

<b>DOC. TITLE:</b> RE00214653 Declaration of Conformity MDR Woundcare Products			
<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1

## DECLARATION OF CONFORMITY



**MDR:** 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.


<b>Declaration of Conformity Number</b>	RE00214653
<b>Technical Documentation Number</b>	RE00172519
<b>Manufacturer's Name</b>	Cardinal Health 200, LLC
<b>Manufacturer's Address</b>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Single Registration Number</b>	US-MF-000006765
<b>Authorized Representative's Name and Address</b>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Notified body's Name and Identification Number</b>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identification Number: 2797
<b>CE Certificate Number</b>	MDR 798506
<b>Product Category</b>	Cotton Gauzes in Rolls [M020107] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>Basic UDI-DI</b>	Refer to attachment 1
<b>EMDN</b>	Refer to attachment 1
<b>Product Code, Trade Name and Description</b>	Refer to attachment 1
<b>Intended Purpose</b>	<p><b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.</p> <p><b>Webril™ &amp; Webril™ II Undercast Padding</b> is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p>

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**DECLARATION OF CONFORMITY**

	<p><b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Classification and Rule</b>	Refer to attachment 1
<b>Common Specifications</b>	Not Applicable (N/A)
<b>Where appropriate, add applicable Union legislation</b>	Not Applicable (N/A)
<b>Conformity Assessment</b>	Annex XI-Part A

**SIGNATURE SECTION**

<b>This EU Declaration of Conformity is issued for and on behalf of and under the sole responsibility of the Legal Manufacturer identified above.</b>	
<b>Place of Issue</b>	Waukegan, IL 60085 USA
<b>Signature/ Date</b>	 <small>Brenda Gerena (May 1, 2024 16:35 CDT)</small>
<b>Name and Function</b>	<p>Brenda Gerena</p> <p>Regulatory Affairs</p>

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**ATTACHMENT 1**

<b>Product Code List</b>				
<b>Product Code</b>	<b>Trade Name and Description</b>	<b>Basic UDI-DI</b>	<b>EMDN</b>	<b>Classification and Rule</b>
2283	Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	0630140000000000000000001346A	M0201050101	Class I (s) Rule 4
2394	Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	0630140000000000000000001346A	M0201050101	Class I (s) Rule 4
2502	Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	0630140000000000000000001346A	M0201050101	Class I (s) Rule 4
2554	Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	0630140000000000000000001346A	M0201050101	Class I (s) Rule 4
6716	Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	0630140000000000000000001125Y	M020107	Class I (s) Rule 4
6725	Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	0630140000000000000000001125Y	M020107	Class I (s) Rule 4
7086	Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	0630140000000000000000001176A	M0201010101	Class I (s) Rule 4
7087	Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	0630140000000000000000001186C	M0201010101	Class I (s) Rule 4
7880	Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	0630140000000000000000001205X	M020107	Class I (s) Rule 4
7884	Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	0630140000000000000000000996Z	M0201020101	Class I (s) Rule 4
3381	Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	0630140000000000000000001516A	M0201050101	Class I (s) Rule 4
6309	Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	0630140000000000000000001516A	M0201050101	Class I (s) Rule 4

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**CROATIAN**


<b>IZJAVA O SUKLADNOSTI</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Mi, Cardinal Health 200 LLC, izjavljujemo da proizvodi na koje se odnosi ova Izjava o sukladnosti EU ispunjavaju odredbe Uredbe o medicinskim proizvodima (EU) 2017/745.
<b>Broj izjave o sukladnosti</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Broj tehničke dokumentacije</b> <i>Technical Documentation Number</i>	RE00172519
<b>Naziv proizvođača</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adresa proizvođača</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Jedinstveni registracijski broj</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Naziv i adresa ovlaštenog predstavnika</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Naziv i identifikacijski broj prijavljenog tijela</b> <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
<b>Broj certifikata CE</b> <i>CE Certificate Number</i>	MDR 798506
<b>Kategorija proizvoda</b> <i>Product Category</i>	Pamučna gaza u rolama [M020107] Cotton Gauzes in Rolls [M020107]  Pamučna gaza, presavijena, bez konca vidljivog pri rendgenskom snimanju, sterilna [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>Osnovni UDI-DI</b> <i>Basic UDI-DI</i>	Pogledajte Prilog I/ Refer to Attachment 1
<b>EMDN</b>	Pogledajte Prilog I/ Refer to Attachment 1
<b>Kôd, trgovački naziv i opis proizvoda</b> <i>Product Code, Trade Name and Description</i>	Pogledajte Prilog I/ Refer to Attachment 1
<b>Namjena</b> <i>Intended Purpose</i>	<b>Zavoji i gaza u rolama Kerlix:</b> upotrebljavaju se kao primarne obloge za apsorpciju eksudata iz rane. Kao sekundarna obloga, zavoji se upotrebljavaju za pojačavanje primarnih obloga i apsorpciju eksudata koji prođe kroz primarne obloge. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.  Pamučna podloška za gips <b>Webriil™ &amp; Webriil™ II</b> služi za amortizaciju između kože i gipsa i za upijanje vlage.

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**IZJAVA O SUKLADNOSTI**  
**DECLARATION OF CONFORMITY**

	<p><b>Webril™ &amp; Webril™ II</b> Undercast Padding is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Super spužve Kerlix™</b> upotrebljavaju se kao primarne obloge na mjestu rane za apsorpciju eksudata. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Kompresse Curity™</b> upotrebljavaju se kao obloge za rane ili popucane kože te brisanje/upijanje tekućina. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Drenažne spužvice i spužvice za infuziju Excilon™</b> upotrebljavaju se kao primarne obloge na nizu rana, uključujući, ali ne ograničavajući se na mjesta umetanja. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Klasifikacija i pravilo</b> <i>Classification and Rule</i>	Pogledajte Prilog I/ Refer to Attachment 1
<b>Zajedničke specifikacije</b> <i>Common Specifications</i>	Nije primjenjivo (N/A)
<b>Dodajte primjenjivo zakonodavstvo</b> <b>Europske unije, gdje je to prikladno</b> <i>Where appropriate, add applicable Union legislation</i>	Nije primjenjivo (N/A)
<b>Ocjena sukladnosti</b> <i>Conformity Assessment</i>	Prilog XI. Dio A/ Annex XI Part A

**ODJELJAK S POTPISIMA**  
**SIGNATURE SECTION**

Ova Izjava o sukladnosti EU izdaje se za i u ime te na isključivu odgovornost prethodno navedenog zakonitog proizvođača.	
<b>Mjesto izdavanja</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Potpis/ Datum</b> <i>Signature/ Date</i>	 <small>Brenda Gerena (May 1, 2024 16:35 CDT)</small>
<b>Ime i funkcija</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Odjel za regulatorna pitanja

**PRILOG I**  
**ATTACHMENT 1**

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<b>Popis kodova proizvoda</b> <i>Product Code List</i>				
<b>Kôd proizvoda</b> <i>Product Code</i>	<b>Trgovački naziv i opis</b> <i>Trade Name and Description</i>	<b>Osnovni UDI-DI</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Klasifikacija i pravilo</b> <i>Classification and Rule</i>
2283	Pamučna podloška za gips Webril, obična završna obrada, 2" x 12' (5,1 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasa/ Class: Is Pravilo/ Rule: 4
2394	Pamučna podloška za gips Webril, obična završna obrada, 3" x 12' (7,6 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasa/ Class: Is Pravilo/ Rule: 4
2502	Pamučna podloška za gips Webril, obična završna obrada, 4" x 12' (10,2 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasa/ Class: Is Pravilo/ Rule: 4
2554	Pamučna podloška za gips Webril, obična završna obrada, 6" x 12' (15,2 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasa/ Class: Is Pravilo/ Rule: 4
6716	Rola zavoja Kerlix, 100 % pamuk, 8 slojeva, velika, 4,5" x 9,3' (11,4 cm x 2,8 m) Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	063014000000000000001125Y	M020107	Klasa/ Class: Is Pravilo/ Rule: 4
6725	Rola zavoja Kerlix, 100 % pamuk, 6 slojeva, srednja, 3 7/16" x 3 3/16' (8,6 cm x 3,3 m) Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	063014000000000000001125Y	M020107	Klasa/ Class: Is Pravilo/ Rule: 4
7086	Drenažne spužvice Excilon, 6 slojeva, 4" x 4" (10,2 cm x 10,2 cm)	063014000000000000001176A	M0201010101	Klasa/ Class: Is Pravilo/ Rule: 4

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<b>Popis kodova proizvoda</b> <i>Product Code List</i>				
	Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)			
7087	Spužvice za infuziju Excilon 6 slojeva, 2" x 2" (5,1 cm x 5,1 cm)  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	06301400000000000001186C	M0201010101	Klasa/ Class: Is Pravilo/ Rule: 4
7880	Rola gaze Kerlix, 6 slojeva, velika, 4,5" x 4 1/8 yd (11,4 cm x 3,7 m), rastezljiva, sterilna  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	06301400000000000001205X	M020107	Klasa/ Class: Is Pravilo/ Rule: 4
7884	Super spužve Kerlix, 6" x 6 3/4" (15,2 cm x 17,1 cm)  Kerlix Super Sponges, 6" x 6- 3/4" (15.2 cm x 17.1 cm)	06301400000000000000996Z	M0201020101	Klasa/ Class: Is Pravilo/ Rule: 4
3381	Kompresse Curity 2" x 2" (5,1 cm x 5,1 cm)  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000001516A	M0201050101	Klasa/ Class: Is Pravilo/ Rule: 4
6309	Kompresa Curity 4" x 4" (10,2 cm x 10,2 cm)  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	06301400000000000001516A	M0201050101	Klasa/ Class: Is Pravilo/ Rule: 4

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**CZECH**

<b>PROHLÁŠENÍ O SHODĚ</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Naše společnost, Cardinal Health 200 LLC, prohlašuje, že výrobky uvedené v tomto EU prohlášení o shodě splňují ustanovení nařízení (EU) 2017/745 o zdravotnických prostředcích.
<b>Číslo prohlášení o shodě</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Číslo technické dokumentace</b> <i>Technical Documentation Number</i>	RE00172519
<b>Název výrobce</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adresa výrobce</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Jediné registrační číslo</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Název a adresa autorizovaného zástupce</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Název a identifikační číslo oznámeného subjektu</b> <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
<b>Číslo certifikátu CE</b> <i>CE Certificate Number</i>	MDR 798506
<b>Kategorie výrobku</b> <i>Product Category</i>	Bavlněné gázy v rolích [M020107] Cotton Gauzes in Rolls [M020107]  Bavlněné gázy, skládané, bez rentgenkontrastního vlákna, sterilní [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>Základní UDI-DI</b> <i>Basic UDI-DI</i>	Viz Příloha I / Refer to Attachment 1
<b>EMDN</b>	Viz Příloha I / Refer to Attachment 1
<b>Kód, obchodní název a popis výrobku</b> <i>Product Code, Trade Name and Description</i>	Viz Příloha I / Refer to Attachment 1
<b>Účel použití</b> <i>Intended Purpose</i>	<b>Bandáže a gázy Kerlix v rolích:</b> Určeny pro použití jako primární krytí pro absorpci exsudátů rány. Jako sekundární krytí se používají bandáže v rolích k posílení primárního krytí a absorbují exsudáty, které pronikly primárním krytím. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.  Podkladová vycpávka <b>Webril™ &amp; Webril™ II</b> je určena jako tlumicí vrstva mezi kůží a sádrou a k absorpci vlhkosti.

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

	<p><b>Webriil™ &amp; Webriil™ II</b> Undercast Padding is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Hubky Kerlix™ Super Sponges</b> jsou určeny k použití jako primární krytí v místě rány k absorpci exsudátu. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Gázové polštářky Curity™</b> jsou určeny k použití jako krytí ran nebo poranění kůže a k otírání/absorbování tekutin. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Drenážní a intravenózní hubky Excilon™</b> jsou určeny k použití jako primární krytí na řadě ran, včetně míst zavedení. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Klasifikace a pravidlo</b> <i>Classification and Rule</i>	Viz Příloha I / Refer to Attachment 1
<b>Obecná specifikace</b> <i>Common Specifications</i>	Nelze uplatnit (N/A)
<b>Dle potřeby doplňte příslušný předpis Unie</b> <i>Where appropriate, add applicable Union legislation</i>	Nelze uplatnit (N/A)
<b>Posouzení shody</b> <i>Conformity Assessment</i>	Příloha XI, část A/ Annex XI Part A

**PODPISOVÁ ČÁST**  
*SIGNATURE SECTION*

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

<b>Místo vydání</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Podpis / Datum</b> <i>Signature/ Date</i>	 <small>Brenda Gerena (May 1, 2024 16:35 CDT)</small>
<b>Jméno a funkce</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Oddělení regulačních záležitostí

**PŘÍLOHA I**  
*ATTACHMENT 1*

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

<b>Kód výrobku</b> <i>Product Code</i>	<b>Obchodní název a popis</b> <i>Trade Name and Description</i>	<b>Základní UDI-DI</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Klasifikace a pravidlo</b>
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<b>Seznam kódů výrobků</b> <i>Product Code List</i>				
				<i>Classification and Rule</i>
2283	Bavlněná podkladová vycpávka Webril, standardní povrch, 5,1 cm x 3,7 m (2" x 12')  Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	06301400000000000001346A	M0201050101	Třída/ Class: Is Pravidlo/ Rule: 4

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<b>Seznam kódů výrobků</b> <i>Product Code List</i>				
2394	Bavlněná podkladová vycpávka Webril, standardní povrch, 7,6 cm x 3,7 m (3" x 12")  Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	0630140000000000000000001346A	M0201050101	Třída/ Class: Is Pravidlo/ Rule: 4
2502	Bavlněná podkladová vycpávka Webril, standardní povrch, 10,2 cm x 3,7 m (4" x 12")  Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	0630140000000000000000001346A	M0201050101	Třída/ Class: Is Pravidlo/ Rule: 4
2554	Bavlněná podkladová vycpávka Webril, standardní povrch, 15,2 cm x 3,7 m (6" x 12")  Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	0630140000000000000000001346A	M0201050101	Třída/ Class: Is Pravidlo/ Rule: 4
6716	Rolovaná bandáž Kerlix, 100% bavlna, 8vrstvá, velká, 11,4 cm x 2,8 m (4 1/2" x 9,3")  Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	0630140000000000000000001125Y	M020107	Třída/ Class: Is Pravidlo/ Rule: 4
6725	Rolovaná bandáž Kerlix, 100% bavlna, 6vrstvá, střední, 8,6 cm x 3,3 m (3 7/16" x 3 3/16")  Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	0630140000000000000000001125Y	M020107	Třída/ Class: Is Pravidlo/ Rule: 4
7086	Drenážní hubky Excilon, 6vrstvé, 10,2 cm x 10,2 cm (4" x 4")  Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	0630140000000000000000001176A	M0201010101	Třída/ Class: Is Pravidlo/ Rule: 4
7087	Intravenózní hubky Excilon, 6vrstvé, 5,1 cm x 5,1 cm (2" x 2")  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	0630140000000000000000001186C	M0201010101	Třída/ Class: Is Pravidlo/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	<b>1</b>
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<b>Seznam kódů výrobků</b> <i>Product Code List</i>				
7880	Rolovaná gáza Kerlix, 100% bavlna, 6vrstvá, velká, 11,4 cm x 3,7 m (4 1/2" x 4 1/8 yd), natažená, sterilní  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	06301400000000000001205X	M020107	Třída/ Class: Is Pravidlo/ Rule: 4
7884	Hubky Kerlix Super Sponges, 15,2 cm x 17,1 cm (6" x 6 3/4")  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	06301400000000000000996Z	M0201020101	Třída/ Class: Is Pravidlo/ Rule: 4
3381	Gázové polštářky Curity 5,1 cm x 5,1 cm (2" x 2")  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000001516A	M0201050101	Třída/ Class: Is Pravidlo/ Rule: 4
6309	Gázová podložka Curity 10,2 cm x 10,2 cm (4" x 4")  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	06301400000000000001516A	M0201050101	Třída/ Class: Is Pravidlo/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**DANISH**

<b>PROHLÁŠENÍ O SHODĚ</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Vi, Cardinal Health 200 LLC, erklærer, at produkterne dækket af denne EU-overensstemmelseserklæring overholder kravene i Forordning (EU) 2017/745 om medicinsk udstyr.
<b>Overensstemmelseserklæringsnummer</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Teknisk dokumentationsnummer</b> <i>Technical Documentation Number</i>	RE00172519
<b>Producentens navn</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Producentens adresse</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Enkelt registreringsnummer</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Navn og adresse på godkendt repræsentant</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Navn og identifikationsnummer på bemyndiget organ</b> <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
<b>CE-certifikationsnummer</b> <i>CE Certificate Number</i>	MDR 798506
<b>Produktkategori</b> <i>Product Category</i>	Bomuldsgazebind i ruller [M020107] Cotton Gauzes in Rolls [M020107]  Bomuldsgazebind, foldede, uden røntgendetekterbar tråd, sterile [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>Grundlæggende UDI-DI</b> <i>Basic UDI-DI</i>	Se bilag I / Refer to Attachment 1
<b>EMDN</b>	Se bilag I / Refer to Attachment 1
<b>Produktkode(r), handelsnavn og beskrivelse</b> <i>Product Code, Trade Name and Description</i>	Se bilag I / Refer to Attachment 1
<b>Tiltænkt formål</b> <i>Intended Purpose</i>	<b>Kerlix-bandage og gazebindsruller:</b> Beregnet til brug som primær forbindelse til at absorbere sårveske. Som sekundære forbindelser bruges bandagerullerne til at forstærke primære forbindelser og absorbere ekssudater, der er passeret gennem primære forbindelser. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**PROHLÁŠENÍ O SHODĚ**  
**DECLARATION OF CONFORMITY**

	<p><b>Webril™ og Webril™ II</b> underbandage er beregnet til at give stødabsorbering mellem huden og bandagen og til at absorbere fugt. <b>Webril™ &amp; Webril™ II Undercast Padding</b> is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Kerlix™ super svampe</b> er beregnet til brug som primære forbindinger på sårstedet for at absorbere ekssudat. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Curity™ gaze puder</b> er beregnet til at forbinde sår eller brud på huden og tørre/absorbere væsker. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Excilon™ dræn- og intravenøse svampe</b> er beregnet til brug som primære forbindinger på en række sår, herunder, men ikke begrænset til, indstikssteder. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressing on a range of wounds including but not limited to insertion sites.</p>
<b>Klassificering og regel</b> <i>Classification and Rule</i>	Se bilag I / Refer to Attachment 1
<b>Fælles specifikationer</b> <i>Common Specifications</i>	Ikke relevant (N/A)
<b>Hvor relevant, tilføj gældende union-lovgivning</b> <i>Where appropriate, add applicable Union legislation</i>	Ikke relevant (N/A)
<b>Overensstemmelsesvurdering</b> <i>Conformity Assessment</i>	Bilag XI, del A/ Annex XI Part A

**SIGNATURAFSNIT**  
**SIGNATURE SECTION**

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

<b>Udstedelsessted</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Underskrift / Dato</b> <i>Signature/ Date</i>	 <small>Brenda Gerena (May 1, 2024 16:35 CDT)</small>
<b>Navn og funktion</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Lovgivningsansliggender

**BILAG I**  
**ATTACHMENT 1**

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Produktkodeliste</b> <i>Product Code List</i>				
<b>Produktkode</b> <i>Product Code</i>	<b>Handelsnavn og beskrivelse</b> <i>Trade Name and Description</i>	<b>Grundlæggende UDI-DI</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Klassificering og regel</b> <i>Classification and Rule</i>
2283	<p>Webril bomuldsunderbandage, almindelig finish, 5,1 cm x 3,7 m (2" x 12')</p> <p>Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)</p>	063014000000000000001346A	M0201050101	Klasse /Class: Is Regel/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Produktkodeliste</b> <i>Product Code List</i>				
2394	Webril bomuldsunderbandage, almindelig finish, 7,6 cm x 3,7 m (3" x 12')  Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasse /Class: Is Regel/ Rule: 4
2502	Webril bomuldsunderbandage, almindelig finish, 10,2 cm x 3,7 m (4" x 12')  Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasse /Class: Is Regel/ Rule: 4
2554	Webril bomuldsunderbandage, almindelig finish, 15,2 cm x 3,7 m (6" x 12')  Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasse /Class: Is Regel/ Rule: 4
6716	Kerlix bandagerulle, 100 % bomuld, 8 lag, stor, 11,4 cm x 2,8 m (4-1/2" x 9,3')  Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	063014000000000000001125Y	M020107	Klasse /Class: Is Regel/ Rule: 4
6725	Kerlix bandagerulle 100 % bomuld, 6 lag medium, 8,6 cm x 3,3 m (3-7/16" x 3-3/16')  Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	063014000000000000001125Y	M020107	Klasse /Class: Is Regel/ Rule: 4
7086	Excilon drænsvampe, 6 lag, 10,2 cm x 10,2 cm (4" x 4")  Excilon Drain Sponges, 6 Ply, 4" x 4"	063014000000000000001176A	M0201010101	Klasse /Class: Is Regel/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	<b>1</b>
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<b>Produktkodeliste</b> <i>Product Code List</i>				
	(10.2cm x 10.2cm)			
7087	Excilon intravenøse Svampe, 6 lag, 5,1 cm x 5,1 cm (2" x 2")  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	06301400000000000001186C	M0201010101	Klasse /Class: Is Regel/ Rule: 4
7880	Kerlix gazerulle, 6 lag, stor, 11,4 cm x 3,7 m (4-1/2" x 4-1/8 yd) strakt, steril  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	06301400000000000001205X	M020107	Klasse /Class: Is Regel/ Rule: 4
7884	Kerlix supersvampe 15,2 cm x 17,1 cm (6" x 6-3/4")  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	06301400000000000000996Z	M0201020101	Klasse /Class: Is Regel/ Rule: 4
3381	Curity gaze puder 5,1 cm x 5,1 cm (2" x 2")  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000001516A	M0201050101	Klasse /Class: Is Regel/ Rule: 4
6309	Curity gaze pude 10,2 cm x 10,2 cm (4" x 4")  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	06301400000000000001516A	M0201050101	Klasse /Class: Is Regel/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**DUTCH**

<b>CONFORMITEITSVERKLARING</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Wij, Cardinal Health 200 LLC, verklaren dat de producten die onder deze EU-conformiteitsverklaring vallen, voldoen aan Verordening (EU) 2017/745 betreffende medische hulpmiddelen.
<b>Nummer conformiteitsverklaring</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Nummer technische documentatie</b> <i>Technical Documentation Number</i>	RE00172519
<b>Naam fabrikant</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adres van de fabrikant</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Enkel registratienummer</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Naam en adres van de erkende vertegenwoordiger</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Naam en identificatienummer van de aangemelde instantie</b> <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
<b>Nummer CE-markering</b> <i>CE Certificate Number</i>	MDR 798506
<b>Productcategorie</b> <i>Product Category</i>	Katoenen gaasverband op rollen [M020107] Cotton Gauzes in Rolls [M020107]  Katoenen gaasverband, gevouwen, zonder röntgendetecteerbare draad, steriel [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>Basis UDI-DI</b> <i>Basic UDI-DI</i>	Zie Bijlage I/ Refer to Attachment 1
<b>EMDN</b>	Zie Bijlage I/ Refer to Attachment 1
<b>Productcode, handelsnaam en beschrijving</b> <i>Product Code, Trade Name and Description</i>	Zie Bijlage I/ Refer to Attachment 1
<b>Beoogd doel</b> <i>Intended Purpose</i>	<b>Kerlix-verband- en gaasverbandrollen:</b> bedoeld voor gebruik als primair verband om wondexsudaat te absorberen. Als secundair verband worden de verbandrollen gebruikt om primaire verbanden te versterken en exsudaat te absorberen dat door de primaire verbanden is gelekt. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**CONFORMITEITSVERKLARING**  
*DECLARATION OF CONFORMITY*

	<p>De orthopedische padding <b>Webril™ &amp; Webril™ II</b> voor onder gips biedt bescherming tussen de huid en het gips en neemt vocht op. <b>Webril™ &amp; Webril™ II Undercast Padding</b> is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Kerlix™-supersponzen zijn bedoeld</b> als primaire verbanden op de wondlocatie om exsudaat te absorberen. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Curity™-gaaskompressen</b> zijn bedoeld om te worden gebruikt als verband voor wonden of huidbreuken en het afvegen/absorberen van vloeistoffen. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Excilon™-sponzen voor drains en IV</b> zijn bedoeld voor gebruik als primair verband op verschillende wonden, waaronder maar niet beperkt tot inbrenghaakjes. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Classificatie en regel</b> <i>Classification and Rule</i>	Zie Bijlage I/ Refer to Attachment 1
<b>Algemene specificaties</b> <i>Common Specifications</i>	Niet van toepassing (N/A)
<b>Voeg, indien van toepassing, de toepasselijke wetgeving van de Unie toe</b> <i>Where appropriate, add applicable Union legislation</i>	Niet van toepassing (N/A)
<b>Conformiteitsbeoordeling</b> <i>Conformity Assessment</i>	Bijlage XI Deel A/ Annex XI Part A

**HANDTEKENINGGEDEELTE**  
*SIGNATURE SECTION*

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

<b>Plaats van afgifte</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Handtekening/Datum</b> <i>Signature/ Date</i>	 Brenda Gerena (May 1, 2024 16:35 CDT)
<b>Naam en functie</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Regelgevingszaken

**BIJLAGE I**  
*ATTACHMENT 1*

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Produktkodeliste</b> <i>Product Code List</i>				
<b>Productcode</b> <i>Product Code</i>	<b>Handelsnaam en beschrijving</b> <i>Trade Name and Description</i>	<b>Basis UDI-DI</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Classificatie en regel</b> <i>Classification and Rule</i>
2283	Katoenen orthopedische padding van Webril voor onder gips, normale afwerking, 5,1 cm x 3,7 m  Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasse /Class: Is Regel/ Rule: 4
2394	Katoenen orthopedische padding van Webril voor onder gips, normale afwerking, 7,6 cm x 3,7 m  Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasse /Class: Is Regel/ Rule: 4
2502	Katoenen orthopedische padding van Webril voor onder gips, normale afwerking, 10,2 cm x 3,7 m  Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasse /Class: Is Regel/ Rule: 4
2554	Katoenen orthopedische padding van Webril voor onder gips, normale afwerking, 15,2 cm x 3,7 m  Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasse /Class: Is Regel/ Rule: 4
6716	Kerlix™-verbandrol, 100% katoen, 8-laags, groot, 11,4 cm x 2,8 m  Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	063014000000000000001125Y	M020107	Klasse /Class: Is Regel/ Rule: 4
6725	Kerlix-verbandrol, 100% katoen, 6-laags, middelgroot, 8,6 cm x 3,3 m  Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16'	063014000000000000001125Y	M020107	Klasse /Class: Is Regel/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Produktkodeliste</b> <i>Product Code List</i>				
	(8.6 cm x 3.3 m)			
7086	Excilon-sponzen voor drains, 6-laags, 4" x 4" (10,2 cm x 10,2 cm)  Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	06301400000000000001176A	M0201010101	Klasse /Class: Is Regel/ Rule: 4
7087	Excilon I.V.- sponzen, 6-laags, 2" x 2" (5,1 cm x 5,1 cm)  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	06301400000000000001186C	M0201010101	Klasse /Class: Is Regel/ Rule: 4
7880	Kerlix-gaasrol, 6-laags, groot, 11,4 cm x 3,7 m uitgerekt, steriel  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	06301400000000000001205X	M020107	Klasse /Class: Is Regel/ Rule: 4
7884	Kerlix-supersponzen, 15,2 cm x 17,1 cm  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	06301400000000000000996Z	M0201020101	Klasse /Class: Is Regel/ Rule: 4
3381	Curity-gaaskompressen 5,1 cm x 5,1 cm  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000001516A	M0201050101	Klasse /Class: Is Regel/ Rule: 4
6309	Curity-gaaskompressen 10,2 cm x 10,2 cm  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	06301400000000000001516A	M0201050101	Klasse /Class: Is Regel/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**FINNISH**

<b>VAATIMUSTENMUKAISUUSVAKUUTUS</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Me, Cardinal Health 200 LLC, vakuutamme, että tässä EU-vaatimustenmukaisuusvakuutuksessa kuvatut tuotteet täyttävät lääkintälaitteasetuksen (EU) 2017/745 vaatimukset.
<b>VAATIMUSTENMUKAISUUSVAKUUTUS</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Teknisen dokumentin numero</b> <i>Technical Documentation Number</i>	RE00172519
<b>Valmistajan nimi</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Valmistajan osoite</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Yksittäinen rekisterinumero</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Valtuutetun edustajan nimi ja osoite</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Ilmoitetun laitoksen nimi ja tunnusnumero</b> <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
<b>CE-sertifikaatin numero</b> <i>CE Certificate Number</i>	MDR 798506
<b>Tuotekategoria</b> <i>Product Category</i>	Puuvillaharso rullina [M020107] Cotton Gauzes in Rolls [M020107]  Puuvillaharso, taitettu, ilman röntgenkuvissa havaittavaa lankaa, steriili [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>Yksilöllinen laitemallin tunniste (Basic UDI-DI)</b> <i>Basic UDI-DI</i>	Katso liite I/ Refer to Attachment 1
<b>EMDN</b>	Katso liite I/ Refer to Attachment 1
<b>Tuotekoodi, kaupan nimi ja kuvaus</b> <i>Product Code, Trade Name and Description</i>	Katso liite I/ Refer to Attachment 1
<b>Käyttötarkoitus</b> <i>Intended Purpose</i>	<b>Kerlix-sideharso- ja harsorullat:</b> Tarkoitettu käytettäväksi ensisijaisina sidoksina haavaeritteiden imemiseen. Toissijaisina sidoksina sideharsorullia käytetään vahvistamaan ensisijaisia sidoksia ja imemään ensisijaiset sidokset läpäisseitä eritteitä. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.  <b>Webriil™- ja Webriil™ II -kipsinaluspehmusteet</b> on tarkoitettu pehmusteeksi ihon ja kipsin väliin sekä imemään kosteutta.


<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**VAATIMUSTENMUKAISUUSVAKUUTUS**  
*DECLARATION OF CONFORMITY*

	<p><b>Webri™ &amp; Webri™ II</b> Undercast Padding is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Kerlix™-superharsotaitokset</b> on tarkoitettu käytettäväksi ensisijaisina sidoksina haavakohdan eritteiden imemiseen. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Curity™-harsotyynyt</b> on tarkoitettu haavojen tai ihovaurioiden sitomiseen ja nesteiden pyyhkimiseen/imemiseen. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Excilon™-dreeni- ja -IV-harsotaitokset</b> on tarkoitettu käytettäväksi ensisijaisina sidoksina erilaisille haavoille, mukaan lukien muun muassa sisäänvientikohdat. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Luokittelu ja sääntö</b> <i>Classification and Rule</i>	Katso liite I/ Refer to Attachment 1
<b>Yleiset tekniset tiedot</b> <i>Common Specifications</i>	Ei sovellu (N/A)
<b>Lisää tarvittaessa soveltuva unionin lainsäädäntö</b> <i>Where appropriate, add applicable Union legislation</i>	Ei sovellu (N/A)
<b>Vaatimustenmukaisuuden arviointi</b> <i>Conformity Assessment</i>	Liite XI osa A/ Annex XI Part A

**ALLEKIRJOITUSOSIO**  
*SIGNATURE SECTION*

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

<b>Paikka</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Allekirjoitus/ Päivämäärä</b> <i>Signature/ Date</i>	 <small>Brenda Gerena (May 1, 2024 16:35 CDT)</small>
<b>Nimi ja asema</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Sääntelyasiat

**LIITE I**  
*ATTACHMENT 1*

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Tuotekoodiluettelo</b> <i>Product Code List</i>				
<b>Tuotekoodi</b> <i>Product Code</i>	<b>Kauppanimi ja kuvaus</b> <i>Trade Name and Description</i>	<b>Yksilöllinen laitemallin tunnistus (Basic UDI-DI) Basic UDI-DI</b>	<b>EMDN</b>	<b>Luokittelu ja sääntö</b> <i>Classification and Rule</i>
2283	Webril -puuvillainen kipsinaluspehmuste, tavallinen pinta, 2" x 12' (5,1 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	06301400000000000001346A	M0201050101	Luokka/ Classification: Is Sääntö/ Rule: 4
2394	Webril -puuvillainen kipsinaluspehmuste, tavallinen pinta, 3" x 12' (7,6 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	06301400000000000001346A	M0201050101	Luokka/ Classification: Is Sääntö/ Rule: 4
2502	Webril -puuvillainen kipsinaluspehmuste, tavallinen pinta, 4" x 12' (10,2 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	06301400000000000001346A	M0201050101	Luokka/ Classification: Is Sääntö/ Rule: 4
2554	Webril -puuvillainen kipsinaluspehmuste, tavallinen pinta, 6" x 12' (15,2 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	06301400000000000001346A	M0201050101	Luokka/ Classification: Is Sääntö/ Rule: 4
6716	Kerlix-sideharsorulla, 100 % puuvillaa, 8-kerroksinen, suuri, 4-1/2" x 9,3' (11,4 cm x 2,8 m)  Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large,	06301400000000000001125Y	M020107	Luokka/ Classification: Is Sääntö/ Rule: 4

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<b>Tuotekoodiluettelo</b> <i>Product Code List</i>				
	4-1/2" x 9.3' (11.4 cm x 2.8 m)			
6725	Kerlix-sideharsorulla, 100 % puuvillaa, 6-kerroksinen, keskikokoinen, 3-7/16" x 3-3/16' (8,6 cm x 3,3 m)  Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	063014000000000000001125Y	M020107	Luokka/ Classification: Is Sääntö/ Rule: 4
7086	Excilon-dreeniharsotaitokset, 6-kerroksiset, 4" x 4" (10,2 cm x 10,2 cm)  Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	063014000000000000001176A	M0201010101	Luokka/ Classification: Is Sääntö/ Rule: 4
7087	Excilon-IV- harsotaitokset, 6-kerroksiset, 2" x 2" (5,1 cm x 5,1 cm)  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	063014000000000000001186C	M0201010101	Luokka/ Classification: Is Sääntö/ Rule: 4
7880	Kerlix-harsorulla, 6-kerroksinen, suuri, 4-1/2" x 4-1/8 yd (11,4 cm x 3,7 m) venytettyä, steriili  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	063014000000000000001205X	M020107	Luokka/ Classification: Is Sääntö/ Rule: 4
7884	Kerlix-superharsotaitokset, 6" x 6-3/4" (15,2 cm x 17,1 cm)  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	063014000000000000000996Z	M0201020101	Luokka/ Classification: Is Sääntö/ Rule: 4
3381	Curity-harsotyyny 2" x 2" (5,1 cm x 5,1 cm)  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	063014000000000000001516A	M0201050101	Luokka/ Classification: Is Sääntö/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	<b>1</b>
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<b>Tuotekoodiluettelo</b> <i>Product Code List</i>				
6309	Curity-harsotyynyt 4" x 4" (10,2 cm x 10,2 cm)  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	06301400000000000001516A	M0201050101	Luokka/ Classification: Is Sääntö/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**FRENCH**

<b>DÉCLARATION DE CONFORMITÉ</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Nous, Cardinal Health 200 LLC, déclarons que les produits couverts par la présente déclaration de conformité de l'Union européenne satisfont à la disposition du règlement (UE) 2017/745 sur les dispositifs médicaux.
<b>Numéro de la déclaration de conformité</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Numéro de la documentation technique</b> <i>Technical Documentation Number</i>	RE00172519
<b>Nom du fabricant</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adresse du fabricant</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Numéro d'enregistrement unique</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Nom et adresse du représentant agréé</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Nom et numéro d'identification de l'organisme notifié</b> <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
<b>Numéro de certificat CE</b> <i>CE Certificate Number</i>	MDR 798506
<b>Catégorie de produit</b> <i>Product Category</i>	Gazes de coton en rouleaux [M020107] Cotton Gauzes in Rolls [M020107]  Gazes de coton, pliées, sans fil détectable par rayons X, stériles [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>UDI-DI de base</b> <i>Basic UDI-DI</i>	Voir PJ I/ Refer to Attachment 1
<b>EMDN</b>	Voir PJ I/ Refer to Attachment 1
<b>Code, nom commercial et description du produit</b> <i>Product Code, Trade Name and Description</i>	Voir PJ I/ Refer to Attachment 1
<b>Usage prévu</b> <i>Intended Purpose</i>	<b>Rouleaux de bandage et de gaze Kerlix :</b> conçus pour être utilisés comme pansements primaires pour absorber les exsudats de la plaie. Les rouleaux de bandage peuvent être utilisés en tant que pansements secondaires pour renforcer les pansements primaires et absorber les exsudats qui ont traversé les pansements primaires. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**DÉCLARATION DE CONFORMITÉ**  
*DECLARATION OF CONFORMITY*

	<p>Le rembourrage sous-plâtre <b>Webril™ &amp; Webril™ II</b> est destiné à protéger la peau et le plâtre, ainsi qu'à absorber l'humidité. <b>Webril™ &amp; Webril™ II Undercast Padding</b> is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Les compresses Kerlix™ Super</b> sont destinées à être utilisées comme pansements primaires sur le site de la plaie afin d'absorber l'exsudat. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Les compresses de gaze Curity™</b> sont destinées à être utilisées pour panser des plaies ou des déchirures cutanées et essuyer/absorber des liquides. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Les compresses absorbantes I.V. pour le drainage Excilon™</b> sont destinées à être utilisées comme pansements primaires sur plusieurs types de plaies, y compris, mais sans s'y limiter, les sites d'insertion. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Classification et règle</b> <i>Classification and Rule</i>	Voir PJ I/ Refer to Attachment 1
<b>Caractéristiques communes</b> <i>Common Specifications</i>	Sans objet (N/A)
<b>Le cas échéant, ajouter la législation de l'Union européenne en vigueur</b> <i>Where appropriate, add applicable Union legislation</i>	Sans objet (N/A)
<b>Évaluation de la conformité</b> <i>Conformity Assessment</i>	Annexe XI, Partie A/ Annex XI Part A

**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.**

<b>Lieu de délivrance</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Signature/Date</b> <i>Signature/Date</i>	 <small>Brenda Gerena (May 1, 2024 16:35 CDT)</small>
<b>Nom et fonction</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Affaires réglementaires

PJ I  
ATTACHMENT 1

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Liste de référence produit</b> <i>Product Code List</i>				
<b>Code du produit</b> <i>Product Code</i>	<b>Nom commercial et description du produit</b> <i>Trade Name and Description</i>	<b>UDI-DI de base</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Classification et règle</b> <i>Classification and Rule</i>
2283	Rembouillage sous-plâtre en coton Webril, fini standard, 2" x 12' (5,1 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	063014000000000000001346A	M0201050101	Classification/ Classification: Is Règle/ Rule: 4
2394	Rembouillage sous-plâtre en coton Webril, fini standard, 3" x 12' (7,6 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	063014000000000000001346A	M0201050101	Classification/ Classification: Is Règle/ Rule: 4
2502	Rembouillage sous-plâtre en coton Webril, fini standard, 4" x 12' (10,2 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Classification/ Classification: Is Règle/ Rule: 4
2554	Rembouillage sous-plâtre en coton Webril, fini standard, 6" x 12' (15,2 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Classification/ Classification: Is Règle/ Rule: 4
6716	Rouleau de bandage Kerlix, 100 % coton, 8 plis, large, 4-1/2" x 9.3' (11,4 cm x 2,8 m)  Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	063014000000000000001125Y	M020107	Classification/ Classification: Is Règle/ Rule: 4
6725	Rouleau de bandage Kerlix, 100 % coton, 6 plis, moyen, 3-7/16" x 3-3/16' (8,6 cm x 3,3 m)  Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	063014000000000000001125Y	M020107	Classification/ Classification: Is Règle/ Rule: 4
7086	Compresse de drainage Excilon, 6 plis, 4" x 4" (10,2 cm x 10,2 cm)	063014000000000000001176A	M0201010101	Classification/ Classification: Is Règle/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Liste de référence produit</b> <i>Product Code List</i>				
	Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)			
7087	Compresses absorbantes I.V. Excilon, 6 plis, 2" x 2" (5,1 cm x 5,1 cm)  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	063014000000000000001186C	M0201010101	Classification/ Classification: Is Règle/ Rule: 4
7880	Rouleau de gaze Kerlix, 6 plis, large, 4-1/2" x 4-1/8 yd (11,4 cm x 3,7 m), élastique, stérile  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	063014000000000000001205X	M020107	Classification/ Classification: Is Règle/ Rule: 4
7884	Compresses absorbantes supérieures Kerlix, 6" x 6-3/4" (15,2 cm x 17,1 cm)  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	063014000000000000000996Z	M0201020101	Classification/ Classification: Is Règle/ Rule: 4
3381	Tampons de gaze Curity 2" x 2" (5,1 cm x 5,1 cm)  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	063014000000000000001516A	M0201050101	Classification/ Classification: Is Règle/ Rule: 4
6309	Tampons de gaze Curity 4" x 4" (10,2 cm x 10,2 cm)  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	063014000000000000001516A	M0201050101	Classification/ Classification: Is Règle/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**GERMAN**

<b>KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY</b>	
	<b>MDR:</b> Wir, Cardinal Health 200 LLC, erklären, dass die Produkte, die in dieser EU-Konformitätserklärung behandelt werden, den Bestimmungen der Medizinprodukteverordnung (EU) 2017/745 entsprechen.
<b>Nummer der Konformitätserklärung</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Technische Dokumentennummer</b> <i>Technical Documentation Number</i>	RE00172519
<b>Name des Herstellers</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adresse des Herstellers</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Einzel-Registrierungsnummer</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Name und Adresse des bevollmächtigten Vertreters</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Name und Identifikationsnummer der benannten Stelle</b> <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
<b>CE-Zertifikat-Nummer</b> <i>CE Certificate Number</i>	MDR 798506
<b>Produktkategorie</b> <i>Product Category</i>	Baumwoll-Mullverband in Rollen [M020107] Cotton Gauzes in Rolls [M020107]  Baumwoll-Mullverband, gefaltet, ohne Röntgenkontrastfaden, steril [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>Grundlegende UDI-DI</b> <i>Basic UDI-DI</i>	Siehe Anhang I/ Refer to Attachment 1
<b>EMDN</b>	Siehe Anhang I/ Refer to Attachment 1
<b>Produktcode, Handelsname und Beschreibung</b> <i>Product Code, Trade Name and Description</i>	Siehe Anhang I/ Refer to Attachment 1
<b>Verwendungszweck</b> <i>Intended Purpose</i>	<b>Kerlix Verband und Mullbinden:</b> sind für die Verwendung als Primärverband zur Aufnahme von Wundexsudat vorgesehen. Als Sekundärverband werden Verbandsrollen zur Verstärkung von Primärverbänden und zur Absorption von Exsudat verwendet, das Primärverbände durchdrungen hat. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**KONFORMITÄTSERKLÄRUNG**  
*DECLARATION OF CONFORMITY*

	<p><b>Webril™ und Webril™ II</b> Polstermaterial dient zur Polsterung zwischen Haut und Gips und zur Absorption von Feuchtigkeit. <b>Webril™ &amp; Webril™ II</b> Undercast Padding is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Kerlix™ Superschwämme</b> sind als Primärverband für die Absorption von Exsudat vorgesehen. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Curity™ Mullbinden</b> sind zum Verbinden von Wunden oder Hautrissen und zum Abwischen/Absorbieren von Flüssigkeiten vorgesehen. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Excilon™ Saug- und I.V-Schwämme</b> sind für die Verwendung als Primärverbände an einer Reihe von Wunden vorgesehen, einschließlich, aber nicht beschränkt auf Einführungsstellen. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Klassifizierung und Richtlinie</b> <i>Classification and Rule</i>	Siehe Anhang I/ Refer to Attachment 1
<b>Allgemeine Spezifikationen</b> <i>Common Specifications</i>	Nicht zutreffend (N/A)
<b>Gegebenenfalls anwendbare Rechtsvorschriften der Gewerkschaft hinzufügen</b> <i>Where appropriate, add applicable Union legislation</i>	Nicht zutreffend (N/A)
<b>Konformitätsbewertung</b> <i>Conformity Assessment</i>	Anhang XI Teil A/ Annex XI Part A

**UNTERSCHRIFTSABSCHNITT**  
*SIGNATURE SECTION*

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

<b>Ausstellungsort</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Unterschrift /Datum</b> <i>Signature/Date</i>	 Brenda Gerena (May 1, 2024 16:35 CDT)
<b>Name und Funktion</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Zulassungsangelegenheiten

ANHANG I

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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*ATTACHMENT 1*

<b>Produktcodeliste</b> <i>Product Code List</i>				
<b>Produktcode</b> <i>Product Code</i>	<b>Handelsname und Beschreibung</b> <i>Trade Name and Description</i>	<b>Grundlegende UDI-DI</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Klassifizierung und Richtlinie</b> <i>Classification and Rule</i>
2283	Webril Baumwoll-Polstermaterial, normale Oberfläche, 5,1 cm x 3,7 m (2" x 12')  Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	06301400000000000001346A	M0201050101	Klasse/ Classification: Is Richtlinie/Rule: 4
2394	Webril Baumwoll-Polstermaterial, normale Oberfläche, 7,6 cm x 3,7 m (3" x 12')  Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	06301400000000000001346A	M0201050101	Klasse/ Classification: Is Richtlinie/Rule: 4
2502	Webril Baumwoll-Polstermaterial, normale Oberfläche, 10,2 cm x 3,7 m (4" x 12')  Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	06301400000000000001346A	M0201050101	Klasse/ Classification: Is Richtlinie/Rule: 4
2554	Webril Baumwoll-Polstermaterial, normale Oberfläche, 15,2 cm x 3,7 m (6" x 12')  Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	06301400000000000001346A	M0201050101	Klasse/ Classification: Is Richtlinie/Rule: 4
6716	Kerlix Verbandsrolle, 100 % Baumwolle, 8-lagig, groß, 11,4 cm x 2,8 m (4-1/2" x 9.3')	06301400000000000001125Y	M020107	Klasse/ Classification: Is Richtlinie/Rule: 4

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<b>Produktcodeliste</b> <i>Product Code List</i>				
	Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)			
6725	Kerlix Verbandsrolle 100 % Baumwolle, 6-lagig, mittel, 8,6 cm x 3,3 m (3 7/16" x 3 3/16')  Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	063014000000000000001125Y	M020107	Klasse/ Classification: Is Richtlinie/Rule: 4
7086	Excilon Saugschwämme, 6-lagig 10,2 cm x 10,2 cm (4" x 4")  Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	063014000000000000001176A	M0201010101	Klasse/ Classification: Is Richtlinie/Rule: 4
7087	Excilon I.V. Schwämme, 6-lagig 5,1 cm x 5,1 cm (2" x 2")  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	063014000000000000001186C	M0201010101	Klasse/ Classification: Is Richtlinie/Rule: 4
7880	Kerlix Mullbinde, 6-lagig, groß 11,4 cm x 3,7 m (4 1/2" x 12,3'), gedehnt, steril  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	063014000000000000001205X	M020107	Klasse/ Classification: Is Richtlinie/Rule: 4
7884	Kerlix Superschwämme, 15,2 cm x 17,1 cm (6" x 6-3/4")  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	063014000000000000000996Z	M0201020101	Klasse/ Classification: Is Richtlinie/Rule: 4
3381	Curity Mulltupfer 5,1 cm x 5,1 cm (2" x 2")  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	063014000000000000001516A	M0201050101	Klasse/ Classification: Is Richtlinie/Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	<b>1</b>
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<b>Produktcodeliste</b> <i>Product Code List</i>				
6309	Curity Mulltupfer 10,2 cm x 10,2 cm (4" x 4")  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	06301400000000000001516A	M0201050101	Klasse/ Classification: Is Richtlinie/Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**GREEK**


<b>ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Εμείς, η Cardinal Health 200 LLC, δηλώνουμε ότι τα προϊόντα που καλύπτονται στην παρούσα Δήλωση συμμόρφωσης ΕΕ πληρούν τις διατάξεις του Κανονισμού (ΕΕ) 2017/745 για τα ιατροτεχνολογικά προϊόντα.
<b>Αριθμός δήλωσης συμμόρφωσης</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Αριθμός τεχνικού φακέλου</b> <i>Technical Documentation Number</i>	RE00172519
<b>Όνομα κατασκευαστή</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Διεύθυνση κατασκευαστή</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Ενιαίος αριθμός καταχώρισης</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Όνομα και διεύθυνση εξουσιοδοτημένου αντιπροσώπου</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Όνομα και αριθμός αναγνώρισης κοινοποιημένου οργανισμού</b> <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
<b>Αριθμός πιστοποιητικού CE</b> <i>CE Certificate Number</i>	MDR 798506
<b>Κατηγορία προϊόντος</b> <i>Product Category</i>	Βαμβακερές γάζες σε ρολά [M020107] Cotton Gauzes in Rolls [M020107]  Βαμβακερές γάζες, διπλωμένες, χωρίς νήμα ανιχνεύσιμο με ακτίνες X, αποστειρωμένες [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>Βασικό UDI-DI</b> <i>Basic UDI-DI</i>	Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1
<b>EMDN</b>	Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1
<b>Κωδικός προϊόντος, εμπορική επωνυμία και περιγραφή</b> <i>Product Code, Trade Name and Description</i>	Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1
<b>Προοριζόμενος σκοπός</b> <i>Intended Purpose</i>	<b>Ρολά επίδεσμου και γάζας Kerlix:</b> Προορίζονται για χρήση ως κύριος επίδεσμος, για την απορρόφηση των εξιδρωμάτων του τραύματος. Ως δευτερεύοντες επίδεσμοι, τα ρολά επίδεσμου χρησιμοποιούνται για την ενίσχυση των κύριων επιδέσμων και την απορρόφηση των εξιδρωμάτων που έχουν διαπεράσει τους κύριους επιδέσμους. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ**  
**DECLARATION OF CONFORMITY**

	<p>Το ενισχυτικό υπόστρωμα γύψου <b>Webril™ &amp; Webril™ II</b> προορίζεται να παρέχει μια αντικραδασική επένδυση μεταξύ του δέρματος και του γύψου, καθώς και να απορροφά την υγρασία. <b>Webril™ &amp; Webril™ II Undercast Padding</b> is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Οι πανίσχυροι σπόγγοι Kerlix™</b> προορίζονται για χρήση ως κύριοι επίδεσμοι στο σημείο του τραύματος, για την απορρόφηση του εξιδρώματος. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Τα επιθέματα γάζας Curity™</b> προορίζονται για την επίδεση τραυμάτων ή ρήξεων του δέρματος και για το σκούπισμα/απορρόφηση υγρών. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Οι σπόγγοι παροχέτευσης και ενδοφλέβιου καθετήρα Excilon™</b> προορίζονται για χρήση ως κύρια επιθέματα σε μια σειρά τραυμάτων, συμπεριλαμβανομένων, μεταξύ άλλων, των θέσεων εισαγωγής. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Ταξινόμηση και κανόνας</b> <i>Classification and Rule</i>	Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1
<b>Κοινές προδιαγραφές</b> <i>Common Specifications</i>	Δεν ισχύει (N/A)
<b>Όπου αρμόζει, προσθέστε την εφαρμοστέα νομοθεσία της Ένωσης</b> <i>Where appropriate, add applicable Union legislation</i>	Δεν ισχύει (N/A)
<b>Αξιολόγηση της συμμόρφωσης</b> <i>Conformity Assessment</i>	Παράρτημα XI Μέρος A/ Annex XI Part A

**ΕΝΟΤΗΤΑ ΥΠΟΓΡΑΦΗΣ**  
**SIGNATURE SECTION**

<b>Η παρούσα Δήλωση συμμόρφωσης ΕΕ εκδίδεται στο όνομα και για λογαριασμό και με την αποκλειστική ευθύνη του Νόμιμου κατασκευαστή που ταυτοποιείται παραπάνω.</b>	
<b>Τόπος έκδοσης</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Υπογραφή/Ημερομηνία</b> <i>Signature/Date</i>	 Brenda Gerena (May 1, 2024 16:35 CDT)
<b>Όνομα και λειτουργία</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Ρυθμιστικές υποθέσεις

**ΠΡΟΣΑΡΤΗΜΑ I**  
**ATTACHMENT I**

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Κατάλογος κωδικών προϊόντος</b> <i>Product Code List</i>				
<b>Κωδικός προϊόντος</b> <i>Product Code</i>	<b>Εμπορική επωνυμία και περιγραφή</b> <i>Trade Name and Description</i>	<b>Βασικό UDI-DI</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Ταξινόμηση και κανόνας</b> <i>Classification and Rule</i>
2283	Βαμβακερό ενισχυτικό υπόστρωμα γύψου Webril, κανονικό φινίρισμα, 2" x 12' (5,1 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	063014000000000000001346A	M0201050101	Κατηγορία/ Classification: Is Κανόνας/ Rule: 4
2394	Βαμβακερό ενισχυτικό υπόστρωμα γύψου Webril, κανονικό φινίρισμα, 3" x 12' (7,6 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	063014000000000000001346A	M0201050101	Κατηγορία/ Classification: Is Κανόνας/ Rule: 4
2502	Βαμβακερό ενισχυτικό υπόστρωμα γύψου Webril, κανονικό φινίρισμα, 4" x 12' (10,2 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Κατηγορία/ Classification: Is Κανόνας/ Rule: 4
2554	Βαμβακερό ενισχυτικό υπόστρωμα γύψου Webril, κανονικό φινίρισμα, 6" x 12' (15,2 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Κατηγορία/ Classification: Is Κανόνας/ Rule: 4
6716	Ρολό επιδέσμου Kerlix, 100% βαμβάκι, 8 φύλλων, μεγάλο μέγεθος, 4-1/2" x 9,3' (11,4 cm x 2,8 m)	063014000000000000001125Y	M020107	Κατηγορία/ Classification: Is Κανόνας/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Κατάλογος κωδικών προϊόντος</b> <i>Product Code List</i>				
	Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)			
6725	Ρολό επιδέσμου Kerlix, 100% βαμβάκι, 6 φύλλων, μεσαίο μέγεθος, 3-7/16" x 3-3/16' (8,6 cm x 3,3 m)  Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	063014000000000000001125Y	M020107	Κατηγορία/ Classification: Is Κανόνας/ Rule: 4
7086	Σπόγγοι παροχέτευσης Excilon, 6 φύλλων, 4" x 4" (10,2cm x 10,2cm)  Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	063014000000000000001176A	M0201010101	Κατηγορία/ Classification: Is Κανόνας/ Rule: 4
7087	Σπόγγοι ενδοφλέβιου καθετήρα Excilon 6 φύλλων, 2" x 2" (5,1cm x 5,1cm)  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	063014000000000000001186C	M0201010101	Κατηγορία/ Classification: Is Κανόνας/ Rule: 4
7880	Ρολό επιδέσμου Kerlix, 6 φύλλων, μεγάλο μέγεθος 4-1/2" x 4-1/8 yd (11,4 cm x 3,7 m), ελαστικός, αποστειρωμένος  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	063014000000000000001205X	M020107	Κατηγορία/ Classification: Is Κανόνας/ Rule: 4
7884	Πανίσχυροι σπόγγοι Kerlix, 6" x 6-3/4" (15,2 cm x 17,1 cm)  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	063014000000000000000996Z	M0201020101	Κατηγορία/ Classification: Is Κανόνας/ Rule: 4
3381	Επιθέματα γάζας Curity 2" x 2" (5,1 cm x 5,1 cm)	063014000000000000001516A	M0201050101	Κατηγορία/ Classification: Is Κανόνας/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	<b>1</b>
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**Κατάλογος κωδικών προϊόντος**  
*Product Code List*

	Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)			
6309	Επίθεμα γάζας Curity 4" x 4" (10,2cm x 10,2cm)  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	06301400000000000001516A	M0201050101	Κατηγορία/ Classification: Is Κανόνας/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	<b>1</b>
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**ITALIAN**

<b>DICHIARAZIONE DI CONFORMITÀ</b> <b>DECLARATION OF CONFORMITY</b>	
	<p><b>MDR:</b> 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.</p>
<b>Numero della dichiarazione di conformità</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Numero di documentazione tecnica</b> <i>Technical Documentation Number</i>	RE00172519
<b>Nome del fabbricante</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Indirizzo del fabbricante</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Numero di registrazione unico</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Nome e indirizzo del mandatario</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Nome e numero di identificazione dell'organismo notificato</b> <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
<b>Numero di certificato CE</b> <i>CE Certificate Number</i>	MDR 798506
<b>Categoria di prodotto</b> <i>Product Category</i>	Garze di cotone in rotoli [M020107] Cotton Gauzes in Rolls [M020107]  Garze di cotone, piegate, senza filo rilevabile ai raggi X, sterili [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>UDI-DI di base</b> <i>Basic UDI-DI</i>	Consultare l'Allegato I/ Refer to Attachment 1
<b>EMDN</b>	Consultare l'Allegato I/ Refer to Attachment 1
<b>Codice prodotto, denominazione commerciale e descrizione</b> <i>Product Code, Trade Name and Description</i>	Consultare l'Allegato I/ Refer to Attachment 1
<b>Destinazione d'uso</b> <i>Intended Purpose</i>	<p><b>Le bende e le garze in rotolo Kerlix</b> sono destinate all'uso come medicazione primaria per assorbire gli essudati delle ferite. Come medicazioni secondarie, le bende in rotolo sono utilizzate per rinforzare le medicazioni primarie e assorbire gli essudati che sono passati attraverso le medicazioni primarie.</p> <p><b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.</p>

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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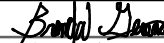
**DICHIARAZIONE DI CONFORMITÀ**  
**DECLARATION OF CONFORMITY**

	<p>L'imbottitura per ingessature <b>Webril™ &amp; Webril™ II</b> è destinata a fornire un'imbottitura tra la pelle e il gesso e ad assorbire l'umidità. <b>Webril™ &amp; Webril™ II Undercast Padding</b> is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Le Super Spugne Kerlix™</b> sono destinate a essere utilizzate come medicazioni primarie nel sito della ferita per assorbire l'essudato. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>I tamponi di garza Curity™</b> sono destinati a essere utilizzati per la medicazione di ferite o lesioni cutanee e per asciugare/assorbire i liquidi. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Le spugne per drenaggio ed EV Excilon™</b> sono indicate per l'uso come medicazione primaria su una vasta gamma di ferite, inclusi, a titolo esemplificativo ma non esaustivo, i siti di inserimento. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Classificazione e regola</b> <i>Classification and Rule</i>	Consultare l'Allegato I/ Refer to Attachment 1
<b>Specifiche comuni</b> <i>Common Specifications</i>	Non applicabile (N/A)
<b>Ove necessario, aggiungere la legislazione pertinente dell'Unione</b> <i>Where appropriate, add applicable Union legislation</i>	Non applicabile (N/A)
<b>Valutazione della conformità</b> <i>Conformity Assessment</i>	Allegato XI, Parte A/Annex XI Part A

**SEZIONE FIRMA**

**SIGNATURE SECTION**

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

<b>Luogo di rilascio</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Firma/Data</b> <i>Signature/Date</i>	 Brenda Gerena (May 1, 2024 16:35 CDT)
<b>Nome e mansion</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Affari regolatori

ALLEGATO I  
ATTACHMENT 1

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Elenco codice prodotto</b> <i>Product Code List</i>				
<b>Codice prodotto</b> <i>Product Code</i>	<b>Denominazione commerciale e descrizione</b> <i>Trade Name and Description</i>	<b>UDI-DI di base</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Classificazione e regola</b> <i>Classification and Rule</i>
2283	<p>Imbottitura per ingessature in cotone Webril, finitura regolare, 5,1 cm x 3,7 m</p> <p>Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)</p>	063014000000000000001346A	M0201050101	Classe/ Classification: Is Regola/ Rule: 4
2394	<p>Imbottitura per ingessature in cotone Webril, finitura regolare, 7,6 cm x 3,7 m</p> <p>Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)</p>	063014000000000000001346A	M0201050101	Classe/ Classification: Is Regola/ Rule: 4
2502	<p>Imbottitura per ingessature in cotone Webril, finitura regolare, 10,2 cm x 3,7 m</p> <p>Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)</p>	063014000000000000001346A	M0201050101	Classe/ Classification: Is Regola/ Rule: 4
2554	<p>Imbottitura per ingessature in cotone Webril, finitura regolare, 15,2 cm x 3,7 m</p> <p>Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)</p>	063014000000000000001346A	M0201050101	Classe/ Classification: Is Regola/ Rule: 4
6716	<p>Bende in rotolo Kerlix, 100% cotone, 8 strati, Large, 11,4 cm x 2,8 m</p> <p>Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)</p>	063014000000000000001125Y	M020107	Classe/ Classification: Is Regola/ Rule: 4
6725	<p>Bende in rotolo Kerlix, 100% cotone, 6 strati, Medium, 8,6 cm x 3,3 m</p> <p>Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16'</p>	063014000000000000001125Y	M020107	Classe/ Classification: Is Regola/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	<b>1</b>
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<b>Elenco codice prodotto</b> <i>Product Code List</i>				
	(8.6 cm x 3.3 m)			
7086	Spugne di drenaggio Excilon, 6 strati, 10,2 cm x 10,2 cm  Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	06301400000000000001176A	M0201010101	Classe/ Classification: Is Regola/ Rule: 4
7087	Spugne per E.V. Excilon, 6 strati, 5,1 cm x 5,1 cm  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	06301400000000000001186C	M0201010101	Classe/ Classification: Is Regola/ Rule: 4
7880	Garza in rotolo Kerlix, 6 strati, Large, 11,4 cm x 3,7 m elastica, sterile  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	06301400000000000001205X	M020107	Classe/ Classification: Is Regola/ Rule: 4
7884	Super spugne Kerlix, 15,2 cm x 17,1 cm  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	06301400000000000000996Z	M0201020101	Classe/ Classification: Is Regola/ Rule: 4
3381	Tamponi di garza Curity 5,1 cm x 5,1 cm  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000001516A	M0201050101	Classe/ Classification: Is Regola/ Rule: 4
6309	Tampone di garza Curity 10,2 cm x 10,2 cm  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	06301400000000000001516A	M0201050101	Classe/ Classification: Is Regola/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**NORWEGIAN**

<b>SAMSVARERKLÆRING</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Vi, Cardinal Health 200 LLC, erklærer at produktene som dekkes i denne EU-samsvarserklæringen oppfyller bestemmelsene i forordningen om medisinsk utstyr (EU) 2017/745.
<b>Samsvarserklæringsnummer</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Teknisk dokumentasjonsnummer</b> <i>Technical Documentation Number</i>	RE00172519
<b>Produsentens navn</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Produsentens adresse</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Enkeltregistreringsnummer</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Autorisert representants navn og adresse</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Teknisk kontrollorgans navn og identifikasjonsnummer</b> <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
<b>CE-sertifikatnummer</b> <i>CE Certificate Number</i>	MDR 798506
<b>Produktkategori</b> <i>Product Category</i>	Bomullsgasbind på ruller [M020107] Cotton Gauzes in Rolls [M020107]  Bomullsgasbind, brettet, uten røntgenregistrerbar tråd, steril [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>Grunnleggende UDI-DI</b> <i>Basic UDI-DI</i>	Se Tillegg I/ Refer to Attachment 1
<b>EMDN</b>	Se Tillegg I/ Refer to Attachment 1
<b>Produktkode, handelsnavn og beskrivelse</b> <i>Product Code, Trade Name and Description</i>	Se Tillegg I/ Refer to Attachment 1
<b>Tiltenkt formal</b> <i>Intended Purpose</i>	<b>Kerlix-bandasje og gasbind på ruller:</b> tiltenkt brukt som primærbandasje for å absorbere såreksudat. Som sekundærbandasje brukes disse bandasjerullene til å forsterke primærbandasjer og absorbere eksudat som har trukket gjennom primærbandasjene. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.

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**SAMSVARSERKLÆRING**  
**DECLARATION OF CONFORMITY**

	<p><b>Webril™ &amp; Webril™ II</b>-undergipspolstring skal fungere som et mykt lag mellom huden og gipsen og absorbere fuktighet. <b>Webril™ &amp; Webril™ II</b> Undercast Padding is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Kerlix™-supersvamper</b> er beregnet for bruk som primærbandasjer på sårstedet for å absorbere eksudat. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Curity™-gasbindputer</b> er ment å brukes til å bandasjere sår eller brudd i huden og tørke av / absorbere væsker. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Excilon™-svamper til dreناسje og i.v.</b> er beregnet for bruk som primærbandasjer på en rekke typer sår, inkludert, men ikke begrenset til, innføringssteder. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Klassifisering og regel</b> <i>Classification and Rule</i>	Se Tillegg I / Refer to Attachment 1
<b>Vanlige spesifikasjoner</b> <i>Common Specifications</i>	Ikke relevant (N/A)
<b>Legg til gjeldende EU-lovgivning der det er relevant</b> <i>Where appropriate, add applicable Union legislation</i>	Ikke relevant (N/A)
<b>Samsvarsvurdering</b> <i>Conformity Assessment</i>	Tillegg XI, del A/ Annex XI Part A

**SIGNATURDEL**  
**SIGNATURE SECTION**

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

<b>Utstedelsessted</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Signatur/Dato</b> <i>Signature/Date</i>	 <small>Brenda Gerena (May 1, 2024 16:35 CDT)</small>
<b>Navn og funksjon</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Juridisk avdeling

**TILLEGG I**  
**ATTACHMENT I**

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<b>Produktkodeliste</b> <i>Product Code List</i>				
<b>Produktkode</b> <i>Product Code</i>	<b>Handelsnavn og beskrivelse</b> <i>Trade Name and Description</i>	<b>Grunnleggende UDI-DI</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Klassifisering og regel</b> <i>Classification and Rule</i>
2283	Webril-undergipspolstring i bomull, vanlig finish, 2" x 12' (5,1 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasse/ Classification: Is Regel/ Rule: 4
2394	Webril-undergipspolstring i bomull, vanlig finish, 3" x 12' (7,6 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasse/ Classification: Is Regel/ Rule: 4
2502	Webril-undergipspolstring i bomull, vanlig finish, 4" x 12' (10,2 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasse/ Classification: Is Regel/ Rule: 4
2554	Webril-undergipspolstring i bomull, vanlig finish, 6" x 12' (15,2 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasse/ Classification: Is Regel/ Rule: 4
6716	Kerlix-bandasje på rull, 100 % bomull, 8 lag, stor, 4-1/2" x 9,3' (11,4 cm x 2,8 m) Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	063014000000000000001125Y	M020107	Klasse/ Classification: Is Regel/ Rule: 4
6725	Kerlix-bandasje på rull, 100 % bomull, 6 lag, medium, 3-7/16" x 3-3/16' (8,6 cm x 3,3 m) Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	063014000000000000001125Y	M020107	Klasse/ Classification: Is Regel/ Rule: 4
7086	Excilon-svamper til drenering, 6 lag, 4" x 4" (10,2 cm x 10,2 cm)	063014000000000000001176A	M0201010101	Klasse/ Classification: Is Regel/ Rule: 4

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<b>Produktkodeliste</b> <i>Product Code List</i>				
	Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)			
7087	Excilon -svamper til drenasje, 6 lag, 2" x 2" (5,1 cm x 5,1 cm)  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	063014000000000000001186C	M0201010101	Klasse/ Classification: Is Regel/ Rule: 4
7880	Kerlix-gasbind på rull, 6 lag, stor, 4-1/2" x 4-1/8 yd (11,4 cm x 3,7 m) strukket, steril  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	063014000000000000001205X	M020107	Klasse/ Classification: Is Regel/ Rule: 4
7884	Kerlix-supersvamper, 6" x 6-3/4" (15,2 cm x 17,1 cm)  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	063014000000000000000996Z	M0201020101	Klasse/ Classification: Is Regel/ Rule: 4
3381	Curity-gasbindputer, 2" x 2" (5,1 cm x 5,1 cm)  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	063014000000000000001516A	M0201050101	Klasse/ Classification: Is Regel/ Rule: 4
6309	Curity-gasbindputer, 4" x 4" (10,2 cm x 10,2 cm)  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	063014000000000000001516A	M0201050101	Klasse/ Classification: Is Regel/ Rule: 4

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**POLISH**

<b>DEKLARACJA ZGODNOŚCI</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> My, Cardinal Health 200 LLC, oświadczamy, że produkty objęte Deklaracją zgodności UE spełniają wymagania rozporządzenia w sprawie wyrobów medycznych (EU) 2017/745.
<b>Numer Deklaracji zgodności</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Numer dokumentacji technicznej</b> <i>Technical Documentation Number</i>	RE00172519
<b>Nazwa producenta</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adres producenta</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Pojedynczy numer rejestracyjny</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Nazwa i adres autoryzowanego przedstawiciela</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Nazwa i numer identyfikacyjny jednostki notyfikowanej</b> <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
<b>Numer certyfikatu CE</b> <i>CE Certificate Number</i>	MDR 798506
<b>Kategoria produktów</b> <i>Product Category</i>	Gaza bawełniana w rolkach [M020107] Cotton Gauzes in Rolls [M020107]  Gazy bawełniane, złożone, bez nici wykrywalnej przez promieniowanie rentgenowskie, sterylne [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>Podstawowy unikalny identyfikator urządzenia UDI-DI</b> <i>Basic UDI-DI</i>	Patrz Załącznik I/ Refer to Attachment 1
<b>EMDN</b>	Patrz Załącznik I/ Refer to Attachment 1
<b>Kod produktu, nazwa handlowa i opis</b> <i>Product Code, Trade Name and Description</i>	Patrz Załącznik I/ Refer to Attachment 1
<b>Przeznaczenie</b> <i>Intended Purpose</i>	<b>Bandaż Kerlix i gaza w rolkach:</b> przeznaczone do stosowania jako opatrunek podstawowy w celu wchłaniania wysięków z ran. Jako opatrunek wtórny bandaż w rolce jest używany do wzmacniania opatrunków pierwotnych i wchłaniania wysięków, które przedostały się przez opatrunki pierwotne. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.

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**DEKLARACJA ZGODNOŚCI**  
**DECLARATION OF CONFORMITY**

	<p>Podkład bawełniany pod opatrunek gipsowy <b>Webril™ oraz Webril™ II</b> ma na celu zapewnienie amortyzacji między skórą a gipsem oraz wchłanianie wilgoci. <b>Webril™ &amp; Webril™ II Undercast Padding</b> is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Gąbki Kerlix™ Super</b> są przeznaczone do stosowania jako opatrunki pierwotne w miejscu rany w celu wchłaniania wysięku. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Podkładki z gazy Curity™</b> są przeznaczone do opatrywania ran lub pęknięć skóry oraz wycierania/wchłaniania płynów. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Gąbki trenażowe i I.V Excilon™</b> są przeznaczone do stosowania jako podstawowy opatrunek na wielu ranach, w tym m.in. w miejscach wprowadzania narzędzi. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Klasyfikacja i reguła</b> <i>Classification and Rule</i>	Patrz Załącznik I/ Refer to Attachment 1
<b>Wspólne specyfikacje</b> <i>Common Specifications</i>	Nie dotyczy (N/A)
<b>W stosownych przypadkach dodać obowiązujące przepisy unijne</b> <i>Where appropriate, add applicable Union legislation</i>	Nie dotyczy (N/A)
<b>Ocena zgodności</b> <i>Conformity Assessment</i>	Załącznik XI, część A/ Annex XI Part A

**SEKCJA PODPISÓW**  
**SIGNATURE SECTION**

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

<b>Miejsce wydania</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Podpis/Data</b> <i>Signature/Date</i>	 Brenda Gerena (May 1, 2024 16:35 CDT)
<b>Imię i nazwisko oraz stanowisko</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Dział spraw regulacyjnych

ZAŁĄCZNIK 1  
ATTACHMENT 1

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<b>Lista kodów produktu</b> <i>Product Code List</i>				
<b>Kod produktu</b> <i>Product Code</i>	<b>Nazwa handlowa i opis</b> <i>Trade Name and Description</i>	<b>Podstawowy unikalny identyfikator urządzenia</b> <b>UDI-DI</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Klasyfikacja i reguła</b> <i>Classification and Rule</i>
2283	Podkład bawełniany pod opatrunek gipsowy Webril, wykończenie regularne, 2" x 12' (5,1 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasa/ Classification: Is Reguła/ Rule: 4
2394	Podkład bawełniany pod opatrunek gipsowy Webril, wykończenie regularne, 3" x 12' (7,6 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasa/ Classification: Is Reguła/ Rule: 4
2502	Podkład bawełniany pod opatrunek gipsowy Webril, wykończenie regularne, 4" x 12' (10,2 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasa/ Classification: Is Reguła/ Rule: 4
2554	Podkład bawełniany pod opatrunek gipsowy Webril, wykończenie regularne, 6" x 12' (15,2 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Klasa/ Classification: Is Reguła/ Rule: 4
6716	Bandaż w rolce Kerlix, 100% bawełna, 8 warstw, duży, 4- 1/2" x 9,3' (11,4 cm x 2,8 m)  Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	063014000000000000001125Y	M020107	Klasa/ Classification: Is Reguła/ Rule: 4
6725	Bandaż w rolce Kerlix, 100% bawełna, 6 warstw, średni, 3-7/16" x 3-3/16' (8,6 cm x 3,3 m)  Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16'	063014000000000000001125Y	M020107	Klasa/ Classification: Is Reguła/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Lista kodów produktu</b> <i>Product Code List</i>				
	(8.6 cm x 3.3 m)			
7086	Gąbki drenażowe Excilon, 6 warstw, 4" x 4" (10,2 cm x 10,2 cm)  Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	06301400000000000001176A	M0201010101	Klasa/ Classification: Is Reguła/ Rule: 4
7087	Excilon I.V. Gąbki, 6 warstw, 2" x 2" (5,1 cm x 5,1 cm)  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	06301400000000000001186C	M0201010101	Klasa/ Classification: Is Reguła/ Rule: 4
7880	Bandaż w rolce Kerlix, 6 warstw, duży, 4-1/2" x 4-1/8 yd (11,4 cm x 3,7 m), elastyczny, sterylny  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	06301400000000000001205X	M020107	Klasa/ Classification: Is Reguła/ Rule: 4
7884	Gąbki Kerlix Super, 6" x 6-3/4" (15,2 cm x 17,1 cm)  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	06301400000000000000996Z	M0201020101	Klasa/ Classification: Is Reguła/ Rule: 4
3381	Podkładki z gazy Curity 2" x 2" (5,1 cm x 5,1 cm)  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000001516A	M0201050101	Klasa/ Classification: Is Reguła/ Rule: 4
6309	Podkładka z gazy Curity 4 "x 4" (10,2 cm x 10,2 cm)  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	06301400000000000001516A	M0201050101	Klasa/ Classification: Is Reguła/ Rule: 4

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**PORTUGUESE**

<b>DECLARAÇÃO DE CONFORMIDADE</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> 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.
<b>Número de Declaração de Conformidade</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Número de documentação técnica</b> <i>Technical Documentation Number</i>	RE00172519
<b>Nome do fabricante</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Endereço do fabricante</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Número único de registo</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Nome e endereço do representante autorizado</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Nome e número de identificação do organismo notificado</b> <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
<b>Número do certificado CE</b> <i>CE Certificate Number</i>	MDR 798506
<b>Categoria do produto</b> <i>Product Category</i>	Gazes de algodão em rolos [M020107] Cotton Gauzes in Rolls [M020107]  Gazes de algodão, dobradas, sem fio radiopaco, estéreis [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>UDI-DI básico</b> <i>Basic UDI-DI</i>	Consultar o Anexo I/ Refer to Attachment 1
<b>EMDN</b>	Consultar o Anexo I/ Refer to Attachment 1
<b>Código, nome comercial e descrição do produto</b> <i>Product Code, Trade Name and Description</i>	Consultar o Anexo I/ Refer to Attachment 1
<b>Finalidade</b> <i>Intended Purpose</i>	<b>Rolos de gaze e atadura Kerlix:</b> são usados como curativos primários para absorver exsudatos de feridas. Os rolos de atadura Kerlix são usados como curativos secundários para reforçar os curativos primários e absorver exsudatos que atravessam os curativos primários. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.

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

	<p>O acolchoamento para talas de gesso <b>Webril™ e Webril™ II</b> é usado para proporcionar uma proteção entre a pele e o gesso e absorver a umidade. <b>Webril™ &amp; Webril™ II Undercast Padding</b> is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p>As <b>superesponjas Kerlix™</b> são usadas como curativos primários no local da ferida para absorver exsudato. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p>As <b>compressas de gaze Curity™</b> são usadas para fazer curativos de feridas ou incisões na pele e para limpar/absorver fluidos. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p>As <b>esponjas de drenagem Excilon™ IV</b> são usadas como curativos primários em uma variedade de feridas, incluindo locais de inserção, entre outras. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Classificação e regra</b> <i>Classification and Rule</i>	Consultar o Anexo I/ Refer to Attachment 1
<b>Especificações comuns</b> <i>Common Specifications</i>	Não aplicável (N/A)
<b>Se for o caso, adicione a legislação aplicável ao nível da União</b> <i>Where appropriate, add applicable Union legislation</i>	Não aplicável (N/A)
<b>Avaliação de conformidade</b> <i>Conformity Assessment</i>	Anexo XI, Parte A / Annex XI Part A

**SECCÃO DE ASSINATURA**  
**SIGNATURE SECTION**

Esta Declaração de Conformidade da UE é emitida em nome e sob a responsabilidade exclusiva do Fabricante legal identificado acima.

<b>Local de emissão</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Assinatura/Data</b> <i>Signature/Date</i>	 <small>Brenda Gerena (May 1, 2024 16:35 CDT)</small>
<b>Nome e cargo</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Assuntos Regulamentares

**ANEXO I**  
**ATTACHMENT I**

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**Lista de códigos dos produtos**  
*Product Code List*

<b>Código do produto</b> <i>Product Code</i>	<b>Nome comercial e descrição</b> <i>Trade Name and Description</i>	<b>UDI-DI básico</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Classificação e regra</b> <i>Classification and Rule</i>
2283	Acólchoamento de algodão para talas de gesso Webril, acabamento regular, 5,1 cm x 3,7 m (2 pol. x 12 pés)  Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	063014000000000000001346A	M0201050101	Classe/ Classification: Is Regra/ Rule: 4
2394	Acólchoamento de algodão para talas de gesso Webril, acabamento regular, 7,6 cm x 3,7 m (3 pol. x 12 pés)  Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	063014000000000000001346A	M0201050101	Classe/ Classification: Is Regra/ Rule: 4
2502	Acólchoamento de algodão para talas de gesso Webril, acabamento regular, 10,2 cm x 3,7 m (4 pol. x 12 pés)  Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Classe/ Classification: Is Regra/ Rule: 4
2554	Acólchoamento de algodão para talas de gesso Webril, acabamento regular, 15,2 cm x 3,7 m (6 pol. x 12 pés)  Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Classe/ Classification: Is Regra/ Rule: 4
6716	Rolo de atadura Kerlix, 100% algodão, 8 camadas, grande, 11,4 cm x 2,8 m (4-1/2 pol. x 9,3 pés)  Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	063014000000000000001125Y	M020107	Classe/ Classification: Is Regra/ Rule: 4
6725	Rolo de atadura Kerlix, 100% algodão, 6 camadas, médio,	063014000000000000001125Y	M020107	Classe/ Classification: Is


<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	<b>1</b>
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**Lista de códigos dos produtos**  
*Product Code List*

	8,6 cm x 3,3 m (3-7/16 pol. x 3-3/16 pés)  Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16" (8.6 cm x 3.3 m)			Regra/ Rule: 4
7086	Esponja de drenagem Excilon, 6 camadas 10,2 cm x 10,2 cm (4 pol. x 4 pol.)  Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	0630140000000000000000001176A	M0201010101	Classe/ Classification: Is Regra/ Rule: 4
7087	Excilon IV Esponjas, 6 camadas, 5,1 cm x 5,1 cm (2 pol. x 2 pol.)  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	0630140000000000000000001186C	M0201010101	Classe/ Classification: Is Regra/ Rule: 4
7880	Rolo de gaze Kerlix, 6 camadas, grande, 11,4 cm x 3,7 m (4-1/2 pol. x 4-1/8 yd) esticado, estéril  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	0630140000000000000000001205X	M020107	Classe/ Classification: Is Regra/ Rule: 4
7884	Super esponjas Kerlix, 15,2 cm x 17,1 cm (6 pol. x 6-3/4 pol.)  Kerlix Super Sponges, 6" x 6- 3/4" (15.2 cm x 17.1 cm)	0630140000000000000000000996Z	M0201020101	Classe/ Classification: Is Regra/ Rule: 4
3381	Compressas de gaze Curity, 5,1 cm x 5,1 cm (2 pol. x 2 pol.)  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	0630140000000000000000001516A	M0201050101	Classe/ Classification: Is Regra/ Rule: 4
6309	Compressa de gaze Curity, 10,2 cm x 10,2 cm (4 pol. x 4 pol.)  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	0630140000000000000000001516A	M0201050101	Classe/ Classification: Is Regra/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**ROMANIAN**

<b>DECLARAȚIE DE CONFORMITATE</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Noi, Cardinal Health 200 LLC, declarăm că produsele acoperite în această Declarație de conformitate UE respectă prevederile Regulamentului privind dispozitivele medicale (UE) 2017/745.
<b>Număr declarație de conformitate</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Număr documentație tehnică</b> <i>Technical Documentation Number</i>	RE00172519
<b>Numele producătorului</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adresa producătorului</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Număr unic de înregistrare</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Numele și adresa reprezentantului autorizat</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Numele și numărul de identificare al Organismului notificat</b> <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
<b>Numărul certificatului CE</b> <i>CE Certificate Number</i>	MDR 798506
<b>Categoria de produs</b> <i>Product Category</i>	Feșe de tifon din bumbac [M020107] Cotton Gauzes in Rolls [M020107]  Tifoane din bumbac, pliate, fără fir detectabil cu raze X, sterile [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>UDI-DI de bază</b> <i>Basic UDI-DI</i>	Consultați Anexa I/ Refer to Attachment 1
<b>EMDN</b>	Consultați Anexa I/ Refer to Attachment 1
<b>Cod produs, Nume comercial și Descriere</b> <i>Product Code, Trade Name and Description</i>	Consultați Anexa I/ Refer to Attachment 1
<b>Destinația utilizării</b> <i>Intended Purpose</i>	<b>Feșe de pansat și de tifon Kerlix:</b> sunt destinate utilizării ca pansament primar pentru a absorbi exudatele plăgilor. Ca pansamente secundare, feșele de pansat Kerlix sunt folosite pentru a consolida pansamentele primare și pentru a absorbi exudatele care au trecut prin pansamentele primare. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**DECLARAȚIE DE CONFORMITATE**  
*DECLARATION OF CONFORMITY*

	<p>Tampoanele cu umplutură <b>Webril™ &amp; Webril™ II</b> sunt destinate să ofere protecție între piele și atelă și să absoarbă umezeala. <b>Webril™ &amp; Webril™ II Undercast Padding</b> is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Bureții Kerlix™ Super</b> sunt destinați să fie utilizați ca pansamente primare la locul plăgii pentru a absorbi exudatul. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Tampoane de tifon Curity™</b> sunt destinate utilizării pentru pansarea plăgilor sau a leziunilor pielii și pentru ștergerea/absorbția fluidelor. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Bureții pentru drenaj și I.V. Excilon™</b> sunt destinați utilizării ca pansamente primare pe diverse leziuni, inclusiv, dar fără a se limita la, locurile de introducere. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Clasificare și regulă</b> <i>Classification and Rule</i>	Consultați Anexa I/ Refer to Attachment 1
<b>Specificații comune</b> <i>Common Specifications</i>	Nu este cazul (N/A)
<b>Când este cazul, adăugați legislația aplicabilă din Uniune</b> <i>Where appropriate, add applicable Union legislation</i>	Nu este cazul (N/A)
<b>Evaluarea de conformitate</b> <i>Conformity Assessment</i>	Anexa XI, Partea A/ Annex XI Part A

**SECȚIUNEA DE SEMNĂTURI**  
*SIGNATURE SECTION*

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

<b>Locul emiterii</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Semnătura/Data</b> <i>Signature/Date</i>	 Brenda Gerena (May 1, 2024 16:35 CDT)
<b>Nume și funcție</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Afaceri de reglementare

ANEXA I  
*ATTACHMENT 1*

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**Listă cu Coduri de produse**  
*Product Code List*

<b>Cod produs</b> <i>Product Code</i>	<b>Nume comercial și descriere</b> <i>Trade Name and Description</i>	<b>UDI-DI de bază</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Clasificare și regulă</b> <i>Classification and Rule</i>
2283	Tampoane cu umplutură de bumbac Webril, finisaj obișnuit, 2" x 12' (5,1 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	06301400000000000001346A	M0201050101	Clasă/ Class: Is Regulă/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Listă cu Coduri de produse</b> <i>Product Code List</i>				
2394	Tamponare cu umplutură de bumbac Webril, finisaj obișnuit, 3" x 12' (7,6 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	0630140000000000000000001346A	M0201050101	Clasă/ Class: Is Regulă/ Rule: 4
2502	Tamponare cu umplutură de bumbac Webril, finisaj obișnuit, 4" x 12' (10,2 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	0630140000000000000000001346A	M0201050101	Clasă/ Class: Is Regulă/ Rule: 4
2554	Tamponare cu umplutură de bumbac Webril, finisaj obișnuit, 6" x 12' (15,2 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	0630140000000000000000001346A	M0201050101	Clasă/ Class: Is Regulă/ Rule: 4
6716	Fașă de bandaj Kerlix, 100% bumbac, 8 straturi, mare, 4-1/2" x 9,3' (11,4 cm x 2,8 m)  Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	0630140000000000000000001125Y	M020107	Clasă/ Class: Is Regulă/ Rule: 4
6725	Fașă de bandaj Kerlix, 100% bumbac, 6 straturi, medie, 3-7/16" x 3-3/16' (8,6 cm x 3,3 m)  Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	0630140000000000000000001125Y	M020107	Clasă/ Class: Is Regulă/ Rule: 4
7086	Bureți de drenaj Excilon, 6 straturi, 4" x 4" (10,2 cm x 10,2 cm)  Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	0630140000000000000000001176A	M0201010101	Clasă/ Class: Is Regulă/ Rule: 4
7087	Excilon I.V. Bureți, 6 straturi, 2" x 2" (5,1 cm x 5,1 cm)  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	0630140000000000000000001186C	M0201010101	Clasă/ Class: Is Regulă/ Rule: 4
7880	Fașă de tifon Kerlix, 6 straturi, mare, 4-1/2" x 4-1/8 yd	0630140000000000000000001205X	M020107	Clasă/ Class: Is Regulă/ Rule: 4


<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**Listă cu Coduri de produse**  
*Product Code List*

	(11,4 cm x 3,7 m), elastică, sterilă  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile			
7884	Bureți Kerlix Super, 6" x 6-3/4" (15,2 cm x 17,1 cm)  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	0630140000000000000996Z	M0201020101	Clasă/ Class: Is Regulă/ Rule: 4
3381	Tampoane de tifon Curity 2" x 2" (5,1 cm x 5,1 cm)  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	0630140000000000001516A	M0201050101	Clasă/ Class: Is Regulă/ Rule: 4
6309	Tampon de tifon Curity 4" x 4" (10,2 cm x 10,2 cm)  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	0630140000000000001516A	M0201050101	Clasă/ Class: Is Regulă/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**SLOVAK**

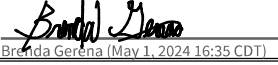
<b>VYHLÁSENIE O ZHODE</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Vyhlasujeme, Cardinal Health 200 LLC, že produkty uvedené v tomto vyhlásení o zhode EÚ spĺňajú ustanovenia nariadenia o zdravotníckych pomôckach (EÚ) 2017/745.
<b>Číslo vyhlásenia o zhode</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Číslo technickej dokumentácie</b> <i>Technical Documentation Number</i>	RE00172519
<b>Názov výrobcu</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adresa výrobcu</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Jednotné registračné číslo</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Meno a adresa oprávneného zástupcu</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Meno a identifikačné číslo informovaného orgánu</b> <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
<b>Číslo certifikátu CE</b> <i>CE Certificate Number</i>	MDR 798506
<b>Kategória výrobku</b> <i>Product Category</i>	Cotton Gauzes in Rolls [M020107] Cotton Gauzes in Rolls [M020107]  Bavlnené gázy, skladané, bez röntgenového detekovateľného vlákna, sterilné [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>Základné UDI-DI</b> <i>Basic UDI-DI</i>	Pozrite si Prílohu I/ Refer to Attachment 1
<b>EMDN</b>	Pozrite si Prílohu I/ Refer to Attachment 1
<b>Kód výrobku, obchodný názov a popis</b> <i>Product Code, Trade Name and Description</i>	Pozrite si Prílohu I/ Refer to Attachment 1
<b>Zamýšľaný účel</b> <i>Intended Purpose</i>	<b>Rolky na obvaz a gázu Kerlix:</b> Na použitie ako primárny obvaz na absorpciu exsudátov z rán. Ako sekundárne obvazy sa obvazové rolky používajú na spevnenie primárnych obvazov a absorbovanie exsudátov, ktoré prešli cez primárne obvazy. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.  Podkladová výstelka <b>Webril™ &amp; Webril™ II</b> je určená na tlmenie medzi kožou a sadrou a na absorpciu vlhkosti.

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**VYHLÁSENIE O ZHODE**  
**DECLARATION OF CONFORMITY**

	<p><b>Webril™ &amp; Webril™ II</b> Undercast Padding is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p>Špongie <b>Kerlix™ Super</b> sú určené na použitie ako primárne obvazy v mieste rany na absorpciu exsudátu.</p> <p><b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Gázové vankúšky Curity™</b> sú určené na použitie na obliekanie rán alebo kožných prestávok a na utieranie/absorpciu tekutín.</p> <p><b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p>Špongie <b>Excilon™ Drain a I.V</b> sú určené na použitie ako primárne obvazy na rôzne rany, okrem iného aj na miesta zavedenia.</p> <p><b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Klasifikácia a pravidlo</b> <i>Classification and Rule</i>	Pozrite si Prílohu I/ Refer to Attachment 1
<b>Bežné špecifikácie</b> <i>Common Specifications</i>	Nevzťahuje sa (N/A)
<b>V prípade potreby doplňte príslušné právne predpisy Únie</b> <i>Where appropriate, add applicable Union legislation</i>	Nevzťahuje sa (N/A)
<b>Posúdenie zhody</b> <i>Conformity Assessment</i>	Príloha XI, časť A/ Annex XI Part A

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

<b>Toto vyhlásenie o zhode EÚ sa vydáva pre zákonného výrobcu, v jeho mene a na jeho výhradnú zodpovednosť.</b>	
<b>Miesto vydania</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Podpis/ Dátum</b> <i>Signature/Date</i>	 Brenda Gerena (May 1, 2024 16:35 CDT)
<b>Meno a pozícia</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Regulačné záležitosti

**PRÍLOHU I**  
**ATTACHMENT 1**

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

<b>Kód výrobku</b> <i>Product Code</i>	<b>Obchodný názov a popis</b> <i>Trade Name and Description</i>	<b>Základné UDI-DI</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Klasifikácia a pravidlo</b>
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<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	<b>1</b>
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<b>Zoznam kódov výrobkov</b> <i>Product Code List</i>				
				<i>Classification and Rule</i>
2283	Bavlnený vankúšik Webril, bežná úprava, 2" x 12' (5,1 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	06301400000000000001346A	M0201050101	Trieda/ Class: Is Pravidlo/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Zoznam kódov výrobkov</b> <i>Product Code List</i>				
2394	Bavlnený vankúšik Webril, bežná úprava, 3" x 12' (7,6 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	063014000000000000001346A	M0201050101	Trieda/ Class: Is Pravidlo/ Rule: 4
2502	Bavlnený vankúšik Webril, bežná úprava, 4" x 12' (10,2 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Trieda/ Class: Is Pravidlo/ Rule: 4
2554	Bavlnený vankúšik Webril, bežná úprava, 6" x 12' (15,2 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Trieda/ Class: Is Pravidlo/ Rule: 4
6716	Obväz Kerlix, 100 % bavlna, 8 vrstiev, veľký, 4 – 1/2" x 9,3' (11,4 cm x 2,8 m) Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	063014000000000000001125Y	M020107	Trieda/ Class: Is Pravidlo/ Rule: 4
6725	Obväz Kerlix 100 % bavlna, 6 vrstiev, stredný 3 – 7/16" x 3 – 3/16' (8,6 cm x 3,3 m) Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	063014000000000000001125Y	M020107	Trieda/ Class: Is Pravidlo/ Rule: 4
7086	Odtokové špongie Excilon, 6 vrstiev, 10,2 cm x 10,2 cm (4" x 4") Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	063014000000000000001176A	M0201010101	Trieda/ Class: Is Pravidlo/ Rule: 4
7087	Excilon I.V. Špongie, 6 vrstiev, 5,1 cm x 5,1 cm (2" x 2") Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	063014000000000000001186C	M0201010101	Trieda/ Class: Is Pravidlo/ Rule: 4
7880	Gáza Kerlix, 6 vrstiev, veľká, 4 – 1/2" x 4 – 1/8 yd (11,4 cm x 3,7 m) Elastická, sterilná	063014000000000000001205X	M020107	Trieda/ Class: Is Pravidlo/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	<b>1</b>
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**Zoznam kódov výrobkov**  
*Product Code List*

	Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile			
7884	Špongie Kerlix Super, 15,2 cm x 17,1 cm (6" x 6 – 3/4")  Kerlix Super Sponges, 6" x 6- 3/4" (15.2 cm x 17.1 cm)	0630140000000000000996Z	M0201020101	Trieda/ Class: Is Pravidlo/ Rule: 4
3381	Gázové vankúšiky Curity 2" x 2" (5.1 cm x 5.1 cm)  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	0630140000000000001516A	M0201050101	Trieda/ Class: Is Pravidlo/ Rule: 4
6309	Gázová podložka Curity 4" x 4" (10,2 cm x 10,2 cm)  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	0630140000000000001516A	M0201050101	Trieda/ Class: Is Pravidlo/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**SPANISH**

<b>DECLARACIÓN DE CONFORMIDAD</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Nosotros, Cardinal Health 200 LLC, declaramos que los productos contemplados en la presente Declaración de conformidad de la UE cumplen con la disposición del Reglamento sobre productos sanitarios (UE) 2017/745.
<b>Número de declaración de conformidad</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Número de documentación técnica</b> <i>Technical Documentation Number</i>	RE00172519
<b>Nombre del fabricante</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Dirección del fabricante</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Número de registro único</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Nombre y dirección del representante autorizado</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Nombre y número de identificación del organismo notificado</b> <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
<b>Número de certificado CE</b> <i>CE Certificate Number</i>	MDR 798506
<b>Categoría del product</b> <i>Product Category</i>	Gasas de algodón en rollos [M020107] Cotton Gauzes in Rolls [M020107]  Gasas de algodón, plegadas, sin hilo detectable por rayos X, estériles [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>UDI-DI básico</b> <i>Basic UDI-DI</i>	Consulte el Archivo adjunto I/ Refer to Attachment 1
<b>EMDN</b>	Consulte el Archivo adjunto I/ Refer to Attachment 1
<b>Código del producto, nombre comercial y descripción</b> <i>Product Code, Trade Name and Description</i>	Consulte el Archivo adjunto I/ Refer to Attachment 1
<b>Propósito</b> <i>Intended Purpose</i>	<b>Rollos de vendaje y gasas Kerlix:</b> diseñados para utilizarse como compresa primaria a fin de absorber los exudados de la herida. Como compresa secundaria, los rollos de vendaje se utilizan para reforzar las compresas primarias y absorber los exudados que han atravesado las compresas primarias. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**DECLARACIÓN DE CONFORMIDAD**  
*DECLARATION OF CONFORMITY*

	<p><b>El acolchado para escayola de algodón Webril™ y Webril™ II</b> está diseñado para proporcionar amortiguación entre la piel y el escayola, y para absorber la humedad. <b>Webril™ &amp; Webril™ II Undercast Padding</b> is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Las compresas Super Kerlix™</b> están diseñadas para usarse como compresas primarias en el sitio de la herida para absorber el exudado. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>El acolchado de gasa Curity™</b> está diseñado para usarse para curar heridas o roturas en la piel, y limpiar/absorber líquidos. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Las compresas intravenosas y de drenaje Excilon™</b> están diseñadas para utilizarse como apósitos primarios en una variedad de heridas, incluidos, entre otros, los puntos de inserción. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Clasificación y regla</b> <i>Classification and Rule</i>	Consulte el Archivo adjunto I/ Refer to Attachment 1
<b>Especificaciones comunes</b> <i>Common Specifications</i>	No corresponde (N/A)
<b>Cuando proceda, añada la legislación de la Unión Europea aplicable</b> <i>Where appropriate, add applicable Union legislation</i>	No corresponde (N/A)
<b>Evaluación de conformidad</b> <i>Conformity Assessment</i>	Anexo XI parte A/ Annex XI Part A

**SECCIÓN DE FIRMA**  
*SIGNATURE SECTION*

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

<b>Lugar de emisión</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Firma / Fecha</b> <i>Signature/Date</i>	 Brenda Gerena (May 1, 2024 16:35 CDT)
<b>Nombre y función</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Asuntos normativos

ARCHIVO ADJUNTO I  
*ATTACHMENT 1*

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**Lista de códigos del product**  
*Product Code List*


<b>Código del product</b> <i>Product Code</i>	<b>Nombre comercial y descripción</b> <i>Trade Name and Description</i>	<b>UDI-DI básico</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Clasificación y regla</b> <i>Classification and Rule</i>
2283	Almohadilla de algodón para escayola Webril, acabado regular, 2" x 12' (5,1 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	063014000000000000001346A	M0201050101	Clase/ Class: Is Regla/ Rule: 4
2394	Acolchado para escayola de algodón Webril, acabado regular, 3" x 12' (7,6 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	063014000000000000001346A	M0201050101	Clase/ Class: Is Regla/ Rule: 4
2502	Acolchado para escayola de algodón Webril, acabado regular, 4" x 12' (10,2 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Clase/ Class: Is Regla/ Rule: 4
2554	Acolchado para escayola de algodón Webril, acabado regular, 6" x 12' (15,2 cm x 3,7 m)  Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	063014000000000000001346A	M0201050101	Clase/ Class: Is Regla/ Rule: 4
6716	Rollos de venda de gasa Kerlix, 100 % algodón, 8 capas, grande, 4-1/2" x 9,3' (11,4 cm x 2,8 m)  Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	063014000000000000001125Y	M020107	Clase/ Class: Is Regla/ Rule: 4
6725	Rollos de venda de gasa Kerlix, 100% algodón, 6 capas medianas, 3-7/16" x 3-3/16' (8,6 cm x 3,3 m)  Kerlix Bandage Roll 100% Cotton, 6 Ply Medium,	063014000000000000001125Y	M020107	Clase/ Class: Is Regla/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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<b>Lista de códigos del product</b> <i>Product Code List</i>				
	3-7/16" x 3-3/16' (8.6 cm x 3.3 m)			
7086	Compresa de drenaje Excilon, 6 capas, 4" x 4" (10,2 cm x 10,2 cm)  Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	063014000000000000001176A	M0201010101	Clase/ Class: Is Regla/ Rule: 4
7087	Compresas intravenosas Excilon, 6 capas, 2" x 2" (5,1 cm x 5,1 cm)  Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	063014000000000000001186C	M0201010101	Clase/ Class: Is Regla/ Rule: 4
7880	Rollos de gasa Kerlix, 6 capas, grande, 4-1/2" x 4-1/8 yd (11,4 cm x 3,7 m) estirado, estéril  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile	063014000000000000001205X	M020107	Clase/ Class: Is Regla/ Rule: 4
7884	Compresas Super Kerlix, 6" x 6-3/4" (15,2 cm x 17,1 cm)  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	063014000000000000000996Z	M0201020101	Clase/ Class: Is Regla/ Rule: 4
3381	Almohadillas de gasa Curity 2" x 2" (5,1 cm x 5,1 cm)  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	063014000000000000001516A	M0201050101	Clase/ Class: Is Regla/ Rule: 4
6309	Almohadilla de gasa Curity 4" x 4" (10,2 cm x 10,2 cm)  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	063014000000000000001516A	M0201050101	Clase/ Class: Is Regla/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**SWEDISH**

<b>FÖRSÄKRAN OM ÖVERENSSTÄMMELSE</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Vi, Cardinal Health 200 LLC, försäkrar härmed att produkterna som omfattas av denna EU-försäkran om överensstämmelse uppfyller bestämmelserna om medicintekniska produkter i förordning (EU) 2017/745.
<b>Nummer på försäkran om överensstämmelse</b> <i>Declaration of Conformity Number</i>	RE00214653
<b>Nummer på teknisk documentation</b> <i>Technical Documentation Number</i>	RE00172519
<b>Tillverkarens namn</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Tillverkarens address</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Unikt registreringsnummer</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Namn på auktoriserad representant och address</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Namn på anmält organ och identifikationsnummer</b> <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
<b>Nummer på CE-certifikat</b> <i>CE Certificate Number</i>	MDR 798506
<b>Produktkategori</b> <i>Product Category</i>	Bomullsgasbindor på rullar [M020107] Cotton Gauzes in Rolls [M020107]  Bomullsgasbindor, vikta, utan röntgendetekterbar tråd, sterila [M0201020101] Cotton Gauzes, Folded, Without X-Ray Detectable Thread, Sterile [M0201020101]
<b>Grundläggande UDI-DI</b> <i>Basic UDI-DI</i>	Medföljande dokument I/ Refer to Attachment 1
<b>EMDN</b>	Medföljande dokument I/ Refer to Attachment 1
<b>Produktkod, handelsnamn och beskrivning</b> <i>Product Code, Trade Name and Description</i>	Medföljande dokument I/ Refer to Attachment 1
<b>Avsedd användning</b> <i>Intended Purpose</i>	<b>Kerlix bandage och gasbindor på rullar:</b> avsedda att användas som ett primärt förband för att absorbera sårexsudat. Som sekundära förband används Kerlix bandagerullar för att förstärka primära förband och absorbera exsudat som har passerat genom det primära förbandet. <b>Kerlix Bandage and Gauze Rolls:</b> Intended for use as a primary dressing to absorb wound exudates. As secondary dressings, the bandage rolls are used to reinforce primary dressings and absorb exudates that have passed through primary dressings.

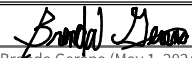
<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**FÖRSÄKRAN OM ÖVERENSSTÄMMELSE**  
*DECLARATION OF CONFORMITY*

	<p><b>Webril™ och Webril™ II</b> vaddering under gips är avsedd att mildra påverkan mot huden av gipset samt för absorbering av fukt. <b>Webril™ &amp; Webril™ II Undercast Padding</b> is intended to provide cushioning between the skin and the cast and to absorb moisture.</p> <p><b>Kerlix™ supersvampar</b> är avsedda att användas som primära förband på sårstället för att absorbera exsudat. <b>Kerlix™ Super Sponges</b> are intended to be used as primary dressings at the wound site to absorb exudate.</p> <p><b>Curity™ gasbindor</b> är avsedda att användas för att lägga om sår eller hudsprickor och för att torka/absorbera vätskor. <b>Curity™ Gauze Pads</b> are intended to be used for dressing wounds or skin breaks and wiping/absorbing fluids.</p> <p><b>Excilon™ dränerings- och IV-svampar</b> är avsedda att användas som primära förband på en rad sår, inklusive men inte begränsat till införingsställen. <b>Excilon™ Drain and I.V Sponges</b> are intended for use as primary dressings on a range of wounds including but not limited to insertion sites.</p>
<b>Klassificering och regel</b> <i>Classification and Rule</i>	Medföljande dokument I/ Refer to Attachment 1
<b>Gemensamma specifikationer</b> <i>Common Specifications</i>	Ej tillämpligt (N/A)
<b>Lägg till tillämplig EU-lagstiftning</b> <i>Where appropriate, add applicable Union legislation</i>	Ej tillämpligt (N/A)
<b>Bedömning av överensstämmelse</b> <i>Conformity Assessment</i>	Bilaga XI del A/ Annex XI Part A

**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.

<b>Plats för utfärdande</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Underskrift/ Datum</b> <i>Signature/Date</i>	 Brenda Gerena (May 1, 2024 16:35 CDT)
<b>Namn och funktion</b> <i>Name and Function</i>	Brenda Gerena Regulatory Affairs Myndighetsärenden

**DOKUMENT I**  
*ATTACHMENT 1*

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**Lista de códigos del product**  
*Product Code List*

<b>Produktkod</b> <i>Product Code</i>	<b>Handelsnamn och beskrivning</b> <i>Trade Name and Description</i>	<b>Grundläggande UDI-DI</b> <i>Basic UDI-DI</i>	<b>EMDN</b>	<b>Klassificering och regel</b> <i>Classification and Rule</i>
2283	Webril bomullsvaddering under gips, regelbunden finish, 2" x 12' (5,1 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	06301400000000000001346A	M0201050101	Klass/ Class: 1s Regel/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	1
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**Lista de códigos del product**  
*Product Code List*

2394	Webril bomullsvaddering under gips, regelbunden finish, 3" x 12' (7,6 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	06301400000000000001346A	M0201050101	Klass/ Class: Is Regel/ Rule: 4
2502	Webril bomullsvaddering under gips, regelbunden finish, 4" x 12' (10,2 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	06301400000000000001346A	M0201050101	Klass/ Class: Is Regel/ Rule: 4
2554	Webril™ bomullsvaddering under gips, regelbunden finish, 6" x 12' (15,2 cm x 3,7 m) Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	06301400000000000001346A	M0201050101	Klass/ Class: Is Regel/ Rule: 4
6716	Kerlix bandagerulle, 100 % bomull, 8 skikt, stor, 4-1/2" x 9.3' (11,4 cm x 2,8 m) Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	06301400000000000001125Y	M020107	Klass/ Class: Is Regel/ Rule: 4
6725	Kerlix bandagerulle, 100 % bomull, 6 skikt, medium, 3-7/16" x 3-3/16' (8,6 cm x 3,3 m) Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	06301400000000000001125Y	M020107	Klass/ Class: Is Regel/ Rule: 4
7086	Excilon dräneringssvampar, 6 skikt, 4" x 4" (10,2 cm x 10,2 cm) Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	06301400000000000001176A	M0201010101	Klass/ Class: Is Regel/ Rule: 4
7087	Excilon IV-. svampar, 6 skikt, 2" x 2" (5,1 cm x 5,1 cm) Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	06301400000000000001186C	M0201010101	Klass/ Class: Is Regel/ Rule: 4
7880	Kerlix gasvävrulle, 6 skikt, stor,	06301400000000000001205X	M020107	Klass/ Class: Is Regel/ Rule: 4

<b>DOCUMENT NO:</b>	RE00214653	<b>REVISION:</b>	<b>1</b>
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**Lista de códigos del product**  
*Product Code List*

	4-1/2" x 4-1/8 yd (11,4 cm x 3,7 m) sträckt, steril  Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched, Sterile			
7884	Kerlix supersvampar, 6" x 6-3/4" (15,2 cm x 17,1 cm)  Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	0630140000000000000996Z	M0201020101	Klass/ Class: Is Regel/ Rule: 4
3381	Curity gasbindor 2" x 2" (5,1 cm x 5,1 cm)  Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	06301400000000000001516A	M0201050101	Klass/ Class: Is Regel/ Rule: 4
6309	Curity gasbinda 4" x 4" (10,2 cm x 10,2 cm)  Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	06301400000000000001516A	M0201050101	Klass/ Class: Is Regel/ Rule: 4






# Translated\_RE00214653

Final Audit Report

2024-05-01

Created:	2024-05-01
By:	leena.gupta@cardinalhealth.com
Status:	Signed
Transaction ID:	CBJCHBCAABAApYL_n06tS0kHArmT2DNJXxRz95NBSwgP

## "Translated\_RE00214653" History

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-  Document emailed to Brenda Gerena (brenda.gerena@cardinalhealth.com) for signature  
2024-05-01 - 9:33:49 PM GMT
-  Email viewed by Brenda Gerena (brenda.gerena@cardinalhealth.com)  
2024-05-01 - 9:34:58 PM GMT- IP address: 104.47.56.254
-  Document e-signed by Brenda Gerena (brenda.gerena@cardinalhealth.com)  
Signature Date: 2024-05-01 - 9:35:44 PM GMT - Time Source: server- IP address: 165.225.59.55
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