

DOC. TITLE: Declaration of Conformity MDR Kendall SCD Controller Compression System			
DOCUMENT NO:	RE00222095	REVISION:	2

DECLARATION OF CONFORMITY



CardinalHealth

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

Declaration of Conformity Number	RE00222095
Technical Documentation Number	RE00217172
Manufacturer's Name	Cardinal Health 200, LLC
Manufacturer's Address	3651 Birchwood Drive Waukegan, IL 60085 USA
Single Registration Number	US-MF-000006765
Authorized Representative's Name and Address	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Notified body's Name and Identification Number	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Identification Number SRN: 2797
CE Certificate Number	MDR 784266
Product Category	Pneumatic Compression Equipment [Z120607]
Basic UDI-DI	0630140000000000000000001546G 0630140000000000000000005436X
EMDN	Z120607
Product Code, Trade Name and Description	Refer to Attachment 1
Intended Purpose	The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.
Classification and Rule	Class: IIa Rule: 9
Common Specifications	Not Applicable
Where appropriate, add applicable Union legislation	We, Cardinal Health 200 LLC, hereby declare the above listed Medical Device(s) complies with: RoHS 2011/65/EU
Conformity Assessment	Annex IX Chapters I and III

SIGNATURE SECTION

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

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Place of Issue	Waukegan, IL 60085 USA
Signature/Date	<u>Soumitra Shilotri</u> Soumitra Shilotri (Mar 4, 2025 19:15 EST)
Name and Function	Soumitra Shilotri Regulatory Affairs

ATTACHMENT 1


Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
29525	Kendall SCD 700 Sequential Compression System (with U.S. power cord)	063014000000000000001546G	Z120607	Class: IIa Rule: 9
295250	Kendall SCD 700 Sequential Compression System (with E.U. power cord)	063014000000000000001546G	Z120607	Class: IIa Rule: 9
295251	Kendall SCD 700 Sequential Compression System (with U.K. power cord)	063014000000000000001546G	Z120607	Class: IIa Rule: 9
295255	Kendall SCD 700 Sequential Compression System (with Australian power cord)	063014000000000000001546G	Z120607	Class: IIa Rule: 9
295257	Kendall SCD 700 Sequential Compression System (with Japanese power cord)	063014000000000000001546G	Z120607	Class: IIa Rule: 9
295258	Kendall SCD 700 Sequential Compression System (with Brazilian power cord)	063014000000000000001546G	Z120607	Class: IIa Rule: 9
295259	Kendall SCD 700 Sequential Compression System (with India power cord)	063014000000000000001546G	Z120607	Class: IIa Rule: 9
82100	Kendall SCD SmartFlow Compression System with EU power cord adapter	063014000000000000005436X	Z120607	Class: IIa Rule: 9
82101	Kendall SCD SmartFlow Compression System with UK power cord adapter	063014000000000000005436X	Z120607	Class: IIa Rule: 9
82102	Kendall SCD SmartFlow Compression System with Swiss power cord adapter	063014000000000000005436X	Z120607	Class: IIa Rule: 9

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Product Code List				
82105	Kendall SCD SmartFlow Compression System with Australia power cord adapter	06301400000000000005436X	Z120607	Class: IIa Rule: 9
82107	Kendall SCD SmartFlow Compression System with Japan power cord adapter	06301400000000000005436X	Z120607	Class: IIa Rule: 9
82108	Kendall SCD SmartFlow Compression System with Brazil power cord adapter	06301400000000000005436X	Z120607	Class: IIa Rule: 9
82109	Kendall SCD SmartFlow Compression System with India power cord adapter	06301400000000000005436X	Z120607	Class: IIa Rule: 9

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CROATIAN

IZJAVA O SUKLADNOSTI DECLARATION OF CONFORMITY	
	MDR: Mi, Cardinal Health 200 LLC, izjavljujemo da proizvodi na koje se odnosi ova Izjava o sukladnosti EU ispunjavaju odredbe Uredbe o medicinskim proizvodima (EU) 2017/745.
Broj izjave o sukladnosti <i>Declaration of Conformity Number</i>	RE00222095
Broj tehničke dokumentacije <i>Technical Documentation Number</i>	RE00217172
Naziv proizvođača <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Adresa proizvođača <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Jedinstveni registracijski broj <i>Single Registration Number</i>	US-MF-000006765
Naziv i adresa ovlaštenog predstavnika <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Naziv i identifikacijski broj prijavljenog tijela <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identifikacijski broj: 2797
Broj certifikata CE <i>CE Certificate Number</i>	MDR 784266
Kategorija proizvoda <i>Product Category</i>	Oprema za pneumatsku kompresiju [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
Osnovni UDI-DI <i>Basic UDI-DI</i>	063014000000000000001546G 0630140000000000000005436X
EMDN	Z120607
Kôd, trgovački naziv i opis proizvoda <i>Product Code, Trade Name and Description</i>	Pogledajte Prilog I Refer to Attachment 1
Namjena <i>Intended Purpose</i>	Kendall SCD kontroleri namijenjeni su primjeni povremene pneumatske kompresije za povećanje venskog protoka krvi kod rizičnih pacijenata kako bi se spriječila duboka venska tromboza i plućna embolija. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Klasifikacija i pravilo <i>Classification and Rule</i>	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9
Zajedničke specifikacije <i>Common Specifications</i>	Nije primjenjivo Not Applicable
Dodajte primjenjivo zakonodavstvo Europske unije, gdje je to prikladno	Mi, Cardinal Health 200 LLC, izjavljujemo da su navedeni medicinski proizvodi u skladu s:

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IZJAVA O SUKLADNOSTI <i>DECLARATION OF CONFORMITY</i>	
<i>Where appropriate, add applicable Union legislation</i>	RoHS 2011/65/EU
Ocjena sukladnosti <i>Conformity Assessment</i>	Prilog IX. Poglavlja I. i III./ Annex IX Chapters I and III

ODJELJAK S POTPISIMA <i>SIGNATURE SECTION</i>	
Ova Izjava o sukladnosti EU izdaje se za i u ime te na isključivu odgovornost prethodno navedenog zakonitog proizvođača.	
Mjesto izdavanja <i>Place of Issue</i>	Waukegan, IL 60085 USA
Potpis/ Datum <i>Signature/ Date</i>	<u>Soumitra Shilotri</u> <small>Soumitra Shilotri (Mar 4, 2025 19:15 EST)</small>
Ime i funkcija <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Odjel za regulatorna pitanja

PRILOG I
ATTACHMENT 1

Popis kodova proizvoda <i>Product Code List</i>				
Kôd proizvoda <i>Product Code</i>	Trgovački naziv i opis <i>Trade Name and Description</i>	Osnovni UDI-DI <i>Basic UDI-DI</i>	EMDN	Klasifikacija i pravilo <i>Classification and Rule</i>
29525	Kendall SCD 700 sustav sekvencijalne kompresije (s američkim kabelom za napajanje) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	063014000000000000001546G	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9
295250	Kendall SCD 700 sustav sekvencijalne kompresije (s europskim kabelom za napajanje) <i>Kendall SCD 700 Sequential Compression System (with E.U. power cord)</i>	063014000000000000001546G	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9
295251	Kendall SCD 700 sustav sekvencijalne kompresije	063014000000000000001546G	Z120607	Klasa: IIa Pravilo: 9

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Popis kodova proizvoda <i>Product Code List</i>				
	(s kabelom za napajanje za U.K.) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>			Class: IIa Rule: 9
295255	Kendall SCD 700 sustav sekvencijalne kompresije (s australijskim kabelom za napajanje) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9
295257	Kendall SCD 700 sustav sekvencijalne kompresije (s japanskim kabelom za napajanje) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9
295258	Kendall SCD 700 sustav sekvencijalne kompresije (s brazilskim kabelom za napajanje) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9
295259	Kendall SCD 700 sustav sekvencijalne kompresije (s indijskim kabelom za napajanje) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	063014000000000000001546G	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9
82100	Kendall SCD SmartFlow sustav kompresije s adapterom za kabel za napajanje s europskim <i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>	063014000000000000005436X	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9
82101	Kendall SCD SmartFlow sustav kompresije s adapterom za kabel za napajanje u U.K. <i>Kendall SCD SmartFlow</i>	063014000000000000005436X	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9

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Popis kodova proizvoda <i>Product Code List</i>				
	<i>Compression System with UK power cord adapter</i>			
82102	Kendall SCD SmartFlow sustav kompresije s adapterom za kabel za napajanje u Švicarskoj <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9
82105	Kendall SCD SmartFlow sustav kompresije s adapterom za kabel za napajanje u Australiji <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9
82107	Kendall SCD SmartFlow sustav kompresije s adapterom za kabel za napajanje u Japanu <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>	06301400000000000005436X	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9
82108	Kendall SCD SmartFlow sustav kompresije s adapterom za kabel za napajanje u Brazilu <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9
82109	Kendall SCD SmartFlow sustav kompresije s adapterom za kabel za napajanje u Indiji <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>	06301400000000000005436X	Z120607	Klasa: IIa Pravilo: 9 Class: IIa Rule: 9


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CZECH

PROHLÁŠENÍ O SHODĚ <i>DECLARATION OF CONFORMITY</i>	
	MDR: Naše společnost, Cardinal Health 200 LLC, prohlašuje, že výrobky uvedené v tomto EU prohlášení o shodě splňují ustanovení nařízení (EU) 2017/745 o zdravotnických prostředcích.
Číslo prohlášení o shodě <i>Declaration of Conformity Number</i>	RE00222095
Číslo technické dokumentace <i>Technical Documentation Number</i>	RE00217172
Název výrobce <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Adresa výrobce <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Jediné registrační číslo <i>Single Registration Number</i>	US-MF-000006765
Název a adresa autorizovaného zástupce <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Název a identifikační číslo oznámeného subjektu <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identifikační číslo: 2797
Číslo certifikátu CE <i>CE Certificate Number</i>	MDR 784266
Kategorie výrobku <i>Product Category</i>	Pneumatická kompresní zařízení [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
Základní UDI-DI <i>Basic UDI-DI</i>	063014000000000000001546G 0630140000000000000005436X
EMDN	Z120607
Kód, obchodní název a popis výrobku <i>Product Code, Trade Name and Description</i>	Viz Příloha I Refer to Attachment 1
Účel použití <i>Intended Purpose</i>	Regulátory Kendall SCD jsou určeny k přerušované pneumatické kompresi, která zvyšuje průtok žilní krve u rizikových pacientů s cílem zabránit hluboké žilní trombóze a plicní embolii. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Klasifikace a pravidlo <i>Classification and Rule</i>	Třída: IIa Pravidlo: 9 Class: IIa Rule: 9
Obecná specifikace <i>Common Specifications</i>	Nelze uplatnit Not Applicable

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PROHLÁŠENÍ O SHODĚ <i>DECLARATION OF CONFORMITY</i>	
Dle potřeby doplňte příslušný předpis Unie <i>Where appropriate, add applicable Union legislation</i>	Společnost, Cardinal Health 200 LLC, tímto prohlašuje, že výše uvedené zdravotnické prostředky jsou ve shodě s: RoHS 2011/65/EU
Posouzení shody <i>Conformity Assessment</i>	Příloha IX, kapitoly I a III/ Annex IX Chapters I and III

PODPISOVÁ ČÁST <i>SIGNATURE SECTION</i>	
Toto EU prohlášení o shodě se vydává jménem a na výhradní odpovědnost oprávněného výrobce uvedeného výše.	
Místo vydání <i>Place of Issue</i>	Waukegan, IL 60085 USA
Podpis / Datum <i>Signature/ Date</i>	 Soumitra Shilotri (Mar 4, 2025 19:15 EST)
Jméno a funkce <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Oddělení regulačních záležitostí

PŘÍLOHA I
ATTACHMENT 1

Seznam kódů výrobků <i>Product Code List</i>				
Kód výrobku <i>Product Code</i>	Obchodní název a popis <i>Trade Name and Description</i>	Základní UDI-DI <i>Basic UDI-DI</i>	EMDN	Klasifikace a pravidlo <i>Classification and Rule</i>
29525	Sekvenční kompresní systém Kendall SCD 700 (s napájecím kabelem pro USA) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	063014000000000000001546G	Z120607	Třída: IIa Pravidlo: 9 Class: IIa Rule: 9
295250	Sekvenční kompresní systém Kendall SCD 700 (s napájecím kabelem pro EU) <i>Kendall SCD 700 Sequential Compression System (with E.U. power cord)</i>	063014000000000000001546G	Z120607	Třída: IIa Pravidlo: 9 Class: IIa Rule: 9
295251	Sekvenční kompresní systém Kendall SCD 700 (s napájecím kabelem pro	063014000000000000001546G	Z120607	Třída: IIa Pravidlo: 9 Class: IIa

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Seznam kódů výrobků <i>Product Code List</i>				
	Spojené království) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>			Rule: 9
295255	Sekvenční kompresní systém Kendall SCD 700 (s napájecím kabelem pro Austrálii) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Třída: IIa Pravidlo: 9 Class: IIa Rule: 9
295257	Sekvenční kompresní systém Kendall SCD 700 (s napájecím kabelem pro Japonsko) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Třída: IIa Pravidlo: 9 Class: IIa Rule: 9
295258	Sekvenční kompresní systém Kendall SCD 700 (s napájecím kabelem pro Brazílii) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Třída: IIa Pravidlo: 9 Class: IIa Rule: 9
295259	Sekvenční kompresní systém Kendall SCD 700 (s napájecím kabelem pro Indii) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	063014000000000000001546G	Z120607	Třída: IIa Pravidlo: 9 Class: IIa Rule: 9
82100	Kompresní systém Kendall SCD SmartFlow s adaptérem napájecího kabelu pro EU <i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>	063014000000000000005436X	Z120607	Třída: IIa Pravidlo: 9 Class: IIa Rule: 9
82101	Kompresní systém Kendall SCD SmartFlow s adaptérem napájecího kabelu pro Spojené království <i>Kendall SCD SmartFlow</i>	063014000000000000005436X	Z120607	Třída: IIa Pravidlo: 9 Class: IIa Rule: 9

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Seznam kódů výrobků <i>Product Code List</i>				
	<i>Compression System with UK power cord adapter</i>			
82102	Kompresní systém Kendall SCD SmartFlow s adaptérem napájecího kabelu pro Švýcarsko <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Třída: Ia Pravidlo: 9 Class: Ia Rule: 9
82105	Kompresní systém Kendall SCD SmartFlow s adaptérem napájecího kabelu pro Austrálii <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Třída: Ia Pravidlo: 9 Class: Ia Rule: 9
82107	Kompresní systém Kendall SCD SmartFlow s adaptérem napájecího kabelu pro Japonsko <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>	06301400000000000005436X	Z120607	Třída: Ia Pravidlo: 9 Class: Ia Rule: 9
82108	Kompresní systém Kendall SCD SmartFlow s adaptérem napájecího kabelu pro Brazílii <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Třída: Ia Pravidlo: 9 Class: Ia Rule: 9
82109	Kompresní systém Kendall SCD SmartFlow s adaptérem napájecího kabelu pro Indii <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>	06301400000000000005436X	Z120607	Třída: Ia Pravidlo: 9 Class: Ia Rule: 9

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DANISH

PROHLÁŠENÍ O SHODĚ DECLARATION OF CONFORMITY	
	MDR: Vi, Cardinal Health 200 LLC, erklærer, at produkterne dækket af denne EU-overensstemmelseserklæring overholder kravene i Forordning (EU) 2017/745 om medicinsk udstyr.
Overensstemmelseserklæringsnummer <i>Declaration of Conformity Number</i>	RE00222095
Teknisk dokumentationsnummer <i>Technical Documentation Number</i>	RE00217172
Producentens navn <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Producentens adresse <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Enkelt registreringsnummer <i>Single Registration Number</i>	US-MF-000006765
Navn og adresse på godkendt repræsentant <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Navn og identifikationsnummer på bemyndiget organ <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identifikationsnummer: 2797
CE-certifikationsnummer <i>CE Certificate Number</i>	MDR 784266
Produktkategori <i>Product Category</i>	Pneumatisk kompressionsudstyr [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
Grundlæggende UDI-DI <i>Basic UDI-DI</i>	063014000000000000001546G 0630140000000000000005436X
EMDN	Z120607
Produktkode(r), handelsnavn og beskrivelse <i>Product Code, Trade Name and Description</i>	Se bilag I Refer to Attachment 1
Tiltænkt formål <i>Intended Purpose</i>	Kendall SCD-controllere er beregnet til at tilføre intermitterende pneumatisk kompression for at øge gennemstrømningen af veneblod hos risikopatienter med det formål at forebygge Deep Vein Thrombosis og lungeemboli. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Klassificering og regel <i>Classification and Rule</i>	Klasse: IIa Regel: 9 Class: IIa Rule: 9
Fælles specifikationer <i>Common Specifications</i>	Ikke relevant Not Applicable

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PROHLÁŠENÍ O SHODĚ <i>DECLARATION OF CONFORMITY</i>	
Hvor relevant, tilføj gældende union-lovgivning <i>Where appropriate, add applicable Union legislation</i>	Vi, Cardinal Health 200 LLC, erklærer hermed, at ovennævnte medicinske udstyr overholder: RoHS 2011/65/EU
Overensstemmelsesvurdering <i>Conformity Assessment</i>	Bilag IX, kapitel I og III/ Annex IX Chapters I and III

SIGNATURAFSNIT <i>SIGNATURE SECTION</i>	
Denne EU-overensstemmelseserklæring er udstedt for og på vegne af og under eneansvar for den juridiske producent, der er identificeret ovenfor.	
Udstedelsessted <i>Place of Issue</i>	Waukegan, IL 60085 USA
Underskrift / Dato <i>Signature/ Date</i>	 Soumitra Shilotri (Mar 4, 2025 19:15 EST)
Navn og function <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Lovgivningsanliggender

BILAG I
ATTACHMENT 1

Produktkodeliste <i>Product Code List</i>				
Produktkode <i>Product Code</i>	Handelsnavn og beskrivelse <i>Trade Name and Description</i>	Grundlæggende UDI-DI <i>Basic UDI-DI</i>	EMDN	Klassificering og regel <i>Classification and Rule</i>
29525	Kendall SCD 700 Sequential Compression System (med US-strømkabel) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295250	Kendall SCD 700 Sequential Compression System (med EU-strømkabel) <i>Kendall SCD 700 Sequential Compression System (with E.U. power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295251	Kendall SCD 700 Sequential	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9

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Produktkodeliste <i>Product Code List</i>				
	Compression System (med UK-strømkabel) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>			Class: IIa Rule: 9
295255	Kendall SCD 700 Sequential Compression System (med australsk strømkabel) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295257	Kendall SCD 700 Sequential Compression System (med japansk strømkabel) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295258	Kendall SCD 700 Sequential Compression System (med brasiliansk strømkabel) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295259	Kendall SCD 700 Sequential Compression System (med indisk strømkabel) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82100	Kendall SCD SmartFlow Compression System	063014000000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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Produktkodeliste <i>Product Code List</i>				
	med EU- strømkabeladapter <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with EU power cord</i> <i>adapter</i>			
82101	Kendall SCD SmartFlow Compression System med UK- strømkabeladapter <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with UK power cord</i> <i>adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82102	Kendall SCD SmartFlow Compression System med schweizisk strømkabeladapter <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with Swiss power cord</i> <i>adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82105	Kendall SCD SmartFlow Compression System med australsk strømkabeladapter <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with Australia power</i> <i>cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82107	Kendall SCD SmartFlow Compression System med japansk strømkabeladapter <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with Japan power</i> <i>cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82108	Kendall SCD SmartFlow Compression System med brasiliansk	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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Produktkodeliste <i>Product Code List</i>				
	strømkabeladapter <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>			
82109	Kendall SCD SmartFlow Compression System med indisk strømkabeladapter <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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DUTCH

CONFORMITEITSVERKLARING DECLARATION OF CONFORMITY	
	MDR: Wij, Cardinal Health 200 LLC, verklaren dat de producten die onder deze EU-conformiteitsverklaring vallen, voldoen aan Verordening (EU) 2017/745 betreffende medische hulpmiddelen.
Numerum conformiteitsverklaring <i>Declaration of Conformity Number</i>	RE00222095
Numerum technische documentatie <i>Technical Documentation Number</i>	RE00217172
Naam fabrikant <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Adres van de fabrikant <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Enkel registratienummer <i>Single Registration Number</i>	US-MF-000006765
Naam en adres van de erkende vertegenwoordiger <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Naam en identificatienummer van de aangemelde instantie <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identificatienummer: 2797
Numerum CE-markering <i>CE Certificate Number</i>	MDR 784266
Productcategorie <i>Product Category</i>	Pneumatische compressieapparatuur [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
Basis UDI-DI <i>Basic UDI-DI</i>	063014000000000000001546G 0630140000000000000005436X
EMDN	Z120607
Productcode, handelsnaam en beschrijving <i>Product Code, Trade Name and Description</i>	Zie Bijlage I Refer to Attachment 1
Beoogd doel <i>Intended Purpose</i>	De KENDALL SCD regeleenheden zijn bedoeld om periodieke pneumatische compressie toe te passen om de veneuze bloedstroom bij risicopatiënten te verhogen, teneinde diepveneuze trombose en longembolie te helpen voorkomen. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Classificatie en regel <i>Classification and Rule</i>	Klasse: IIa Regel: 9 Class: IIa Rule: 9
Algemene specificaties <i>Common Specifications</i>	Niet van toepassing Not Applicable

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CONFORMITEITSVERKLARING <i>DECLARATION OF CONFORMITY</i>	
Voeg, indien van toepassing, de toepasselijke wetgeving van de Unie toe <i>Where appropriate, add applicable Union legislation</i>	Wij, Cardinal Health 200 LLC, verklaren hierbij dat het/de hierboven genoemde medische hulpmiddel(en) voldoet/voldoen aan: RoHS 2011/65/EU
Conformiteitsbeoordeling <i>Conformity Assessment</i>	Bijlage IX Hoofdstuk I en III/ Annex IX Chapters I and III

HANDTEKENINGGEDEELTE <i>SIGNATURE SECTION</i>	
Deze EU-conformiteitsverklaring wordt voor en namens en uitsluitend onder de verantwoordelijkheid van de fabrikant afgegeven.	
Plaats van afgifte <i>Place of Issue</i>	Waukegan, IL 60085 USA
Handtekening/Datum <i>Signature/ Date</i>	<u>Soumitra Shilotri</u> Soumitra Shilotri (Mar 4, 2025 19:15 EST)
Naam en functie <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Regelgevingszaken

BIJLAGE I
ATTACHMENT 1

Produktkodeliste <i>Product Code List</i>				
Productcode <i>Product Code</i>	Handelsnaam en beschrijving <i>Trade Name and Description</i>	Basis UDI-DI <i>Basic UDI-DI</i>	EMDN	Classificatie en regel <i>Classification and Rule</i>
29525	Kendall SCD 700 sequentieel compressiesysteem (met Amerikaans netsnoer) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295250	Kendall SCD 700 sequentieel compressiesysteem (met Europees netsnoer) <i>Kendall SCD 700 Sequential Compression System (with E.U. power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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Produktkodeliste <i>Product Code List</i>				
295251	Kendall SCD 700 sequentieel compressiesysteem (met Brits netsnoer) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295255	Kendall SCD 700 sequentieel compressiesysteem (met Australisch netsnoer) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295257	Kendall SCD 700 sequentieel compressiesysteem (met Japans netsnoer) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295258	Kendall SCD 700 sequentieel compressiesysteem (met Braziliaans netsnoer) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295259	Kendall SCD 700 sequentieel compressiesysteem (met Indiaas netsnoer) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82100	Kendall SCD SmartFlow- compressiesysteem	063014000000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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Produktkodeliste <i>Product Code List</i>				
	met med Europees netsnoeradapter <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with EU power cord</i> <i>adapter</i>			
82101	Kendall SCD SmartFlow- compressiesysteem met Britse netsnoeradapter <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with UK power cord</i> <i>adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82102	Kendall SCD SmartFlow- compressiesysteem met Zwitserse netsnoeradapter <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with Swiss power cord</i> <i>adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82105	Kendall SCD SmartFlow- compressiesysteem met Australische netsnoeradapter <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with Australia power</i> <i>cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82107	Kendall SCD SmartFlow- compressiesysteem met Japanse netsnoeradapter <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with Japan power cord</i> <i>adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82108	Kendall SCD SmartFlow- compressiesysteem met Braziliaanse	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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Produktkodeliste <i>Product Code List</i>				
	netsnoeradapter <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with Brazil power cord</i> <i>adapter</i>			
82109	Kendall SCD SmartFlow- compressiesysteem met Indiase netsnoeradapter <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with India power cord</i> <i>adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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FINNISH

VAATIMUSTENMUKAISUUSVAKUUTUS DECLARATION OF CONFORMITY	
	MDR: Me, Cardinal Health 200 LLC, vakuutamme, että tässä EU-vaatimustenmukaisuusvakuutuksessa kuvatut tuotteet täyttävät lääkintälaitteasetuksen (EU) 2017/745 vaatimukset.
VAATIMUSTENMUKAISUUSVAKUUTUS Declaration of Conformity Number	RE00222095
Teknisen dokumentin numero Technical Documentation Number	RE00217172
Valmistajan nimi Manufacturer's Name	Cardinal Health 200, LLC
Valmistajan osoite Manufacturer's Address	3651 Birchwood Drive Waukegan, IL 60085 USA
Yksittäinen rekisterinumero Single Registration Number	US-MF-000006765
Valtuutetun edustajan nimi ja osoite Authorized Representative's Name and Address	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Ilmoitetun laitoksen nimi ja tunnusnumero Notified body's Name and Identification Number	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Tunnusnumero: 2797
CE-sertifikaatin numero CE Certificate Number	MDR 784266
Tuotekategoria Product Category	Pneumaattiset kompressiolaitteet [Z120607] Pneumatic Compression Equipment [Z120607]
Yksilöllinen laitemallin tunniste (Basic UDI-DI) Basic UDI-DI	063014000000000000001546G 0630140000000000000005436X
EMDN	Z120607
Tuotekoodi, kaupan nimi ja kuvaus Product Code, Trade Name and Description	Katso liite I Refer to Attachment 1
Käyttötarkoitus Intended Purpose	Kendall SCD -ohjaimet on tarkoitettu antamaan jaksoittaista pneumaattista kompressiohoitoa laskimoverenkierron lisäämiseksi riskipotilailla ja siten syvän laskimotukoksen ja keuhkoembolian ehkäisemiseksi. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Luokittelu ja sääntö Classification and Rule	Luokka: Iia Sääntö: 9 Class: Iia Rule: 9
Yleiset tekniset tiedot Common Specifications	Ei sovellu Not Applicable

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VAATIMUSTENMUKAISUUSVAKUUTUS <i>DECLARATION OF CONFORMITY</i>	
Lisää tarvittaessa soveltuva unionin lainsäädäntö <i>Where appropriate, add applicable Union legislation</i>	Me, Cardinal Health 200 LLC, vakuutamme täten, että yllä luetellut lääkinälliset laitteet vastaavat seuraavia: RoHS 2011/65/EU
Vaatimustenmukaisuuden arviointi <i>Conformity Assessment</i>	Liite IX kappaleet I ja III/ Annex IX Chapters I and III

ALLEKIRJOITUSOSIO <i>SIGNATURE SECTION</i>	
Tämä EU-vaatimustenmukaisuusvakuutus on annettu edellä mainitun laillisen valmistajan puolesta ja sen omalla, yksinomaisella vastuulla.	
Paikka <i>Place of Issue</i>	Waukegan, IL 60085 USA
Allekirjoitus/ Päivämäärä <i>Signature/ Date</i>	<u>Soumitra Shilotri</u> Soumitra Shilotri (Mar 4, 2025 19:15 EST)
Nimi ja asema <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Sääntelyasiat

LIITE I
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Tuotekoodiluettelo <i>Product Code List</i>				
Tuotekoodi <i>Product Code</i>	Kaupan nimi ja kuvaus <i>Trade Name and Description</i>	Yksilöllinen laitemallin tunniste (Basic UDI-DI) <i>Basic UDI-DI</i>	EMDN	Luokittelu ja sääntö <i>Classification and Rule</i>
29525	Kendall SCD 700 - sekventiaalinen kompressiojärjestelmä (yhdysvaltalaisella virtajohdolla) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	063014000000000000001546G	Z120607	Luokka: IIa Sääntö: 9 Class: IIa Rule: 9
295250	Kendall SCD 700 - sekventiaalinen kompressiojärjestelmä (EU-virtajohdolla) <i>Kendall SCD 700 Sequential Compression System (with E.U. power cord)</i>	063014000000000000001546G	Z120607	Luokka: IIa Sääntö: 9 Class: IIa Rule: 9
295251	Kendall SCD 700 - sekventiaalinen kompressiojärjestelmä	063014000000000000001546G	Z120607	Luokka: IIa Sääntö: 9 Class: IIa

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Tuotekoodiluettelo <i>Product Code List</i>				
	(brittiläisellä virtajohdolla) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>			Rule: 9
295255	Kendall SCD 700 - sekventiaalinen kompressiojärjestelmä (australialaisella virtajohdolla) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	06301400000000000001546G	Z120607	Luokka: IIa Sääntö: 9 Class: IIa Rule: 9
295257	Kendall SCD 700 - sekventiaalinen kompressiojärjestelmä (japanilaisella virtajohdolla) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	06301400000000000001546G	Z120607	Luokka: IIa Sääntö: 9 Class: IIa Rule: 9
295258	Kendall SCD 700 - sekventiaalinen kompressiojärjestelmä (brasilialaisella virtajohdolla) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	06301400000000000001546G	Z120607	Luokka: IIa Sääntö: 9 Class: IIa Rule: 9
295259	Kendall SCD 700 - sekventiaalinen kompressiojärjestelmä (intialaisella virtajohdolla) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	06301400000000000001546G	Z120607	Luokka: IIa Sääntö: 9 Class: IIa Rule: 9
82100	Kendall SCD SmartFlow -kompressiojärjestelmä EU virtajohtoadapterilla <i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>	06301400000000000005436X	Z120607	Luokka: IIa Sääntö: 9 Class: IIa Rule: 9
82101	Kendall SCD SmartFlow -kompressiojärjestelmä	06301400000000000005436X	Z120607	Luokka: IIa Sääntö: 9

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Tuotekoodiluettelo <i>Product Code List</i>				
	brittiläisellä virtajohtoadapterilla <i>Kendall SCD SmartFlow Compression System with UK power cord adapter</i>			Class: Iia Rule: 9
82102	Kendall SCD SmartFlow -kompressiojärjestelmä sveitsiläisellä virtajohtoadapterilla <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Luokka: Iia Sääntö: 9 Class: Iia Rule: 9
82105	Kendall SCD SmartFlow -kompressiojärjestelmä australialaisella virtajohtoadapterilla <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Luokka: Iia Sääntö: 9 Class: Iia Rule: 9
82107	Kendall SCD SmartFlow -kompressiojärjestelmä japanilaisella virtajohtoadapterilla <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>	06301400000000000005436X	Z120607	Luokka: Iia Sääntö: 9 Class: Iia Rule: 9
82108	Kendall SCD SmartFlow -kompressiojärjestelmä brasilialaisella virtajohtoadapterilla <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Luokka: Iia Sääntö: 9 Class: Iia Rule: 9
82109	Kendall SCD SmartFlow -kompressiojärjestelmä intialaisella virtajohtoadapterilla <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>	06301400000000000005436X	Z120607	Luokka: Iia Sääntö: 9 Class: Iia Rule: 9


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FRENCH

DÉCLARATION DE CONFORMITÉ <i>DECLARATION OF CONFORMITY</i>	
 CardinalHealth	MDR: Nous, Cardinal Health 200 LLC, déclarons que les produits couverts par la présente déclaration de conformité de l'Union européenne satisfont à la disposition du règlement (UE) 2017/745 sur les dispositifs médicaux.
Numéro de la déclaration de conformité <i>Declaration of Conformity Number</i>	RE00222095
Numéro de la documentation technique <i>Technical Documentation Number</i>	RE00217172
Nom du fabricant <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Adresse du fabricant <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Numéro d'enregistrement unique <i>Single Registration Number</i>	US-MF-000006765
Nom et adresse du représentant agréé <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Nom et numéro d'identification de l'organisme notifié <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Numéro d'identification: 2797
Numéro de certificat CE <i>CE Certificate Number</i>	MDR 784266
Catégorie de produit <i>Product Category</i>	Dispositifs de compression pneumatique [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
UDI-DI de base <i>Basic UDI-DI</i>	063014000000000000001546G 0630140000000000000005436X
EMDN	Z120607
Code, nom commercial et description du produit <i>Product Code, Trade Name and Description</i>	Voir PJ I Refer to Attachment 1
Usage prévu <i>Intended Purpose</i>	Les contrôleurs Kendall SCD sont destinés à exercer une compression pneumatique intermittente pour accroître le débit sanguin veineux chez des patients à risque afin d'aider à prévenir une thrombose veineuse profonde et une embolie pulmonaire. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Classification et règle <i>Classification and Rule</i>	Classe: IIa Règle:9 Class:IIa

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DÉCLARATION DE CONFORMITÉ <i>DECLARATION OF CONFORMITY</i>	
	Rule: 9
Caractéristiques communes <i>Common Specifications</i>	Sans objet Not Applicable
Le cas échéant, ajouter la législation de l'Union européenne en vigueur <i>Where appropriate, add applicable Union legislation</i>	Nous, Cardinal Health 200 LLC, déclarons par la présente que les dispositifs médicaux répertoriés ci-dessus sont conformes à: RoHS 2011/65/EU
Évaluation de la conformité <i>Conformity Assessment</i>	Annexe IX, Chapitres I et III/ Annex IX Chapters I and III

SECTION SIGNATURE <i>SIGNATURE SECTION</i>	
La présente déclaration de conformité de l'Union européenne est établie pour, au nom de et sous la seule responsabilité du fabricant légal identifié plus haut.	
Lieu de délivrance <i>Place of Issue</i>	Waukegan, IL 60085 USA
Signature/Date <i>Signature/Date</i>	 <small>Soumitra Shilotri (Mar 4, 2025 19:15 EST)</small>
Nom et fonction <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Affaires réglementaires

PJ I
ATTACHMENT 1

Liste de référence produit <i>Product Code List</i>				
Code du produit <i>Product Code</i>	Nom commercial et description du produit <i>Trade Name and Description</i>	UDI-DI de base <i>Basic UDI-DI</i>	EMDN	Classification et règle <i>Classification and Rule</i>
29525	Système de compression séquentielle Kendall SCD 700 (avec cordon d'alimentation norme américaine) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	06301400000000000001546G	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9
295250	Système de compression séquentielle Kendall SCD 700 (avec cordon d'alimentation norme européenne)	06301400000000000001546G	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9

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Liste de référence produit <i>Product Code List</i>				
	<i>Kendall SCD 700 Sequential Compression System (with E.U. power cord)</i>			
295251	Système de compression séquentielle Kendall SCD 700 (avec cordon d'alimentation norme anglaise) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9
295255	Système de compression séquentielle Kendall SCD 700 (avec cordon d'alimentation norme australienne) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9
295257	Système de compression séquentielle Kendall SCD 700 (avec cordon d'alimentation norme japonaise) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9
295258	Système de compression séquentielle Kendall SCD 700 (avec cordon d'alimentation norme brésilienne) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9
295259	Système de compression séquentielle Kendall SCD 700 (avec cordon d'alimentation norme indienne) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9
82100	Système de compression Kendall SCD SmartFlow	063014000000000000005436X	Z120607	Classe: IIa Règle:9

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Liste de référence produit <i>Product Code List</i>				
	avec adaptateur de cordon d'alimentation norme européenne <i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>			Class: IIa Rule: 9
82101	Système de compression Kendall SCD SmartFlow avec adaptateur de cordon d'alimentation norme anglaise <i>Kendall SCD SmartFlow Compression System with UK power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9
82102	Système de compression Kendall SCD SmartFlow avec adaptateur de cordon d'alimentation norme suisse <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9
82105	Système de compression Kendall SCD SmartFlow avec adaptateur de cordon d'alimentation norme australienne <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9
82107	Système de compression Kendall SCD SmartFlow avec adaptateur de cordon d'alimentation norme japonaise <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9
82108	Système de compression Kendall SCD SmartFlow avec adaptateur de cordon d'alimentation norme brésilienne <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9
82109	Système de compression Kendall SCD SmartFlow avec adaptateur de cordon d'alimentation norme indienne	06301400000000000005436X	Z120607	Classe: IIa Règle:9 Class: IIa Rule: 9

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Liste de référence produit <i>Product Code List</i>				
	<i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>			

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GERMAN


KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY	
 CardinalHealth	MDR: Wir, Cardinal Health 200 LLC, erklären, dass die Produkte, die in dieser EU-Konformitätserklärung behandelt werden, den Bestimmungen der Medizinprodukteverordnung (EU) 2017/745 entsprechen.
Nummer der Konformitätserklärung <i>Declaration of Conformity Number</i>	RE00222095
Technische Dokumentennummer <i>Technical Documentation Number</i>	RE00217172
Name des Herstellers <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Adresse des Herstellers <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Einzel-Registrierungsnummer <i>Single Registration Number</i>	US-MF-000006765
Name und Adresse des bevollmächtigten Vertreters <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Name und Identifikationsnummer der benannten Stelle <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identifikationsnummer: 2797
CE-Zertifikat-Nummer <i>CE Certificate Number</i>	MDR 784266
Produktkategorie <i>Product Category</i>	Pneumatische Kompressionsvorrichtung [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
Grundlegende UDI-DI <i>Basic UDI-DI</i>	06301400000000000000001546G 06301400000000000000005436X
EMDN	Z120607
Produktcode, Handelsname und Beschreibung <i>Product Code, Trade Name and Description</i>	Siehe Anhang I Refer to Attachment 1
Verwendungszweck <i>Intended Purpose</i>	Kendall SCD Steuergeräte sind für die Anwendung von intermittierender pneumatischer Kompression zur Erhöhung des Durchflusses des venösen Blutes bei Risikopatienten vorgesehen, um tiefe Beinvenenthrombosen und Lungenembolien zu verhindern. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Klassifizierung und Richtlinie <i>Classification and Rule</i>	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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**KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY**

Allgemeine Spezifikationen <i>Common Specifications</i>	Nicht zutreffend Not Applicable
Gegebenenfalls anwendbare Rechtsvorschriften der Gewerkschaft hinzufügen <i>Where appropriate, add applicable Union legislation</i>	Wir, Cardinal Health 200 LLC, erklären hiermit, dass das/die oben genannte(n) Medizinprodukt(e) den folgenden Anforderungen entspricht/entsprechen: RoHS 2011/65/EU
Konformitätsbewertung <i>Conformity Assessment</i>	Anhang IX Kapitel I und III/ Annex IX Chapters I and III

**UNTERSCHRIFTSABSCHNITT
SIGNATURE SECTION**

Diese EU-Konformitätserklärung wird für und im Namen und unter der alleinigen Verantwortung des oben angegebenen rechtmäßigen Herstellers ausgestellt.	
Ausstellungsort <i>Place of Issue</i>	Waukegan, IL 60085 USA
Unterschrift /Datum <i>Signature/Date</i>	 Soumitra Shilotri (Mar 4, 2025 19:15 EST)
Name und Funktion <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Zulassungsangelegenheiten

**ANHANG I
ATTACHMENT 1**

**Produktcodeliste
Product Code List**

Produktcode <i>Product Code</i>	Handelsname und Beschreibung <i>Trade Name and Description</i>	Grundlegende UDI-DI <i>Basic UDI-DI</i>	EMDN	Klassifizierung und Richtlinie <i>Classification and Rule</i>
29525	Kendall SCD 700 Sequenzielles Kompressionssystem (mit US-Netzkabel) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295250	Kendall SCD 700 Sequenzielles Kompressionssystem (mit EU-Netzkabel) <i>Kendall SCD 700 Sequential</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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Produktcodeliste <i>Product Code List</i>				
	<i>Compression System (with E.U. power cord)</i>			
295251	Kendall SCD 700 Sequenzielles Kompressionssystem (mit GB-Netzkabel) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295255	Kendall SCD 700 Sequenzielles Kompressionssystem (mit Netzkabel für Australien) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295257	Kendall SCD 700 Sequenzielles Kompressionssystem (mit Netzkabel für Japan) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295258	Kendall SCD 700 Sequenzielles Kompressionssystem (mit Netzkabel für Brasilien) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295259	Kendall SCD 700 Sequenzielles Kompressionssystem (mit Netzkabel für Indien) <i>Kendall SCD 700 Sequential Compression System</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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Produktcodeliste <i>Product Code List</i>				
	<i>(with India power cord)</i>			
82100	Kendall SCD SmartFlow Kompressionssystem mit Netzkabeladapter für EU <i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82101	Kendall SCD SmartFlow Kompressionssystem mit Netzkabeladapter für GB <i>Kendall SCD SmartFlow Compression System with UK power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82102	Kendall SCD SmartFlow Kompressionssystem mit Netzkabeladapter für die Schweiz <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82105	Kendall SCD SmartFlow Kompressionssystem mit Netzkabeladapter für Australien <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82107	Kendall SCD SmartFlow Kompressionssystem mit Netzkabeladapter für	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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Produktcodeliste <i>Product Code List</i>				
	Japan <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>			
82108	Kendall SCD SmartFlow Kompressionssystem mit Netzkabeladapter für Brasilien <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82109	Kendall SCD SmartFlow Kompressionssystem mit Netzkabeladapter für Indien <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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GREEK

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ DECLARATION OF CONFORMITY	
 CardinalHealth	MDR: Εμείς, η Cardinal Health 200 LLC, δηλώνουμε ότι τα προϊόντα που καλύπτονται στην παρούσα Δήλωση συμμόρφωσης ΕΕ πληρούν τις διατάξεις του Κανονισμού (ΕΕ) 2017/745 για τα ιατροτεχνολογικά προϊόντα.
Αριθμός δήλωσης συμμόρφωσης <i>Declaration of Conformity Number</i>	RE00222095
Αριθμός τεχνικού φακέλου <i>Technical Documentation Number</i>	RE00217172
Όνομα κατασκευαστή <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Διεύθυνση κατασκευαστή <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Ενιαίος αριθμός καταχώρισης <i>Single Registration Number</i>	US-MF-000006765
Όνομα και διεύθυνση εξουσιοδοτημένου αντιπροσώπου <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Όνομα και αριθμός αναγνώρισης κοινοποιημένου οργανισμού <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Αριθμός αναγνώρισης: 2797
Αριθμός πιστοποιητικού CE <i>CE Certificate Number</i>	MDR 784266
Κατηγορία προϊόντος <i>Product Category</i>	Πνευματικός εξοπλισμός συμπίεσης [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
Βασικό UDI-DI <i>Basic UDI-DI</i>	0630140000000000000000001546G 0630140000000000000000005436X
EMDN	Z120607
Κωδικός προϊόντος, εμπορική επωνυμία και περιγραφή <i>Product Code, Trade Name and Description</i>	Ανατρέξτε στο Προσάρτημα I Refer to Attachment 1
Προοριζόμενος σκοπός <i>Intended Purpose</i>	Οι ελεγκτές Kendall SCD προορίζονται για την εφαρμογή διαλείπουσας πνευματικής συμπίεσης για την αύξηση της φλεβικής ροής αίματος σε ασθενείς που διατρέχουν κίνδυνο, προκειμένου να συμβάλλουν στην πρόληψη της εν τω βάθει φλεβικής θρόμβωσης και της πνευμονικής εμβολής. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Ταξινόμηση και κανόνας <i>Classification and Rule</i>	Κατηγορία: Ια Κανόνας: 9 Class: Ια Rule: 9

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ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ <i>DECLARATION OF CONFORMITY</i>	
Κοινές προδιαγραφές <i>Common Specifications</i>	Δεν ισχύει Not Applicable
Όπου αρμόζει, προσθέστε την εφαρμοστέα νομοθεσία της Ένωσης <i>Where appropriate, add applicable Union legislation</i>	Εμείς, η Cardinal Health 200 LLC, δια της παρούσης δηλώνουμε ότι το(τα) προαναφερόμενο(α) ιατροτεχνολογικό(ά) προϊόν(τα) συμμορφώνεται(συμμορφώνονται) με: RoHS 2011/65/EU
Αξιολόγηση της συμμόρφωσης <i>Conformity Assessment</i>	Παράρτημα IX Κεφάλαια I και III/ Annex IX Chapters I and III

ΕΝΟΤΗΤΑ ΥΠΟΓΡΑΦΗΣ <i>SIGNATURE SECTION</i>	
Η παρούσα Δήλωση συμμόρφωσης ΕΕ εκδίδεται στο όνομα και για λογαριασμό και με την αποκλειστική ευθύνη του Νόμιμου κατασκευαστή που ταυτοποιείται παραπάνω.	
Τόπος έκδοσης <i>Place of Issue</i>	Waukegan, IL 60085 USA
Υπογραφή/Ημερομηνία <i>Signature/Date</i>	<u>Soumitra Shilotri</u> <small>Soumitra Shilotri (Mar 4, 2025 19:15 EST)</small>
Όνομα και λειτουργία <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Ρυθμιστικές υποθέσεις

ΠΡΟΣΑΡΤΗΜΑ I
ATTACHMENT I

Κατάλογος κωδικών προϊόντος <i>Product Code List</i>				
Κωδικός προϊόντος <i>Product Code</i>	Εμπορική επωνυμία και περιγραφή <i>Trade Name and Description</i>	Βασικό UDI-DI <i>Basic UDI-DI</i>	EMDN	Ταξινόμηση και κανόνας <i>Classification and Rule</i>
29525	Σύστημα διαδοχικής συμπίεσης Kendall SCD 700 (με καλώδιο τροφοδοσίας ΗΠΑ) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	06301400000000000001546G	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9
295250	Σύστημα διαδοχικής συμπίεσης Kendall SCD 700 (με καλώδιο τροφοδοσίας ΕΕ) <i>Kendall SCD 700 Sequential Compression</i>	06301400000000000001546G	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9

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Κατάλογος κωδικών προϊόντος <i>Product Code List</i>				
	<i>System (with E.U. power cord)</i>			
295251	Σύστημα διαδοχικής συμπίεσης Kendall SCD 700 (με καλώδιο τροφοδοσίας Ηνωμένου Βασιλείου) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>	06301400000000000001546G	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9
295255	Σύστημα διαδοχικής συμπίεσης Kendall SCD 700 (με καλώδιο τροφοδοσίας Αυστραλίας) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	06301400000000000001546G	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9
295257	Σύστημα διαδοχικής συμπίεσης Kendall SCD 700 (με καλώδιο τροφοδοσίας Ιαπωνίας) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	06301400000000000001546G	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9
295258	Σύστημα διαδοχικής συμπίεσης Kendall SCD 700 (με καλώδιο τροφοδοσίας Βραζιλίας) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	06301400000000000001546G	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9
295259	Σύστημα διαδοχικής συμπίεσης Kendall SCD 700 (με καλώδιο τροφοδοσίας Ινδίας) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	06301400000000000001546G	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9
82100	Σύστημα συμπίεσης Kendall SCD SmartFlow με προσαρμογέα καλωδίου τροφοδοσίας EE <i>Kendall SCD SmartFlow Compression System</i>	06301400000000000005436X	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9

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Κατάλογος κωδικών προϊόντος
Product Code List

	<i>with EU power cord adapter</i>			
82101	Σύστημα συμπίεσης Kendall SCD SmartFlow με προσαρμογέα καλωδίου τροφοδοσίας Ηνωμένου Βασιλείου <i>Kendall SCD SmartFlow Compression System with UK power cord adapter</i>	06301400000000000005436X	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9
82102	Σύστημα συμπίεσης Kendall SCD SmartFlow με προσαρμογέα καλωδίου τροφοδοσίας Ελβετίας <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9
82105	Σύστημα συμπίεσης Kendall SCD SmartFlow με προσαρμογέα καλωδίου τροφοδοσίας Αυστραλίας <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9
82107	Σύστημα συμπίεσης Kendall SCD SmartFlow με προσαρμογέα καλωδίου τροφοδοσίας Ιαπωνίας <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>	06301400000000000005436X	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9
82108	Σύστημα συμπίεσης Kendall SCD SmartFlow με προσαρμογέα καλωδίου τροφοδοσίας Βραζιλίας <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα Rule: 9
82109	Σύστημα συμπίεσης Kendall SCD SmartFlow με προσαρμογέα καλωδίου τροφοδοσίας	06301400000000000005436X	Z120607	Κατηγορία: Πα Κανόνας: 9 Class: Πα

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Κατάλογος κωδικών προϊόντος <i>Product Code List</i>				
	Ινδίας <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>			Rule: 9

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ITALIAN

DICHIARAZIONE DI CONFORMITÀ DECLARATION OF CONFORMITY	
 CardinalHealth	MDR: Noi sottoscritti, Cardinal Health 200 LLC, dichiariamo che i prodotti relativi alla presente Dichiarazione di conformità UE sono conformi alle disposizioni del Regolamento sui dispositivi medici (UE) 2017/745.
Numero della dichiarazione di conformità <i>Declaration of Conformity Number</i>	RE00222095
Numero di documentazione tecnica <i>Technical Documentation Number</i>	RE00217172
Nome del fabbricante <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Indirizzo del fabbricante <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Numero di registrazione unico <i>Single Registration Number</i>	US-MF-000006765
Nome e indirizzo del mandatario <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Nome e numero di identificazione dell'organismo notificato <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Numero di identificazione: 2797
Numero di certificato CE <i>CE Certificate Number</i>	MDR 784266
Categoria di prodotto <i>Product Category</i>	Attrezzatura di compressione pneumatica [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
UDI-DI di base <i>Basic UDI-DI</i>	063014000000000000001546G 0630140000000000000005436X
EMDN	Z120607
Codice prodotto, denominazione commerciale e descrizione <i>Product Code, Trade Name and Description</i>	Consultare l'Allegato I Refer to Attachment 1
Destinazione d'uso <i>Intended Purpose</i>	Il dispositivo di controllo Kendall SCD è progettato per applicare una compressione pneumatica intermittente per aumentare il flusso sanguigno venoso nei pazienti a rischio, al fine di aiutare a prevenire la trombosi venosa profonda e l'embolia polmonare. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Classificazione e regola <i>Classification and Rule</i>	Classe: IIa Regola: 9 Class: IIa Rule: 9

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DICHIARAZIONE DI CONFORMITÀ <i>DECLARATION OF CONFORMITY</i>	
Specifiche comuni <i>Common Specifications</i>	Non applicabile Not Applicable
Ove necessario, aggiungere la legislazione pertinente dell'Unione <i>Where appropriate, add applicable Union legislation</i>	Con la presente noi sottoscritti, Cardinal Health 200 LLC, dichiariamo che i dispositivi medici sopra indicati sono conformi a: RoHS 2011/65/EU
Valutazione della conformità <i>Conformity Assessment</i>	Allegato IX, Capitoli I e III/ Annex IX Chapters I and III

SEZIONE FIRMA <i>SIGNATURE SECTION</i>	
La presente Dichiarazione di conformità UE è stata prodotta per, a nome e sotto esclusiva responsabilità del fabbricante legale sopra indicato.	
Luogo di rilascio <i>Place of Issue</i>	Waukegan, IL 60085 USA
Firma/Data <i>Signature/Date</i>	<u>Soumitra Shilotri</u> <small>Soumitra Shilotri (Mar 4, 2025 19:15 EST)</small>
Nome e mansion <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Affari regolatori

ALLEGATO I
ATTACHMENT 1

Elenco codice prodotto <i>Product Code List</i>				
Codice prodotto <i>Product Code</i>	Denominazione commerciale e descrizione <i>Trade Name and Description</i>	UDI-DI di base <i>Basic UDI-DI</i>	EMDN	Classificazione e regola <i>Classification and Rule</i>
29525	Sistema di compressione sequenziale Kendall SCD 700 (con cavo di alimentazione USA) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	06301400000000000001546G	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9
295250	Sistema di compressione sequenziale Kendall SCD 700 (con cavo di alimentazione U.E.) <i>Kendall SCD 700 Sequential Compression</i>	06301400000000000001546G	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9

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Elenco codice prodotto <i>Product Code List</i>				
	<i>System (with E.U. power cord)</i>			
295251	Sistema di compressione sequenziale Kendall SCD 700 (con cavo di alimentazione per il Regno Unito) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9
295255	Sistema di compressione sequenziale Kendall SCD 700 (con cavo di alimentazione australiano) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9
295257	Sistema di compressione sequenziale Kendall SCD 700 (con cavo di alimentazione giapponese) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9
295258	Sistema di compressione sequenziale Kendall SCD 700 (con cavo di alimentazione brasiliano) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9
295259	Sistema di compressione sequenziale Kendall SCD 700 (con cavo di alimentazione indiano) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9
82100	Sistema di compressione Kendall SCD SmartFlow con adattatore per cavo di alimentazione U.E	063014000000000000005436X	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9


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Elenco codice prodotto <i>Product Code List</i>				
	<i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>			
82101	Sistema di compressione Kendall SCD SmartFlow con adattatore per cavo di alimentazione per il Regno Unito <i>Kendall SCD SmartFlow Compression System with UK power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9
82102	Sistema di compressione Kendall SCD SmartFlow con adattatore per cavo di alimentazione svizzero <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9
82105	Sistema di compressione Kendall SCD SmartFlow con adattatore per cavo di alimentazione australiano <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9
82107	Sistema di compressione Kendall SCD SmartFlow con adattatore per cavo di alimentazione giapponese <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9
82108	Sistema di compressione Kendall SCD SmartFlow con adattatore per cavo di alimentazione brasiliano <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9
82109	Sistema di compressione Kendall SCD SmartFlow con adattatore per cavo di alimentazione indiano <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Regola: 9 Class: IIa Rule: 9

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NORWEGIAN

SAMSVARERKLÆRING <i>DECLARATION OF CONFORMITY</i>	
 CardinalHealth	MDR: Vi, Cardinal Health 200 LLC, erklærer at produktene som dekkes i denne EU-samsvarerklæringen oppfyller bestemmelsene i forordningen om medisinsk utstyr (EU) 2017/745.
Samsvarerklæringsnummer <i>Declaration of Conformity Number</i>	RE00222095
Teknisk dokumentasjonsnummer <i>Technical Documentation Number</i>	RE00217172
Produsentens navn <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Produsentens adresse <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Enkeltregistreringsnummer <i>Single Registration Number</i>	US-MF-000006765
Autorisert representants navn og adresse <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Teknisk kontrollorgans navn og identifikasjonsnummer <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identifikasjonsnummer: 2797
CE-sertifikatnummer <i>CE Certificate Number</i>	MDR 784266
Produktkategori <i>Product Category</i>	Utstyr for pneumatisk kompresjon [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
Grunnleggende UDI-DI <i>Basic UDI-DI</i>	063014000000000000001546G 0630140000000000000005436X
EMDN	Z120607
Produktkode, handelsnavn og beskrivelse <i>Product Code, Trade Name and Description</i>	Se Tillegg I Refer to Attachment 1
Tiltenkt formal <i>Intended Purpose</i>	Kendall SCD-kontrollenhetene er beregnet for å gi intermitterende trykkluftkompresjon for å øke blodgjennomstrømningen i venene hos risikopasienter for å bidra til å forhindre dyp venetrombose og lungeemboli. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Klassifisering og regel <i>Classification and Rule</i>	Klasse: IIa Regel: 9 Class: IIa Rule: 9
Vanlige spesifikasjoner <i>Common Specifications</i>	Ikke relevant Not Applicable

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SAMSVARERKLÆRING <i>DECLARATION OF CONFORMITY</i>	
Legg til gjeldende EU-lovgivning der det er relevant <i>Where appropriate, add applicable Union legislation</i>	Vi, Cardinal Health 200 LLC, erklærer herved at det ovennevnte medisinske utstyret er i samsvar med: RoHS 2011/65/EU
Samsvarsvurdering <i>Conformity Assessment</i>	Tillegg IX, kapittel I og III/ Annex IX Chapters I and III

SIGNATURDEL <i>SIGNATURE SECTION</i>	
Denne EU-samsvarserklæringen utstedes for og på vegne av den ovenfor identifiserte lomessige produsenten, og utelukkende under dennes ansvar.	
Utstedelsessted <i>Place of Issue</i>	Waukegan, IL 60085 USA
Signatur/Dato <i>Signature/Date</i>	<u>Soumitra Shilotri</u> <small>Soumitra Shilotri (Mar 4, 2025 19:15 EST)</small>
Navn og funksjon <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Juridisk avdeling

TILLEGG I
ATTACHMENT 1

Produktkodeliste <i>Product Code List</i>				
Produktkode <i>Product Code</i>	Handelsnavn og beskrivelse <i>Trade Name and Description</i>	Grunnleggende UDI-DI <i>Basic UDI-DI</i>	EMDN	Klassifisering og regel <i>Classification and Rule</i>
29525	Kendall SCD 700 sekvensielt kompresjonssystem (med amerikansk strømledning) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295250	Kendall SCD 700 sekvensielt kompresjonssystem (med europeisk strømledning) <i>Kendall SCD 700 Sequential Compression System</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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Produktkodeliste <i>Product Code List</i>				
	<i>(with E.U. power cord)</i>			
295251	Kendall SCD 700 sekvensielt kompresjonssystem (med britisk strømledning) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295255	Kendall SCD 700 sekvensielt kompresjonssystem (med australsk strømledning) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295257	Kendall SCD 700 sekvensielt kompresjonssystem (med japansk strømledning) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295258	Kendall SCD 700 sekvensielt kompresjonssystem (med brasiliansk strømledning) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
295259	Kendall SCD 700 sekvensielt kompresjonssystem (med indisk strømledning) <i>Kendall SCD 700 Sequential Compression System</i>	063014000000000000001546G	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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Produktkodeliste <i>Product Code List</i>				
	<i>(with India power cord)</i>			
82100	Kendall SCD SmartFlow-kompresjonssystem med adapter for europeisk strømledning <i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82101	Kendall SCD SmartFlow-kompresjonssystem med adapter for britisk strømledning <i>Kendall SCD SmartFlow Compression System with UK power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82102	Kendall SCD SmartFlow-kompresjonssystem med adapter for sveitsisk strømledning <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82105	Kendall SCD SmartFlow-kompresjonssystem med adapter for australsk strømledning <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82107	Kendall SCD SmartFlow-kompresjonssystem med adapter for japansk strømledning <i>Kendall SCD</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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Produktkodeliste <i>Product Code List</i>				
	<i>SmartFlow Compression System with Japan power cord adapter</i>			
82108	Kendall SCD SmartFlow- kompresjonssystem med adapter for brasiliansk strømledning <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9
82109	Kendall SCD SmartFlow- kompresjonssystem med adapter for indisk strømledning <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>	06301400000000000005436X	Z120607	Klasse: IIa Regel: 9 Class: IIa Rule: 9

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POLISH

DEKLARACJA ZGODNOŚCI DECLARATION OF CONFORMITY	
	MDR: My, Cardinal Health 200 LLC, oświadczamy, że produkty objęte Deklaracją zgodności UE spełniają wymagania rozporządzenia w sprawie wyrobów medycznych (EU) 2017/745.
Numer Deklaracji zgodności <i>Declaration of Conformity Number</i>	RE00222095
Numer dokumentacji technicznej <i>Technical Documentation Number</i>	RE00217172
Nazwa producenta <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Adres producenta <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Pojedynczy numer rejestracyjny <i>Single Registration Number</i>	US-MF-000006765
Nazwa i adres autoryzowanego przedstawiciela <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Nazwa i numer identyfikacyjny jednostki notyfikowanej <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Numer identyfikacyjny: 2797
Numer certyfikatu CE <i>CE Certificate Number</i>	MDR 784266
Kategoria produkt <i>Product Category</i>	Pneumatyczne wyposażenie uciskowe [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
Podstawowy unikalny identyfikator urządzenia UDI-DI <i>Basic UDI-DI</i>	063014000000000000001546G 0630140000000000000005436X
EMDN	Z120607
Kod produktu, nazwa handlowa i opis <i>Product Code, Trade Name and Description</i>	Patrz Załącznik I Refer to Attachment 1
Przeznaczenie <i>Intended Purpose</i>	Kendall SCD Controllers jest przeznaczony do stosowania przerywanej kompresji pneumatycznej w celu zwiększenia przepływu krwi żyłnej u pacjentów z grupy ryzyka, co sprzyja zapobieganiu zakrzepicy żył głębokich i zatorowości płucnej. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Klasyfikacja i reguła <i>Classification and Rule</i>	Klasa: IIa Reguła: 9 Class: IIa Rule: 9

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DEKLARACJA ZGODNOŚCI <i>DECLARATION OF CONFORMITY</i>	
Wspólne specyfikacje <i>Common Specifications</i>	Nie dotyczy Not Applicable
W stosownych przypadkach dodać obowiązujące przepisy unijne <i>Where appropriate, add applicable Union legislation</i>	My, Cardinal Health 200 LLC, niniejszym oświadczamy, że wyżej wymienione wyroby medyczne są zgodne z: RoHS 2011/65/EU
Ocena zgodności <i>Conformity Assessment</i>	Załącznik IX, rozdziały I i III/ Annex IX Chapters I and III

SEKCJA PODPISÓW <i>SIGNATURE SECTION</i>	
Niniejsza deklaracja zgodności UE została wydana w imieniu i na wyłączną odpowiedzialność legalnego producenta określonego powyżej.	
Miejsce wydania <i>Place of Issue</i>	Waukegan, IL 60085 USA
Podpis/Data <i>Signature/Date</i>	 <small>Soumitra Shilotri (Mar 4, 2025 19:15 EST)</small>
Imię i nazwisko oraz stanowisko <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Dział spraw regulacyjnych

ZAŁĄCZNIK 1
ATTACHMENT 1

Lista kodów produktu <i>Product Code List</i>				
Kod produktu <i>Product Code</i>	Nazwa handlowa i opis <i>Trade Name and Description</i>	Podstawowy unikalny identyfikator urządzenia UDI-DI <i>Basic UDI-DI</i>	EMDN	Klasyfikacja i reguła <i>Classification and Rule</i>
29525	System sekwencyjnego ucisku pneumatycznego Kendall SCD 700 (z przewodem zasilającym stosowanym w Stanach Zjednoczonych) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	063014000000000000001546G	Z120607	Klasa: IIa Reguła: 9 Class: IIa Rule: 9
295250	System sekwencyjnego ucisku pneumatycznego Kendall SCD 700 (z przewodem zasilającym stosowanym w Unii Europejskiej) <i>Kendall SCD 700</i>	063014000000000000001546G	Z120607	Klasa: IIa Reguła: 9 Class: IIa Rule: 9

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Lista kodów produktu <i>Product Code List</i>				
	<i>Sequential Compression System (with E.U. power cord)</i>			
295251	System sekwencyjnego ucisku pneumatycznego Kendall SCD 700 (z przewodem zasilającym stosowanym w Wielkiej Brytanii) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>	063014000000000000001546G	Z120607	Klasa: IIa Reguła: 9 Class: IIa Rule: 9
295255	System sekwencyjnego ucisku pneumatycznego Kendall SCD 700 (z przewodem zasilającym stosowanym w Australii) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Klasa: IIa Reguła: 9 Class: IIa Rule: 9
295257	System sekwencyjnego ucisku pneumatycznego Kendall SCD 700 (z przewodem zasilającym stosowanym w Japonii) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Klasa: IIa Reguła: 9 Class: IIa Rule: 9
295258	System sekwencyjnego ucisku pneumatycznego Kendall SCD 700 (z przewodem zasilającym stosowanym w Brazylii) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Klasa: IIa Reguła: 9 Class: IIa Rule: 9
295259	System sekwencyjnego ucisku pneumatycznego Kendall SCD 700 (z przewodem zasilającym stosowanym w Indiach) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	063014000000000000001546G	Z120607	Klasa: IIa Reguła: 9 Class: IIa Rule: 9
82100	System uciskowy KENDALL SCD	063014000000000000005436X	Z120607	Klasa: IIa Reguła: 9

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Lista kodów produktu <i>Product Code List</i>				
	SmartFlow z adapterem przewodu zasilającego stosowanym w Unii Europejskiej <i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>			Class: IIa Rule: 9
82101	System uciskowy KENDALL SCD SmartFlow z adapterem przewodu zasilającego stosowanym w Wielkiej Brytanii <i>Kendall SCD SmartFlow Compression System with UK power cord adapter</i>	06301400000000000005436X	Z120607	Klasa: IIa Reguła: 9 Class: IIa Rule: 9
82102	System uciskowy KENDALL SCD SmartFlow z adapterem przewodu zasilającego stosowanym w Szwajcarii <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Klasa: IIa Reguła: 9 Class: IIa Rule: 9
82105	System uciskowy KENDALL SCD SmartFlow z adapterem przewodu zasilającego stosowanym w Australii <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Klasa: IIa Reguła: 9 Class: IIa Rule: 9
82107	System uciskowy KENDALL SCD SmartFlow z adapterem przewodu zasilającego stosowanym w Japonii <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>	06301400000000000005436X	Z120607	Klasa: IIa Reguła: 9 Class: IIa Rule: 9
82108	System uciskowy KENDALL SCD SmartFlow z adapterem przewodu zasilającego stosowanym w Brazylii <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Klasa: IIa Reguła: 9 Class: IIa Rule: 9
82109	System uciskowy KENDALL SCD	06301400000000000005436X	Z120607	Klasa: IIa Reguła: 9

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Lista kodów produktu <i>Product Code List</i>				
	SmartFlow z adapterem przewodu zasilającego stosowanym w Indiach <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>			Class: IIa Rule: 9

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PORTUGUESE

DECLARAÇÃO DE CONFORMIDADE DECLARATION OF CONFORMITY	
 CardinalHealth	MDR: Nos, Cardinal Health 200 LLC, declaramos que os produtos abrangidos por esta Declaração de Conformidade da UE cumprem a disposição do Regulamento relativo a dispositivos médicos (UE) 2017/745.
Número de Declaração de Conformidade <i>Declaration of Conformity Number</i>	RE00222095
Número de documentação técnica <i>Technical Documentation Number</i>	RE00217172
Nome do fabricante <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Endereço do fabricante <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Número único de registo <i>Single Registration Number</i>	US-MF-000006765
Nome e endereço do representante autorizado <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Nome e número de identificação do organismo notificado <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Número de identificação: 2797
Número do certificado CE <i>CE Certificate Number</i>	MDR 784266
Categoria do produto <i>Product Category</i>	Equipamento de Compressão Pneumática [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
UDI-DI básico <i>Basic UDI-DI</i>	06301400000000000000001546G 06301400000000000000005436X
EMDN	Z120607
Código, nome comercial e descrição do produto <i>Product Code, Trade Name and Description</i>	Consultar o Anexo I Refer to Attachment 1
Finalidade <i>Intended Purpose</i>	O Kendall SCD Controllers foi feito para aplicar compressão pneumática intermitente para aumentar o fluxo de sangue venoso em pacientes de risco de modo a ajudar a prevenir a trombose venosa profunda e a embolia pulmonar. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Classificação e regra <i>Classification and Rule</i>	Classe: IIa Regra: 9 Class: IIa Rule: 9

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DECLARAÇÃO DE CONFORMIDADE <i>DECLARATION OF CONFORMITY</i>	
Especificações comuns <i>Common Specifications</i>	Não aplicável Not Applicable
Se for o caso, adicione a legislação aplicável ao nível da União <i>Where appropriate, add applicable Union legislation</i>	Nos, Cardinal Health 200 LLC, declaramos pelo presente que o(s) dispositivo(s) médico(s) acima está/estão em conformidade com: RoHS 2011/65/EU
Avaliação de conformidade <i>Conformity Assessment</i>	Anexo IX, Capítulos I e III / Annex IX Chapters I and III

SECÇÃO DE ASSINATURA <i>SIGNATURE SECTION</i>	
Esta Declaração de Conformidade da UE é emitida em nome e sob a responsabilidade exclusiva do Fabricante legal identificado acima.	
Local de emissão <i>Place of Issue</i>	Waukegan, IL 60085 USA
Assinatura/Data <i>Signature/Date</i>	<u>Soumitra Shilotri</u> <small>Soumitra Shilotri (Mar 4, 2025 19:15 EST)</small>
Nome e cargo <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Assuntos Regulamentares

ANEXO I
ATTACHMENT 1

Lista de códigos dos produtos <i>Product Code List</i>				
Código do produto <i>Product Code</i>	Nome comercial e descrição <i>Trade Name and Description</i>	UDI-DI básico <i>Basic UDI-DI</i>	EMDN	Classificação e regra <i>Classification and Rule</i>
29525	Sistema de Compressão Kendall SCD 700 Sequential (com cabo de alimentação dos EUA) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	06301400000000000001546G	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9
295250	Sistema de Compressão Kendall SCD 700 Sequential (com cabo de alimentação da UE) <i>Kendall SCD 700 Sequential Compression</i>	06301400000000000001546G	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9

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Lista de códigos dos produtos <i>Product Code List</i>				
	<i>System (with E.U. power cord)</i>			
295251	Sistema de Compressão Kendall SCD 700 Sequential (com cabo de alimentação do Reino Unido) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9
295255	Sistema de Compressão Kendall SCD 700 Sequential (com cabo de alimentação australiano) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9
295257	Sistema de Compressão Kendall SCD 700 Sequential (com cabo de alimentação japonês) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9
295258	Sistema de Compressão Kendall SCD 700 Sequential (com cabo de alimentação brasileiro) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9
295259	Sistema de Compressão Kendall SCD 700 Sequential (com cabo de alimentação indiano) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	063014000000000000001546G	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9
82100	Sistema de Compressão Kendall SCD SmartFlow com adaptador de cabo de alimentação da UE <i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>	063014000000000000005436X	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9

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Lista de códigos dos produtos <i>Product Code List</i>				
82101	Sistema de Compressão Kendall SCD SmartFlow com adaptador de cabo de alimentação do Reino Unido <i>Kendall SCD SmartFlow Compression System with UK power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9
82102	Sistema de Compressão Kendall SCD SmartFlow com adaptador de cabo de alimentação da Suíça <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9
82105	Sistema de Compressão Kendall SCD SmartFlow com adaptador de cabo de alimentação da Austrália <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9
82107	Sistema de Compressão Kendall SCD SmartFlow com adaptador de cabo de alimentação do Japão <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9
82108	Sistema de Compressão Kendall SCD SmartFlow com adaptador de cabo de alimentação do Brasil <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9
82109	Sistema de Compressão Kendall SCD SmartFlow com adaptador de cabo de alimentação da Índia <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>	06301400000000000005436X	Z120607	Classe: IIa Regra: 9 Class: IIa Rule: 9

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ROMANIAN

DECLARAȚIE DE CONFORMITATE DECLARATION OF CONFORMITY	
 CardinalHealth	MDR: Noi, Cardinal Health 200 LLC, declarăm că produsele acoperite în această Declarație de conformitate UE respectă prevederile Regulamentului privind dispozitivele medicale (UE) 2017/745.
Număr declarație de conformitate <i>Declaration of Conformity Number</i>	RE00222095
Număr documentație tehnică <i>Technical Documentation Number</i>	RE00217172
Numele producătorului <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Adresa producătorului <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Număr unic de înregistrare <i>Single Registration Number</i>	US-MF-000006765
Numele și adresa reprezentantului autorizat <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Numele și numărul de identificare al Organismului notificat <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Număr de identificare: 2797
Numărul certificatului CE <i>CE Certificate Number</i>	MDR 784266
Categoria de produs <i>Product Category</i>	Echipe de compresie pneumatică [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
UDI-DI de bază <i>Basic UDI-DI</i>	063014000000000000001546G 0630140000000000000005436X
EMDN	Z120607
Cod produs, Nume comercial și Descriere <i>Product Code, Trade Name and Description</i>	Consultați Anexa I Refer to Attachment 1
Destinația utilizării <i>Intended Purpose</i>	Controlerile Kendall SCD sunt destinate aplicării compresiei pneumatice intermitente în vederea creșterii fluxului sanguin venos la pacienții cu risc, cu scopul de a preveni tromboza venoasă profundă și embolia pulmonară. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Clasificare și regulă <i>Classification and Rule</i>	Clasă: IIa Regulă: 9 Class: IIa Rule: 9
Specificații comune <i>Common Specifications</i>	Nu este cazul Not Applicable

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DECLARAȚIE DE CONFORMITATE <i>DECLARATION OF CONFORMITY</i>	
Când este cazul, adăugați legislația aplicabilă din Uniune <i>Where appropriate, add applicable Union legislation</i>	Noi, Cardinal Health 200 LLC, prin prezenta declarăm că dispozitivul/dispozitivele medicale enumerate mai sus respectă: RoHS 2011/65/EU
Evaluarea de conformitate <i>Conformity Assessment</i>	Anexa IX, Capitolele I și III/ Annex IX Chapters I and III

SECȚIUNEA DE SEMNĂTURI <i>SIGNATURE SECTION</i>	
Această Declarație de conformitate UE este emisă în numele și sub responsabilitatea exclusivă a Producătorului Legal identificat mai sus.	
Locul emiterii <i>Place of Issue</i>	Waukegan, IL 60085 USA
Semnătura/Data <i>Signature/Date</i>	<u>Soumitra Shilotri</u> Soumitra Shilotri (Mar 4, 2025 19:15 EST)
Nume și funcție <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Afaceri de reglementare

ANEXA I
ATTACHMENT 1

Listă cu Coduri de produse <i>Product Code List</i>				
Cod produs <i>Product Code</i>	Nume comercial și descriere <i>Trade Name and Description</i>	UDI-DI de bază <i>Basic UDI-DI</i>	EMDN	Clasificare și regulă <i>Classification and Rule</i>
29525	Sistem de compresie secvențială Kendall SCD 700 (cu cablu de alimentare pentru SUA) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	063014000000000000001546G	Z120607	Clasă: IIa Regulă: 9 Class: IIa Rule: 9
295250	Sistem de compresie secvențială Kendall SCD 700 (cu cablu de alimentare pentru UE) <i>Kendall SCD 700 Sequential Compression System (with E.U. power cord)</i>	063014000000000000001546G	Z120607	Clasă: IIa Regulă: 9 Class: IIa Rule: 9

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Listă cu Coduri de produse <i>Product Code List</i>				
295251	Sistem de compresie secvențială Kendall SCD 700 (cu cablu de alimentare pentru Regatul Unit) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>	063014000000000000001546G	Z120607	Clasă: IIA Regulă: 9 Class: IIA Rule: 9
295255	Sistem de compresie secvențială Kendall SCD 700 (cu cablu de alimentare pentru Australia) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Clasă: IIA Regulă: 9 Class: IIA Rule: 9
295257	Sistem de compresie secvențială Kendall SCD 700 (cu cablu de alimentare pentru Japonia) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Clasă: IIA Regulă: 9 Class: IIA Rule: 9
295258	Sistem de compresie secvențială Kendall SCD 700 (cu cablu de alimentare pentru Brazilia) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Clasă: IIA Regulă: 9 Class: IIA Rule: 9
295259	Sistem de compresie secvențială Kendall SCD 700 (cu cablu de alimentare pentru India) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	063014000000000000001546G	Z120607	Clasă: IIA Regulă: 9 Class: IIA Rule: 9
82100	Sistem de compresie Kendall SCD SmartFlow cu adaptor pentru cablu de alimentare pentru UE <i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>	063014000000000000005436X	Z120607	Clasă: IIA Regulă: 9 Class: IIA Rule: 9
82101	Sistem de compresie Kendall SCD SmartFlow cu adaptor pentru cablu de alimentare pentru Marea Britanie <i>Kendall SCD SmartFlow Compression System with UK power cord adapter</i>	063014000000000000005436X	Z120607	Clasă: IIA Regulă: 9 Class: IIA Rule: 9

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Listă cu Coduri de produse <i>Product Code List</i>				
82102	Sistem de compresie Kendall SCD SmartFlow cu adaptor pentru cablu de alimentare pentru Elveția <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Clasă: IIa Regulă: 9 Class: IIa Rule: 9
82105	Sistem de compresie Kendall SCD SmartFlow cu adaptor pentru cablu de alimentare pentru Australia <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Clasă: IIa Regulă: 9 Class: IIa Rule: 9
82107	Sistem de compresie Kendall SCD SmartFlow cu adaptor pentru cablu de alimentare pentru Japonia <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>	06301400000000000005436X	Z120607	Clasă: IIa Regulă: 9 Class: IIa Rule: 9
82108	Sistem de compresie Kendall SCD SmartFlow cu adaptor pentru cablu de alimentare pentru Brazilia <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Clasă: IIa Regulă: 9 Class: IIa Rule: 9
82109	Sistem de compresie Kendall SCD SmartFlow cu adaptor pentru cablu de alimentare pentru India <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>	06301400000000000005436X	Z120607	Clasă: IIa Regulă: 9 Class: IIa Rule: 9

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SLOVAK

VYHLÁSENIE O ZHODE DECLARATION OF CONFORMITY	
	MDR: Vyhlasujeme, Cardinal Health 200 LLC, že produkty uvedené v tomto vyhlásení o zhode EÚ spĺňajú ustanovenia nariadenia o zdravotníckych pomôckach (EÚ) 2017/745.
Číslo vyhlásenia o zhode <i>Declaration of Conformity Number</i>	RE00222095
Číslo technickej dokumentácie <i>Technical Documentation Number</i>	RE00217172
Názov výrobcu <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Adresa výrobcu <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Jednotné registračné číslo <i>Single Registration Number</i>	US-MF-000006765
Meno a adresa oprávneného zástupcu <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Meno a identifikačné číslo informovaného orgánu <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identifikačné číslo: 2797
Číslo certifikátu CE <i>CE Certificate Number</i>	MDR 784266
Kategória výrobku <i>Product Category</i>	Pneumatické kompresné zariadenie [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
Základné UDI-DI <i>Basic UDI-DI</i>	06301400000000000001546G 063014000000000000005436X
EMDN	Z120607
Kód výrobku, obchodný názov a popis <i>Product Code, Trade Name and Description</i>	Pozrite si Prílohu I Refer to Attachment 1
Zamýšľaný účel <i>Intended Purpose</i>	Ovládače Kendall SCD sú určené na aplikáciu prerušovanej pneumatickej kompresie s cieľom zvýšiť prietok venóznej krvi u rizikových pacientov s cieľom zabrániť hlbokkej žilovej trombóze a pľúcnej embólii. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Klasifikácia a pravidlo <i>Classification and Rule</i>	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9
Bežné špecifikácie <i>Common Specifications</i>	Nevzťahuje sa Not Applicable

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VYHLÁSENIE O ZHODE <i>DECLARATION OF CONFORMITY</i>	
V prípade potreby doplňte príslušné právne predpisy Únie <i>Where appropriate, add applicable Union legislation</i>	Cardinal Health 200 LLC, Týmto vyhlasujeme, že uvedené zdravotnícke pomôcky sú v súlade s: RoHS 2011/65/EU
Posúdenie zhody <i>Conformity Assessment</i>	Príloha IX, kapitoly I a III/ Annex IX Chapters I and III

PODPISOVÁ SEKCIA <i>SIGNATURE SECTION</i>	
Toto vyhlásenie o zhode EÚ sa vydáva pre zákonného výrobcu, v jeho mene a na jeho výhradnú zodpovednosť.	
Miesto vydania <i>Place of Issue</i>	Waukegan, IL 60085 USA
Podpis/ Dátum <i>Signature/Date</i>	<u>Soumitra Shilotri</u> <small>Soumitra Shilotri (Mar 4, 2025 19:15 EST)</small>
Meno a pozícia <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Regulačné záležitosti

PRÍLOHU I
ATTACHMENT I

Zoznam kódov výrobkov <i>Product Code List</i>				
Kód výrobku <i>Product Code</i>	Obchodný názov a popis <i>Trade Name and Description</i>	Základné UDI-DI <i>Basic UDI-DI</i>	EMDN	Klasifikácia a pravidlo <i>Classification and Rule</i>
29525	Sekvenčný kompresný systém Kendall SCD 700 (s napájacím káblom pre USA) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	063014000000000000001546G	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9
295250	Sekvenčný kompresný systém Kendall SCD 700 (s napájacím káblom pre EÚ) <i>Kendall SCD 700 Sequential Compression System (with E.U. power cord)</i>	063014000000000000001546G	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9
295251	Sekvenčný kompresný systém Kendall SCD 700 (s napájacím káblom pre Spojené kráľovstvo)	063014000000000000001546G	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9

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Zoznam kódov výrobkov <i>Product Code List</i>				
	<i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>			
295255	Sekvenčný kompresný systém Kendall SCD 700 (s napájacím káblom pre Austráliu) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9
295257	Sekvenčný kompresný systém Kendall SCD 700 (s napájacím káblom pre Japonsko) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9
295258	Sekvenčný kompresný systém Kendall SCD 700 (s napájacím káblom pre Brazíliu) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9
295259	Sekvenčný kompresný systém Kendall SCD 700 (s napájacím káblom pre Indiu) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	063014000000000000001546G	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9
82100	Kompresný systém Kendall SCD SmartFlow s adaptérom pre napájací kábel pre EÚ <i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>	063014000000000000005436X	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9
82101	Kompresný systém Kendall SCD SmartFlow s adaptérom pre napájací kábel pre Spojené kráľovstvo <i>Kendall SCD SmartFlow Compression System with UK power cord adapter</i>	063014000000000000005436X	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9

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Zoznam kódov výrobkov <i>Product Code List</i>				
82102	Kompresný systém Kendall SCD SmartFlow s adaptérom pre napájací kábel pre Švajčiarsko <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9
82105	Kompresný systém Kendall SCD SmartFlow s adaptérom pre napájací kábel pre Austráliu <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9
82107	Kompresný systém Kendall SCD SmartFlow s adaptérom pre napájací kábel pre Japonsko <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>	06301400000000000005436X	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9
82108	Kompresný systém Kendall SCD SmartFlow s adaptérom pre napájací kábel pre Brazíliu <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9
82109	Kompresný systém Kendall SCD SmartFlow s adaptérom pre napájací kábel pre Indiu <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>	06301400000000000005436X	Z120607	Trieda: IIa Pravidlo: 9 Class: IIa Rule: 9

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SPANISH

DECLARACIÓN DE CONFORMIDAD DECLARATION OF CONFORMITY	
 CardinalHealth	MDR: Nosotros, Cardinal Health 200 LLC, declaramos que los productos contemplados en la presente Declaración de conformidad de la UE cumplen con la disposición del Reglamento sobre productos sanitarios (UE) 2017/745.
Número de declaración de conformidad <i>Declaration of Conformity Number</i>	RE00222095
Número de documentación técnica <i>Technical Documentation Number</i>	RE00217172
Nombre del fabricante <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Dirección del fabricante <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Número de registro único <i>Single Registration Number</i>	US-MF-000006765
Nombre y dirección del representante autorizado <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Nombre y número de identificación del organismo notificado <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Número de identificación: 2797
Número de certificado CE <i>CE Certificate Number</i>	MDR 784266
Categoría del product <i>Product Category</i>	Equipos de compresión neumática [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
UDI-DI básico <i>Basic UDI-DI</i>	0630140000000000000000001546G 0630140000000000000000005436X
EMDN	Z120607
Código del producto, nombre comercial y descripción <i>Product Code, Trade Name and Description</i>	Consulte el Archivo adjunto I Refer to Attachment 1
Propósito <i>Intended Purpose</i>	Los controladores Kendall SCD están diseñados para aplicar compresión neumática intermitente para aumentar el flujo sanguíneo venoso en pacientes que corren riesgo de desarrollar trombosis venosa profunda y embolia pulmonar, a fin de ayudar a prevenirlas. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Clasificación y regla <i>Classification and Rule</i>	Clase: IIa Regla: 9 Class: IIa Rule: 9

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DECLARACIÓN DE CONFORMIDAD <i>DECLARATION OF CONFORMITY</i>	
Especificaciones comunes <i>Common Specifications</i>	No corresponde Not Applicable
Cuando proceda, añade la legislación de la Unión Europea aplicable <i>Where appropriate, add applicable Union legislation</i>	Nosotros, Cardinal Health 200 LLC, por la presente declaramos que la lista de dispositivos médicos enumerados anteriormente cumplen con lo siguiente: RoHS 2011/65/EU
Evaluación de conformidad <i>Conformity Assessment</i>	Anexo IX capítulos I y III/ Annex IX Chapters I and III

SECCIÓN DE FIRMA <i>SIGNATURE SECTION</i>	
La presente Declaración de conformidad de la UE se emite para y en nombre de y bajo la responsabilidad exclusiva del fabricante que se identificó anteriormente.	
Lugar de emisión <i>Place of Issue</i>	Waukegan, IL 60085 USA
Firma / Fecha <i>Signature/Date</i>	 <small>Soumitra Shilotri (Mar 4, 2025 19:15 EST)</small>
Nombre y función <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Asuntos normativos

ARCHIVO ADJUNTO I
ATTACHMENT 1

Lista de códigos del product <i>Product Code List</i>				
Código del product <i>Product Code</i>	Nombre comercial y descripción <i>Trade Name and Description</i>	UDI-DI básico <i>Basic UDI-DI</i>	EMDN	Clasificación y regla <i>Classification and Rule</i>
29525	Sistema de compresión secuencial Kendall SCD 700 (con cable de alimentación de los EE. UU.) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	06301400000000000001546G	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9
295250	Sistema de compresión secuencial Kendall SCD 700 (con cable de alimentación de la UE) <i>Kendall SCD 700</i>	06301400000000000001546G	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9

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Lista de códigos del product <i>Product Code List</i>				
	<i>Sequential Compression System (with E.U. power cord)</i>			
295251	Sistema de compresión secuencial Kendall SCD 700 (con cable de alimentación del Reino Unido) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>	063014000000000000001546G	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9
295255	Sistema de compresión secuencial Kendall SCD 700 (con cable de alimentación de Australia) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	063014000000000000001546G	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9
295257	Sistema de compresión secuencial Kendall SCD 700 (con cable de alimentación de Japón) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	063014000000000000001546G	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9
295258	Sistema de compresión secuencial Kendall SCD 700 (con cable de alimentación de Brasil) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	063014000000000000001546G	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9
295259	Sistema de compresión secuencial Kendall SCD 700 (con cable de alimentación de India) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	063014000000000000001546G	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9
82100	Sistema de compresión Kendall SCD SmartFlow	063014000000000000005436X	Z120607	Clase: IIa Regla: 9 Class: IIa

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Lista de códigos del product <i>Product Code List</i>				
	con cable de alimentación de la UE <i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>			Rule: 9
82101	Sistema de compresión Kendall SCD SmartFlow con cable de alimentación del Reino Unido <i>Kendall SCD SmartFlow Compression System with UK power cord adapter</i>	06301400000000000005436X	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9
82102	Sistema de compresión Kendall SCD SmartFlow con cable de alimentación de Suiza <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9
82105	Sistema de compresión Kendall SCD SmartFlow con cable de alimentación de Australia <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9
82107	Sistema de compresión Kendall SCD SmartFlow con cable de alimentación de Japón <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>	06301400000000000005436X	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9
82108	Sistema de compresión Kendall SCD SmartFlow con cable de alimentación de Brasil <i>Kendall SCD SmartFlow Compression System with Brazil power cord adapter</i>	06301400000000000005436X	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9
82109	Sistema de compresión Kendall SCD SmartFlow con cable de alimentación de India <i>Kendall SCD SmartFlow Compression System with India power cord adapter</i>	06301400000000000005436X	Z120607	Clase: IIa Regla: 9 Class: IIa Rule: 9

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SWEDISH

FÖRSÄKRAN OM ÖVERENSSTÄMMELSE DECLARATION OF CONFORMITY	
 CardinalHealth	MDR: Vi, Cardinal Health 200 LLC, försäkrar härmed att produkterna som omfattas av denna EU-försäkran om överensstämmelse uppfyller bestämmelserna om medicintekniska produkter i förordning (EU) 2017/745.
Nummer på försäkran om överensstämmelse <i>Declaration of Conformity Number</i>	RE00222095
Nummer på teknisk documentation <i>Technical Documentation Number</i>	RE00217172
Tillverkarens namn <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Tillverkarens address <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Unikt registreringsnummer <i>Single Registration Number</i>	US-MF-000006765
Namn på auktoriserad representant och address <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Namn på anmält organ och identifikationsnummer <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identifikationsnummer: 2797
Nummer på CE-certifikat <i>CE Certificate Number</i>	MDR 784266
Produktkategori <i>Product Category</i>	Pneumatisk kompressionsutrustning [Z120607] <i>Pneumatic Compression Equipment [Z120607]</i>
Grundläggande UDI-DI <i>Basic UDI-DI</i>	06301400000000000000001546G 06301400000000000000005436X
EMDN	Z120607
Produktkod, handelsnamn och beskrivning <i>Product Code, Trade Name and Description</i>	medföljande dokument I Refer to Attachment 1
Avsedd användning <i>Intended Purpose</i>	Kendall SCD styrenheter är konstruerade för att applicera intermitternt pneumatisk kompression för att öka det venösa blodflödet hos riskpatienter och förhindra djup ventrombos och lungemboli. <i>The Kendall SCD Controllers is intended to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.</i>
Klassificering och regel <i>Classification and Rule</i>	Klass: IIa Regel: 9 Class: IIa Rule: 9

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FÖRSÄKRAN OM ÖVERENSSTÄMMELSE <i>DECLARATION OF CONFORMITY</i>	
Gemensamma specifikationer <i>Common Specifications</i>	Ej tillämpligt Not Applicable
Lägg till tillämplig EU-lagstiftning <i>Where appropriate, add applicable Union legislation</i>	Vi, Cardinal Health 200 LLC, försäkrar härmed att ovannämnda medicinteknisk(a) produkt(er) uppfyller kraven i: RoHS 2011/65/EU
Bedömning av överensstämmelse <i>Conformity Assessment</i>	Bilaga IX kapitel I och III/ Annex IX Chapters I and III

SEKTION FÖR UNDERSKRIFT <i>SIGNATURE SECTION</i>	
Denna EU-försäkran om överensstämmelse utfärdas för och på uppdrag av och under eget ansvar av den juridiska tillverkaren som anges ovan.	
Plats för utfärdande <i>Place of Issue</i>	Waukegan, IL 60085 USA
Underskrift/ Datum <i>Signature/Date</i>	<u>Soumitra Shilotri</u> <small>Soumitra Shilotri (Mar 4, 2025 19:15 EST)</small>
Namn och funktion <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Myndighetsärenden

DOKUMENT I
ATTACHMENT 1

Lista de códigos del product <i>Product Code List</i>				
Produktkod <i>Product Code</i>	Handelsnamn och beskrivning <i>Trade Name and Description</i>	Grundläggande UDI-DI <i>Basic UDI-DI</i>	EMDN	Klassificering och regel <i>Classification and Rule</i>
29525	Kendall SCD 700 Sequential kompressionssystem (med amerikansk nätsladd) <i>Kendall SCD 700 Sequential Compression System (with U.S. power cord)</i>	06301400000000000001546G	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9
295250	Kendall SCD 700 Sequential kompressionssystem (med EU-nätsladd) <i>Kendall SCD 700 Sequential</i>	06301400000000000001546G	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9

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Lista de códigos del product <i>Product Code List</i>				
	<i>Compression System (with E.U. power cord)</i>			
295251	Kendall SCD 700 Sequential kompressionssystem (med brittisk nätsladd) <i>Kendall SCD 700 Sequential Compression System (with U.K. power cord)</i>	06301400000000000001546G	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9
295255	Kendall SCD 700 Sequential kompressionssystem (med australiensisk nätsladd) <i>Kendall SCD 700 Sequential Compression System (with Australian power cord)</i>	06301400000000000001546G	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9
295257	Kendall SCD 700 Sequential kompressionssystem (med japansk nätsladd) <i>Kendall SCD 700 Sequential Compression System (with Japanese power cord)</i>	06301400000000000001546G	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9
295258	Kendall SCD 700 Sequential kompressionssystem (med brasiliansk nätsladd) <i>Kendall SCD 700 Sequential Compression System (with Brazilian power cord)</i>	06301400000000000001546G	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9
295259	Kendall SCD 700 Sequential kompressionssystem (med indisk nätsladd) <i>Kendall SCD 700 Sequential Compression System (with India power cord)</i>	06301400000000000001546G	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9
82100	Kendall SCD SmartFlow kompressionssystem	06301400000000000005436X	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9

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Lista de códigos del product <i>Product Code List</i>				
	med EU adapter till nätsladd <i>Kendall SCD SmartFlow Compression System with EU power cord adapter</i>			
82101	Kendall SCD SmartFlow kompressionssystem med brittisk adapter till nätsladd <i>Kendall SCD SmartFlow Compression System with UK power cord adapter</i>	06301400000000000005436X	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9
82102	Kendall SCD SmartFlow kompressionssystem med schweizisk adapter till nätsladd <i>Kendall SCD SmartFlow Compression System with Swiss power cord adapter</i>	06301400000000000005436X	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9
82105	Kendall SCD SmartFlow kompressionssystem med australiensisk adapter till nätsladd <i>Kendall SCD SmartFlow Compression System with Australia power cord adapter</i>	06301400000000000005436X	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9
82107	Kendall SCD SmartFlow kompressionssystem med japansk adapter till nätsladd <i>Kendall SCD SmartFlow Compression System with Japan power cord adapter</i>	06301400000000000005436X	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9
82108	Kendall SCD SmartFlow kompressionssystem	06301400000000000005436X	Z120607	Klass: IIa Regel: 9 Class: IIa

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Lista de códigos del product <i>Product Code List</i>				
	med brasiliansk adapter till nätsladd <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with Brazil power cord</i> <i>adapter</i>			Rule: 9
82109	Kendall SCD SmartFlow kompressionssystem med indisk adapter till nätsladd <i>Kendall SCD</i> <i>SmartFlow</i> <i>Compression System</i> <i>with India power cord</i> <i>adapter</i>	06301400000000000005436X	Z120607	Klass: IIa Regel: 9 Class: IIa Rule: 9

RE00222095

Final Audit Report

2025-03-05

Created:	2025-03-04
By:	Rabiya Shahid (rabiya.shahid@cardinalhealth.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAIvD1yvePuP91DAm0rQCq8ToP9ctIZ11t

"RE00222095" History

-  Document created by Rabiya Shahid (rabiya.shahid@cardinalhealth.com)
2025-03-04 - 9:51:43 PM GMT- IP address: 134.238.146.199
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2025-03-04 - 10:01:42 PM GMT
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