obsahom alginátu vápenatého, 2" x	06301400000000000002556P	M04040202	Trieda/ Class: IIb

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Zoznam kódov výrobkov
Product Code List

	2" (5,1 cm x 5,1 cm) Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)			Pravidlo/ Rule: 4
9238	Krytie na rany Kendall™ s obsahom alginátu vápenatého, 8" x 4" (20,3 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Trieda/ Class: IIb Pravidlo/ Rule: 4
9242	Krytie na rany Kendall™ s obsahom alginátu vápenatého, 12" x 24" (30,5 cm x 61 cm) Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Trieda/ Class: IIb Pravidlo/ Rule: 4
9239	Krytie na rany Kendall™ s obsahom alginátu vápenatého, 6" x 10" (15,2 cm x 25,4 cm) Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Trieda/ Class: IIb Pravidlo/ Rule: 4
9235	Krytie na rany Kendall™ s obsahom alginátu vápenatého, 2" x 1" (5,1 cm x 2,5 cm) Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Trieda/ Class: IIb Pravidlo/ Rule: 4
9240	Krytie na rany Kendall™ s obsahom alginátu vápenatého, 4" x 5-1/2" (10,2 cm x 14 cm) Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Trieda/ Class: IIb Pravidlo/ Rule: 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: IIb Pravidlo/ Rule: 4

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Zoznam kódov výrobkov
Product Code List

	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) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Trieda/ Class: IIb Pravidlo/ Rule: 4
9243	Krytie na rany Kendall™ Rope s obsahom alginátu vápenatého, 24" (61 cm) Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Trieda/ Class: IIb Pravidlo/ Rule: 4
9244	Krytie na rany Kendall™ Rope s obsahom alginátu vápenatého, 36" (91,4 cm) Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Trieda/ Class: IIb Pravidlo/ Rule: 4

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SPANISH

**DECLARACIÓN DE CONFORMIDAD
DECLARATION OF CONFORMITY**



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.

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

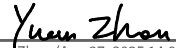
DOCUMENT NO:	RE00205881	REVISION:	2
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DECLARACIÓN DE CONFORMIDAD
DECLARATION OF CONFORMITY

	contamination.
Clasificación y regla <i>Classification and Rule</i>	Consulte el Archivo adjunto I/ Refer to Attachment 1
Especificaciones comunes <i>Common Specifications</i>	No corresponde (N/A)
Cuando proceda, añada la legislación de la Unión Europea aplicable <i>Where appropriate, add applicable Union legislation</i>	No corresponde (N/A)
Evaluación de conformidad <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.

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

ARCHIVO ADJUNTO I
ATTACHMENT 1

Lista de códigos del product
Product Code List

Código del product <i>Product Code</i>	Nombre comercial y descripción <i>Trade Name and Description</i>	UDI-DI básico <i>Basic UDI-DI</i>	EMDN	Clasificación y regla <i>Classification and Rule</i>
9233	Apósito de alginato de calcio Kendall™, 4" x 4" (10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 4" x 4" (10.2 cm x 10.2	06301400000000000002556P	M04040202	Clase/ Class: IIb Regla/ Rule: 4

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Lista de códigos del product
Product Code List

	cm)			
9232	Apósito de alginato de calcio Kendall™, 2" x 2" (5,1 cm x 5,1 cm) Kendall™ Calcium Alginate Dressing, 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000002556P	M04040202	Clase/ Class: Iib Regla/ Rule: 4
9238	Apósito de alginato de calcio Kendall™, 8" x 4" (20,3 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Clase/ Class: Iib Regla/ Rule: 4
9242	Apósito de alginato de calcio Kendall™, 12" x 24" (30,5 cm x 61 cm) Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Clase/ Class: Iib Regla/ Rule: 4
9239	Apósito de alginato de calcio Kendall™, 6" x 10" (15,2 cm x 25,4 cm) Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Clase/ Class: Iib Regla/ Rule: 4
9235	Apósito de alginato de calcio Kendall™, 2" x 1" (5,1 cm x 2,5 cm) Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Clase/ Class: Iib Regla/ Rule: 4
9240	Apósito de alginato de calcio Kendall™, 4" x 5-1/2" (10,2 cm x 14 cm) Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Clase/ Class: Iib Regla/ Rule: 4

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Lista de códigos del product
Product Code List

9236	Apósito de alginato de calcio Kendall™ Plus, 4" x 4" (10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Clase/ Class: Iib Regla/ Rule: 4
9231	Apósito de alginato de calcio Kendall™, cuerda, 12" (30,5 cm) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Clase/ Class: Iib Regla/ Rule: 4
9243	Apósito de alginato de calcio Kendall™, cuerda, 24" (61 cm) Kendall™ Calcium Alginate Dressing, Rope 24" (61 cm)	06301400000000000002556P	M04040202	Clase/ Class: Iib Regla/ Rule: 4
9244	Apósito de alginato de calcio Kendall™, cuerda, 36" (91,4 cm) Kendall™ Calcium Alginate Dressing, Rope 36" (91.4 cm)	06301400000000000002556P	M04040202	Clase/ Class: Iib Regla/ Rule: 4

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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.

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

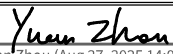
DOCUMENT NO:	RE00205881	REVISION:	2
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FÖRSÄKRAN OM ÖVERENSSTÄMMELSE
DECLARATION OF CONFORMITY

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

SEKTION FÖR UNDERSKRIFT
SIGNATURE SECTION

Denna EU-försäkran om överensstämmelse utfärdas för och på uppdrag av och under eget ansvar av den juridiska tillverkaren som anges ovan.

Plats för utfärdande <i>Place of Issue</i>	Waukegan, IL 60085 USA
Underskrift/ Datum <i>Signature/Date</i>	 Yuan Zhou (Aug 27, 2025 14:09:47 EDT)
Namn och function <i>Name and Function</i>	Yuan Zhou Regulatory Affairs Myndighetsärenden

DOKUMENT I
ATTACHMENT 1

Lista de códigos del product
Product Code List

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

DOCUMENT NO:	RE00205881	REVISION:	2
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Lista de códigos del product
Product Code List

	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) Kendall™ Calcium Alginate Dressing, 8" x 4" (20.3 cm x 10.2 cm)	06301400000000000002556P	M04040202	Klass/ Class: Iib Regel/ Rule: 4
9242	Kendall™ kalciumalginatförband, 12" x 24" (30,5 cm x 61 cm) Kendall™ Calcium Alginate Dressing, 12" x 24" (30.5 cm x 61 cm)	06301400000000000002556P	M04040202	Klass/ Class: Iib Regel/ Rule: 4
9239	Kendall™ kalciumalginatförband, 6" x 10" (15,2 cm x 25,4 cm) Kendall™ Calcium Alginate Dressing, 6" x 10" (15.2 cm x 25.4 cm)	06301400000000000002556P	M04040202	Klass/ Class: Iib Regel/ Rule: 4
9235	Kendall™ kalciumalginatförband, 2" x 1" (5,1 cm x 2,5 cm) Kendall™ Calcium Alginate Dressing, 2" x 1" (5.1 cm x 2.5 cm)	06301400000000000002556P	M04040202	Klass/ Class: Iib Regel/ Rule: 4
9240	Kendall™ kalciumalginatförband, 4" x 5-1/2" (10,2 cm x 14 cm) Kendall™ Calcium Alginate Dressing, 4" x 5-1/2" (10.2 cm x 14 cm)	06301400000000000002556P	M04040202	Klass/ Class: Iib Regel/ Rule: 4
9236	Kendall™ kalciumalginatförband Plus, 4" x 4" (10,2 cm x 10,2 cm) Kendall™ Calcium Alginate Dressing Plus, 4" x 4" (10.2 cm x 10.2 cm)	06301400000000000002556P	M04040202	Klass/ Class: Iib Regel/ Rule: 4
9231	Kendall™ kalciumalginatförband, rep, 12" (30,5 cm) Kendall™ Calcium Alginate Dressing, Rope, 12" (30.5 cm)	06301400000000000002556P	M04040202	Klass/ Class: Iib Regel/ Rule: 4

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Lista de códigos del product

Product Code List

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






RE00205881

Final Audit Report

2025-08-27

Created:	2025-08-27
By:	Leena Gupta (leena.gupta@cardinalhealth.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAURi8bjLnGyZ71o6YIIE14Y80VUeM5oWB

"RE00205881" History

-  Document created by Leena Gupta (leena.gupta@cardinalhealth.com)
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-  Document emailed to Yuan Zhou (yuan.zhou@cardinalhealth.com) for signature
2025-08-27 - 6:06:39 PM GMT
-  Email viewed by Yuan Zhou (yuan.zhou@cardinalhealth.com)
2025-08-27 - 6:08:01 PM GMT- IP address: 104.47.58.254
-  Document e-signed by Yuan Zhou (yuan.zhou@cardinalhealth.com)
Signature Date: 2025-08-27 - 6:09:47 PM GMT - Time Source: server- IP address: 134.238.166.80
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