


DOC. TITLE: Declaration of Conformity MDR Kangaroo Enteral Feeding Pump Sets CAH			
DOCUMENT NO:	RE00184096	REVISION:	1

DECLARATION OF CONFORMITY

 CardinalHealth		MDR: We, Cardinal Health 200 LLC, declare that the products covered in this EU Declaration of Conformity meet the provision of the Medical Device Regulation (EU) 2017/745.
Declaration of Conformity Number	RE00184096	
Technical Documentation Number	RE00167844	
Manufacturer's Name	Cardinal Health 200, LLC	
Manufacturer's Address	3651 Birchwood Drive Waukegan, IL 60085 USA	
Single Registration Number	US-MF-000006765	
Authorized Representative's Name and Address	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland	
Notified body's Name and Identification Number	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identification Number: 2797	
CE Certificate Number	MDR 784266	
Product Category	Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use	
Basic UDI-DI	Refer to Attachment 1	
EMDN	Refer to Attachment 1	
Product Code, Trade Name and Description	Refer to Attachment 1	
Intended Purpose	Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.	
Classification and Rule	Refer to Attachment 1	
Common Specifications	Not Applicable	
Where appropriate, add applicable Union legislation	Not Applicable (N/A)	
Conformity Assessment	Annex IX Chapters I and III	

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SIGNATURE SECTION	
This EU Declaration of Conformity is issued for and on behalf of and under the sole responsibility of the Legal Manufacturer identified above.	
Place of Issue	Waukegan, IL 60085 USA
Signature/ Date	onically signed by: Zafirios Gourgouliatos n: Approved Nov 27, 2024 11:37 PST
Name and Function	Zafirios Gourgouliatos Regulatory Affairs

ATTACHMENT 1

Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
666064	Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Classification: IIa Rule: 2
666106	Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Classification: IIa Rule: 2
672055	Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Classification: IIa Rule: 2
673656	Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Classification: IIa Rule: 2
673662	ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Classification: IIa Rule: 2
668104	Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Classification: IIa Rule: 2
776150	Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Classification: IIa Rule: 2
777056	Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Classification: IIa Rule: 2
777064	Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Classification: IIa Rule: 2
777106	Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Classification: IIa Rule: 2
777163	Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Classification: IIa Rule: 2


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Product Code List				
777401	Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Classification: IIa Rule: 2
777402	Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Classification: IIa Rule: 2
777403	Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Classification: IIa Rule: 2
777405	Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Classification: IIa Rule: 2
777406	Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Classification: IIa Rule: 2
777407	Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Classification: IIa Rule: 2
777408	Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set	063014000000000000001736L	A080101	Classification: IIa Rule: 2
777501	Kangaroo Joey ENPlus Spike Set	063014000000000000001776U	A080101	Classification: IIa Rule: 2
777502	Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Classification: IIa Rule: 2
777503	Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Classification: IIa Rule: 2
777505	Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Classification: IIa Rule: 2
777506	Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Classification: IIa Rule: 2
778104	Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Classification: IIa Rule: 2
778161	Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Classification: IIa Rule: 2
1814717995	Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Classification: IIa Rule: 2

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CROATIAN

IZJAVA O SUKLADNOSTI DECLARATION OF CONFORMITY

 CardinalHealth		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>	RE00184096	
Broj tehničke dokumentacije <i>Technical Documentation Number</i>	RE00167844	
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>	Vrećice i spremnici za enteralno hranjenje (uključujući i hranjenje pomoću pumpe) za jednokratnu uporabu Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use	
Osnovni UDI-DI <i>Basic UDI-DI</i>	Pogledajte Prilog I/ Refer to Attachment 1	
EMDN	Pogledajte Prilog I/ Refer to Attachment 1	
Kôd, trgovački naziv i opis proizvoda <i>Product Code, Trade Name and Description</i>	Pogledajte Prilog I/ Refer to Attachment 1	
Namjena <i>Intended Purpose</i>	Kompleti pumpi za enteralno hranjenje Kangaroo namijenjeni su za primjenu u pacijenata s bilo kojim stanjem koje zahtijeva enteralnu prehranu i/ili enteralnu hidrataciju, što se može postići pomoću pumpe za enteralno hranjenje i kompleta pumpe. Pumpa i kompleti za hranjenje namijenjeni su za korištenje u alternativnoj, akutnoj i kućnim njezi koju pružaju korisnici od laika do kliničara. Svrha ovog proizvoda je isporučiti enteralnu prehranu kontroliranom brzinom pacijentima koji imaju netaknuti gastrointestinalni trakt.	

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IZJAVA O SUKLADNOSTI
DECLARATION OF CONFORMITY

	Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.
Klasifikacija i pravilo <i>Classification and Rule</i>	Pogledajte Prilog I/ Refer to Attachment 1
Zajedničke specifikacije <i>Common Specifications</i>	Nije primjenjivo (N/A)
Dodajte primjenjivo zakonodavstvo Europske unije, gdje je to prikladno <i>Where appropriate, add applicable Union legislation</i>	Nije primjenjivo (N/A)
Ocjena sukladnosti <i>Conformity Assessment</i>	Prilog IX. Poglavlja I. i III./ Annex IX Chapters I and III

ODJELJAK S POTPISIMA
SIGNATURE SECTION

Ova Izjava o sukladnosti EU izdaje se za i u ime te na isključivu odgovornost prethodno navedenog zakonitog proizvođača.	
Mjesto izdavanja <i>Place of Issue</i>	Waukegan, IL 60085 USA
Potpis/ Datum <i>Signature/ Date</i>	ally signed by: Zafirios Gourgouliatos Approved 27. 2024 11:37 PST
Ime i funkcija <i>Name and Function</i>	Zafirios Gourgouliatos Regulatory Affairs Odjel za regulatorna pitanja

PRILOG I
ATTACHMENT I

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>
666064	Komplet Kangaroo Joey 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2

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Popis kodova proizvoda <i>Product Code List</i>				
666106	Komplet Kangaroo Joey 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
672055	Komplet Kangaroo Epump protiv slobodnog protoka 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
673656	Komplet Kangaroo Epump protiv slobodnog protoka 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
673662	ePUMP INT. 1000 mL FEED & FLUSH NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
668104	Komplet za hranjenje i ispiranje Kangaroo Joey 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
776150	Kangaroo Epump i komplet bireta za recertifikaciju Joey Burette 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777056	Komplet bireta Kangaroo ePump 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777064	Komplet Kangaroo ePump 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777106	Komplet Kangaroo ePump 1000 mL Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2

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Popis kodova proizvoda <i>Product Code List</i>				
777163	Komplet Kangaroo ePump 1600 mL Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777401	Kangaroo ePump, komplet šiljaka ENPlus Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777402	Kangaroo ePump, komplet šiljaka Dual ENPlus Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777403	Kangaroo ePump, komplet 3-u-1 ENPlus Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777405	Kangaroo ePump, šiljak ENPlus, vrećica za hranjenje i ispiranje od 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777406	Kangaroo ePump, šiljak 3-u-1 ENPlus, vrećica za hranjenje i ispiranje od 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777407	Kangaroo ePump, šiljak za hranjenje ENPlus i komplet šiljka za ispiranje s odzračnikom Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777408	Kangaroo ePump, komplet za hranjenje i ispiranje 3-u-1 ENPlus Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777501	Kangaroo Joey, komplet šiljaka ENPlus	063014000000000000001776U	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2


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Popis kodova proizvoda <i>Product Code List</i>				
	Kangaroo Joey ENPlus Spike Set			
777502	Kangaroo Joey, komplet šiljaka Dual ENPlus Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777503	Kangaroo Joey, komplet 3-u-1 ENPlus Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777505	Kangaroo Joey, šiljak ENPlus, vrećica za hranjenje i ispiranje od 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
777506	Kangaroo Joey, vrećica za hranjenje i ispiranje 3-u-1 ENPlus Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
778104	Kangaroo ePump, vrećica za hranjenje i ispiranje od 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
778161	Kangaroo ePump, vrećica za hranjenje i ispiranje od 1600 mL / 1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2
1814717995	Adaper za Kangaroo 3-u-1 Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Klasa/ Class: IIa Pravilo/ Rule: 2

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CZECH

PROHLÁŠENÍ O SHODĚ DECLARATION OF CONFORMITY

 CardinalHealth	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>	RE00184096
Číslo technické dokumentace <i>Technical Documentation Number</i>	RE00167844
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>	Vaky a nádoby pro enterální výživu (včetně vaků a nádob s pumpou), jednorázové použití Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
Základní UDI-DI <i>Basic UDI-DI</i>	Viz Příloha I / Refer to Attachment 1
EMDN	Viz Příloha I / Refer to Attachment 1
Kód, obchodní název a popis výrobku <i>Product Code, Trade Name and Description</i>	Viz Příloha I / Refer to Attachment 1
Účel použití <i>Intended Purpose</i>	Soupravy enterální výživové pumpy Kangaroo jsou určeny pro použití u pacientů s jakýmkoli stavem vyžadujícím enterální podávání výživy a/nebo tekutin prostřednictvím enterální výživové pumpy a soupravy pumpy. Pumpa a souprava pro podávání výživy jsou určeny k použití v alternativních, akutních a domácích zařízeních uživateli, kteří mimo jiné zahrnují laiky nebo lékaře. Účelem tohoto prostředku je podávání enterální výživy řízeným průtokem pacientům s nedotčeným gastrointestinálním traktem.

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PROHLÁŠENÍ O SHODĚ
DECLARATION OF CONFORMITY

	Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.
Klasifikace a pravidlo <i>Classification and Rule</i>	Viz Příloha I / Refer to Attachment 1
Obecná specifikace <i>Common Specifications</i>	Nelze uplatnit (N/A)
Dle potřeby doplňte příslušný předpis Unie <i>Where appropriate, add applicable Union legislation</i>	Nelze uplatnit (N/A)
Posouzení shody <i>Conformity Assessment</i>	Příloha IX, kapitoly I a III/ Annex IX Chapters I and III

PODPISOVÁ ČÁST
SIGNATURE SECTION

Toto EU prohlášení o shodě se vydává jménem a na výhradní odpovědnost oprávněného výrobce uvedeného výše.	
Místo vydání <i>Place of Issue</i>	Waukegan, IL 60085 USA
Podpis / Datum <i>Signature/ Date</i>	ly signed by: Zafirios Gourgouliatos proved 7. 2024 11:37 PST
Jméno a funkce <i>Name and Function</i>	Regulatory Affairs Oddělení regulačních záležitostí

PŘÍLOHA I
ATTACHMENT 1

Seznam kódů výrobků
Product Code List

Kód výrobku <i>Product Code</i>	Obchodní název a popis <i>Trade Name and Description</i>	Základní UDI-DI <i>Basic UDI-DI</i>	EMDN	Klasifikace a pravidlo <i>Classification and Rule</i>
666064	Souprava Kangaroo Joey 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2

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Seznam kódů výrobků <i>Product Code List</i>				
666106	Souprava Kangaroo Joey 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
672055	Souprava Kangaroo Epump Anti- free Flow 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
673656	Souprava Kangaroo Epump Anti- free Flow 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
673662	ePUMP INT. 1000 mL VÝŽIVA A PROPLACH NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
668104	Souprava Kangaroo Joey, výživa a proplach 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
776150	Recertifikační souprava Kangaroo Epump a byreta Joey 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777056	Souprava byrety Kangaroo ePump 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777064	Souprava Kangaroo ePump 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777106	Souprava Kangaroo ePump 1000 mL Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2

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Seznam kódů výrobků Product Code List				
777163	Souprava Kangaroo ePump 1600 mL Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777401	Kangaroo ePump, souprava bodců ENPlus Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777402	Kangaroo ePump Dual, souprava bodců ENPlus Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777403	Kangaroo ePump ENPlus, souprava 3v1 Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777405	Kangaroo ePump ENPlus, výživový a proplachovací vak s bodcem 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777406	Kangaroo ePump ENPlus, výživový a proplachovací vak 3v1 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777407	Kangaroo ePump ENPlus, výživová a proplachovací souprava s bodcem Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777408	Kangaroo ePump ENPlus, výživová a proplachovací souprava 3v1 Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2


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Seznam kódů výrobků <i>Product Code List</i>				
777501	Kangaroo Joey, souprava bodců ENPlus Kangaroo Joey ENPlus Spike Set	063014000000000000001776U	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777502	Kangaroo Joey Dual, souprava bodců ENPlus Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777503	Kangaroo Joey ENPlus, souprava 3v1 Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777505	Kangaroo Joey ENPlus, výživový a proplachovací vak s bodcem 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
777506	Kangaroo Joey ENPlus, výživový a proplachovací vak 3v1 Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
778104	Kangaroo ePump, výživový a proplachovací vak 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
778161	Kangaroo ePump, výživový a proplachovací vak 1600 mL / 1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2
1814717995	Adaptér Kangaroo 3v1 Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Třída/ Class: IIa Pravidlo/ Rule: 2

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DANISH

PROHLÁŠENÍ O SHODĚ
DECLARATION OF CONFORMITY

 CardinalHealth		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>	RE00184096	
Teknisk dokumentationsnummer <i>Technical Documentation Number</i>	RE00167844	
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>	Poser og beholdere til enteral ernæring (inkl. via pumpe), engangsbrug Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use	
Grundlæggende UDI-DI <i>Basic UDI-DI</i>	Se bilag I / Refer to Attachment 1	
EMDN	Se bilag I / Refer to Attachment 1	
Produktkode(r), handelsnavn og beskrivelse <i>Product Code, Trade Name and Description</i>	Se bilag I / Refer to Attachment 1	
Tiltænkt formål <i>Intended Purpose</i>	Kangaroo enteral ernæringspumpesæt er beregnet til brug hos patienter med tilstande, der kræver enteral ernæring og/eller enteral hydrering, hvilket kan opnås ved hjælp af en enteral ernæringspumpe og et pumpesæt. Pumpe og tilførselssæt er beregnet til at blive brugt skiftevis ved akut behandling og hjemmepleje af brugere uden specialviden såvel som klinikere. Formålet med denne enhed er at levere enteral ernæring til patienter med en intakt mave-tarm-kanal med en kontrolleret hastighed.	

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PROHLÁŠENÍ O SHODĚ
DECLARATION OF CONFORMITY

	Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.
Klassificering og regel <i>Classification and Rule</i>	Se bilag I / Refer to Attachment 1
Fælles specifikationer <i>Common Specifications</i>	Ikke relevant (N/A)
Hvor relevant, tilføj gældende union-lovgivning <i>Where appropriate, add applicable Union legislation</i>	Ikke relevant (N/A)
Overensstemmelsesvurdering <i>Conformity Assessment</i>	Bilag IX, kapitel I og III/ Annex IX Chapters I and III

SIGNATURAFSNIT
SIGNATURE SECTION

Denne EU-overensstemmelseserklæring er udstedt for og på vegne af og under eneansvar for den juridiske producent, der er identificeret ovenfor.	
Udstedelsessted <i>Place of Issue</i>	Waukegan, IL 60085 USA
Underskrift / Dato <i>Signature/ Date</i>	Electronically signed by: Zafirios Gourgouliatos on: Approved on: Nov 27, 2024 11:37 PST
Navn og funktion <i>Name and Function</i>	Zafirios Gourgouliatos Regulatory Affairs Lovgivningsanliggender

BILAG I
ATTACHMENT 1

Produktkodeliste Product Code List				
Produktkode <i>Product Code</i>	Handelsnavn og beskrivelse <i>Trade Name and Description</i>	Grundlæggende UDI-DI Basic <i>UDI-DI</i>	EMDN	Klassificering og regel <i>Classification and Rule</i>
666064	Kangaroo Joey-sæt 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2

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Produktkodeliste <i>Product Code List</i>				
666106	Kangaroo Joey-sæt 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
672055	Kænguru Epump-sæt med beskyttelse mod frit flow 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Klasse /Class: IIa Regel/ Rule: 2
673656	Kænguru Epump-sæt med beskyttelse mod frit flow 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Klasse /Class: IIa Regel/ Rule: 2
673662	ePUMP INT.1000 mL TILFØRSEL OG SKYLNING NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
668104	Kangaroo Joey-tilførsels- og skyllesæt 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
776150	Kangaroo Epump og Joey-burette recertificeringssæt 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Klasse /Class: IIa Regel/ Rule: 2
777056	Kangaroo ePump-burettesæt 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777064	Kangaroo ePump-sæt 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777106	Kangaroo Epump-sæt 1000 mL Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777163	Kangaroo Epump-sæt 1600 mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2

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Produktkodeliste <i>Product Code List</i>				
	Kangaroo ePump Set 1600mL			
777401	Kangaroo ePump ENPlus-sæt med spike Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777402	Kangaroo ePump Dual ENPlus-sæt med spike Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777403	Kangaroo ePump ENPlus 3-i-1-sæt Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777405	Kangaroo ePump ENPlus-tilførsels- og skyllepose med spike 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777406	Kangaroo ePump ENPlus 3-i-1-tilførsels- og skyllepose 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777407	Kangaroo ePump ENPlus-tilførselssæt med spike og skyllesæt med ventileret spike Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777408	Kangaroo ePump ENPlus 3-i-1-tilførsels- og skyllesæt Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777501	Kangaroo Joey ENPlus-sæt med spike Kangaroo Joey ENPlus Spike Set	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
777502	Kangaroo Joey Dual ENPlus-sæt	063014000000000000001776U	A080101	Klasse /Class: IIa

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Produktkodeliste <i>Product Code List</i>				
	med spike Kangaroo Joey Dual ENPlus Spike Set			Regel/ Rule: 2
777503	Kangaroo Joey ENPlus 3-i-1-sæt Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
777505	Kangaroo Joey ENPlus-tilførsels- og skyllepose med spike 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
777506	Kangaroo Joey ENPlus 3-i-1-tilførsels- og skyllepose Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
778104	Kangaroo ePump-tilførsels- og skyllepose 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
778161	Kangaroo ePump-tilførsels- og skyllepose 1600 mL / 1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
1814717995	Kangaroo 3-i-1-adapter Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Klasse /Class: IIa Regel/ Rule: 2

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DUTCH

CONFORMITEITSVERKLARING DECLARATION OF CONFORMITY



CardinalHealth

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

Nummer conformiteitsverklaring <i>Declaration of Conformity Number</i>	RE00184096
Nummer technische documentatie <i>Technical Documentation Number</i>	RE00167844
Naam fabrikant <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Adres van de fabrikant <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Enkel registratienummer <i>Single Registration Number</i>	US-MF-000006765
Naam en adres van de erkende vertegenwoordiger <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Naam en identificatienummer van de aangemelde instantie <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identificatienummer: 2797
Nummer CE-markering <i>CE Certificate Number</i>	MDR 784266
Productcategorie <i>Product Category</i>	Enterale voedingszakken en containers (ook voor gebruik in combinatie met pompen) voor eenmalig gebruik Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
Basis UDI-DI <i>Basic UDI-DI</i>	Zie Bijlage I/ Refer to Attachment 1
EMDN	Zie Bijlage I/ Refer to Attachment 1
Productcode, handelsnaam en beschrijving <i>Product Code, Trade Name and Description</i>	Zie Bijlage I/ Refer to Attachment 1
Beoogd doel <i>Intended Purpose</i>	De enterale-voedingspompsets van Kangaroo zijn bedoeld voor gebruik bij patiënten met een aandoening waarbij enterale voeding en/of enterale hydratatie is vereist. Dit kan worden bereikt door middel van een enterale-voedingspomp en een pompset. De pomp en voedingstoedieningssets zijn bedoeld voor gebruik in de alternatieve, acute en thuiszorgomgeving door zowel leken als medische professionals. Het doel van dit hulpmiddel is het

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CONFORMITEITSVERKLARING
DECLARATION OF CONFORMITY

	gecontroleerd toedienen van enterale voeding aan patiënten met een intact maag-darmkanaal. Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.
Classificatie en regel <i>Classification and Rule</i>	Zie Bijlage I/ Refer to Attachment 1
Algemene specificities <i>Common Specifications</i>	Niet van toepassing (N/A)
Voeg, indien van toepassing, de toepasselijke wetgeving van de Unie toe <i>Where appropriate, add applicable Union legislation</i>	Niet van toepassing (N/A)
Conformiteitsbeoordeling <i>Conformity Assessment</i>	Bijlage IX Hoofdstuk I en III/ Annex IX Chapters I and III

HANDTEKENINGGEDEELTE
SIGNATURE SECTION

Deze EU-conformiteitsverklaring wordt voor en namens en uitsluitend onder de verantwoordelijkheid van de fabrikant afgegeven.	
Plaats van afgifte <i>Place of Issue</i>	Waukegan, IL 60085 USA
Handtekening/Da <i>Signature/ Date</i>	Electronically signed by: Zafirios Gourgouliatos Reason: Approved Date: Nov 27, 2024 11:37 PST
Naam en functie <i>Name and Function</i>	Zafirios Gourgouliatos Regulatory Affairs Regelgevingszaken

BIJLAGE I
ATTACHMENT I

Produktkodeliste
Product Code List

Productcode <i>Product Code</i>	Handelsnaam en beschrijving <i>Trade Name and Description</i>	Basis UDI-DI <i>Basic UDI-DI</i>	EMDN	Classificatie en regel <i>Classification and Rule</i>
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Produktkodeliste <i>Product Code List</i>				
666064	Kangaroo Joey-set, 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
666106	Kangaroo Joey-set, 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
672055	Kangaroo Epump-set met Anti-Free-Flow-beveiliging, 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Klasse /Class: IIa Regel/ Rule: 2
673656	Kangaroo Epump-set met Anti-Free-Flow-beveiliging, 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Klasse /Class: IIa Regel/ Rule: 2
673662	ePUMP INT. 1000 mL VOEDINGSTOEDIENING en SPOELING NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
668104	Kangaroo Joey-set voor voedingstoediening en spoelen, 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
776150	Hercertificeringsset voor Kangaroo Epump en Joey Burette, 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Klasse /Class: IIa Regel/ Rule: 2
777056	Kangaroo ePump-buretset, 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777064	Kangaroo ePump-set, 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2

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Produktkodeliste <i>Product Code List</i>				
777106	Kangaroo ePump-set, 1000 mL Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777163	Kangaroo ePump-set, 1600 mL Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777401	Kangaroo ePump ENPlus- aanprikset Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777402	Kangaroo ePump dubbele ENPlus-aanprikset Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777403	Kangaroo ePump ENPlus 3-in-1 set Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777405	Kangaroo ePump ENPlus- voedings- en spoelzakje met spike, 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777406	Kangaroo ePump ENPlus 3-in-1 voedings- en spoelzakje met spike, 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777407	Kangaroo ePump ENPlus- voedingszak met spike en spoelset met beluchtingsspike Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
777408	Kangaroo ePump ENPlus 3-in-1 voedings- en spoelset Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2


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Produktkodeliste <i>Product Code List</i>				
777501	Kangaroo Joey ENPlus-aanprikset Kangaroo Joey ENPlus Spike Set	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
777502	Kangaroo Joey dubbele ENPlus-aanprikset Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
777503	Kangaroo Joey ENPlus 3-in-1 set Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
777505	Kangaroo Joey ENPlus-voedings- en spoelzakje met spike, 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
777506	Kangaroo Joey ENPlus 3-in-1 voedings- en spoelzak Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Klasse /Class: IIa Regel/ Rule: 2
778104	Kangaroo ePump-voedings- en spoelzakje met spike, 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
778161	Kangaroo ePump-voedings- en spoelzakje met spike, 1600 mL / 1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Klasse /Class: IIa Regel/ Rule: 2
1814717995	Kangaroo 3-in-1 adapter Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Klasse /Class: IIa Regel/ Rule: 2

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FINNISH

VAATIMUSTENMUKAISUUSVAKUUTUS DECLARATION OF CONFORMITY

 MDR: Me, Cardinal Health 200 LLC, vakuutamme, että tässä EU-vaatimustenmukaisuusvakuutuksessa kuvatut tuotteet täyttävät lääkintälaitteasetuksen (EU) 2017/745 vaatimukset.	
VAATIMUSTENMUKAISUUSVAKUUTUS <i>Declaration of Conformity Number</i>	RE00184096
Teknisen dokumentin numero <i>Technical Documentation Number</i>	RE00167844
Valmistajan nimi <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
Valmistajan osoite <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
Yksittäinen rekisterinumero <i>Single Registration Number</i>	US-MF-000006765
Valtuutetun edustajan nimi ja osoite <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Ilmoitetun laitoksen nimi ja tunnusnumero <i>Notified body's Name and Identification Number</i>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Tunnusnumero: 2797
CE-sertifikaatin numero <i>CE Certificate Number</i>	MDR 784266
Tuotekategoria <i>Product Category</i>	Enteraaliset ravintopussit ja -säiliöt (myös pumpulla käytettävät), kertakäyttöiset Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
Yksilöllinen laitemallin tunniste (Basic UDI-DI) <i>Basic UDI-DI</i>	Katso liite I/ Refer to Attachment 1
EMDN	Katso liite I/ Refer to Attachment 1
Tuotekoodi, kaupp nimi ja kuvaus <i>Product Code, Trade Name and Description</i>	Katso liite I/ Refer to Attachment 1
Käyttötarkoitus <i>Intended Purpose</i>	Enteraaliset Kangaroo-ruokintapumppusarjat on tarkoitettu käytettäväksi potilaille, jotka vaativat enteraalista ruokintaa ja/tai enteraalista nesteytystä, joka voidaan toteuttaa enteraalilla ruokintapumpulla ja pumppusarjalla. Pumppu- ja ruokintasarjat on tarkoitettu käytettäväksi vaihtoehtoisissa hoitolaitoksissa, akuutteisairaanhoidossa ja kotisairaanhoidossa. Niitä saavat käyttää sekä maallikot että lääkärit. Tämän laitteen tarkoituksena on antaa enteraalista ravintoa hallitusti potilaille, joiden maha-suolikanava on

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VAATIMUSTENMUKAISUUSVAKUUTUS DECLARATION OF CONFORMITY	
	<p>ehjä.</p> <p>Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.</p>
Luokittelu ja sääntö <i>Classification and Rule</i>	Katso liite I/ Refer to Attachment 1
Yleiset tekniset tiedot <i>Common Specifications</i>	Ei sovellu (N/A)
Lisää tarvittaessa soveltuva unionin lainsäädäntö <i>Where appropriate, add applicable Union legislation</i>	Ei sovellu (N/A)
Vaatimustenmukaisuuden arviointi <i>Conformity Assessment</i>	Liite IX kappaleet I ja III/ Annex IX Chapters I and III

ALLEKIRJOITUSOSIO SIGNATURE SECTION	
Tämä EU-vaatimustenmukaisuusvakuutus on annettu edellä mainitun laillisen valmistajan puolesta ja sen omalla, yksinomaisella vastuulla.	
Paikka <i>Place of Issue</i>	Waukegan, IL 60085 USA
Allekirjoitus/ Päivämäärä <i>Signature/ Date</i>	<p><i>Electronically signed by: Zafirios Gourgouliatos</i></p> <p><i>Reason: Approved</i></p> <p><i>Date: Nov 27, 2024 11:37 PST</i></p>
Nimi ja asema <i>Name and Function</i>	<p>Zafirios Gourgouliatos</p> <p>Regulatory Affairs</p> <p>Sääntelyasiat</p>

LIITE I
ATTACHMENT I

Tuotekoodiluettelo Product Code List				
Tuotekoodi <i>Product Code</i>	Kauppanimi ja kuvaus <i>Trade Name and Description</i>	Yksilöllinen laitemallin tunniste (Basic UDI-DI) Basic UDI-DI	EMDN	Luokittelu ja sääntö <i>Classification and Rule</i>

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Tuotekoodiluettelo <i>Product Code List</i>				
666064	Kangaroo Joey -sarja, 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
666106	Kangaroo Joey -sarja, 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
672055	Kangaroo Epump -sarja, vapaan virtauksen estävä, 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
673656	Kangaroo Epump -sarja, vapaan virtauksen estävä, 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
673662	ePUMP INT., 1000 mL, RUOKINTA JA HUUHTELU, NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
668104	Kangaroo Joey -ruokinta- ja huuhtelusarja, 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
776150	Kangaroo Epump- ja Joey -byretin uudelleensertifiointisarja, 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777056	Kangaroo ePump -byrettisarja, 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777064	Kangaroo ePump -sarja, 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777106	Kangaroo ePump -sarja, 1000 mL Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2

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Tuotekoodiluettelo <i>Product Code List</i>				
777163	Kangaroo ePump -sarja, 1600 mL Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777401	Kangaroo ePump ENPlus Spike - liitinsarja Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777402	Kangaroo ePump Dual ENPlus Spike -liitinsarja Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777403	Kangaroo ePump ENPlus 3-in-1 - sarja Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777405	Kangaroo ePump ENPlus Spike - ruokinta- ja huuhtelupussi, 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777406	Kangaroo ePump ENPlus 3-in-1 - ruokinta- ja huuhtelupussi, 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777407	Kangaroo ePump ENPlus Spike - ruokintasarja ilmastetulla piikkihuuhtelulla Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777408	Kangaroo ePump ENPlus 3-in-1 - ruokinta- ja huuhtelusarja Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777501	Kangaroo Joey ENPlus Spike - liitinsarja	063014000000000000001776U	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2


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Tuotekoodiluettelo <i>Product Code List</i>				
	Kangaroo Joey ENPlus Spike Set			
777502	Kangaroo Joey Dual ENPlus Spike -liitinsarja Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777503	Kangaroo Joey ENPlus 3-in-1 -sarja Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777505	Kangaroo Joey ENPlus Spike -ruokinta- ja huuhtelupussi, 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
777506	Kangaroo Joey ENPlus 3-in-1 -ruokinta- ja huuhtelupussi Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
778104	Kangaroo ePump -ruokinta- ja huuhtelupussi, 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
778161	Kangaroo ePump -ruokinta- ja huuhtelupussi, 1600 mL / 1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2
1814717995	Kangaroo -3-in-1-sovitin Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Luokka/ Classification: IIa Sääntö/ Rule: 2

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FRENCH

DÉCLARATION DE CONFORMITÉ DECLARATION OF CONFORMITY

 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>	RE00184096
Numéro de la documentation technique <i>Technical Documentation Number</i>	RE00167844
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>	Poches et récipients d'alimentation entérale (y compris ceux à pompe) à usage unique Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
UDI-DI de base <i>Basic UDI-DI</i>	Voir PJ I/ Refer to Attachment 1
EMDN	Voir PJ I/ Refer to Attachment 1
Code, nom commercial et description du produit <i>Product Code, Trade Name and Description</i>	Voir PJ I/ Refer to Attachment 1
Usage prévu <i>Intended Purpose</i>	Les kits de pompes d'alimentation entérale Kangaroo sont destinés aux patients dont l'état exige l'alimentation ou l'hydratation entérale, ce qui est possible par l'entremise d'un système d'alimentation entérale, d'une pompe et d'un groupe pompe. La pompe et les kits d'alimentation sont prévus pour une utilisation dans des environnements de soins alternatifs, actifs et à domicile par des utilisateurs allant des profanes aux cliniciens.

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DÉCLARATION DE CONFORMITÉ DECLARATION OF CONFORMITY	
	<p>Ce dispositif administre de la nutrition entérale à un débit contrôlé aux patients dont le tractus gastro-intestinal est intact.</p> <p>Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.</p>
Classification et règle <i>Classification and Rule</i>	Voir PJ I/ Refer to Attachment 1
Caractéristiques communes <i>Common Specifications</i>	Sans objet (N/A)
Le cas échéant, ajouter la législation de l'Union européenne en vigueur <i>Where appropriate, add applicable Union legislation</i>	Sans objet (N/A)
Évaluation de la conformité <i>Conformity Assessment</i>	Annexe IX, Chapitres I et III/ Annex IX Chapters I and III

SECTION SIGNATURE SIGNATURE SECTION	
La présente déclaration de conformité de l'Union européenne est établie pour, au nom de et sous la seule responsabilité du fabricant légal identifié plus haut.	
Lieu de délivrance <i>Place of Issue</i>	Waukegan, IL 60085 USA
Signature/Date <i>Signature/Date</i>	<p>Electronically signed by: Zafirios Gourgouliatos Reason: Approved Date: Nov 27, 2024 11:37 PST</p>
Nom et fonction <i>Name and Function</i>	<p>Zafirios Gourgouliatos Regulatory Affairs Affaires réglementaires</p>

PJ I
ATTACHMENT I

Liste de référence produit Product Code List				
Code du produit <i>Product Code</i>	Nom commercial et description du produit <i>Trade Name and Description</i>	UDI-DI de base <i>Basic UDI-DI</i>	EMDN	Classification et règle <i>Classification and Rule</i>

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Liste de référence produit
Product Code List

666064	Tubulure Kangaroo Joey 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Classification/ Classification: IIa Règle/ Rule: 2
666106	Tubulure Kangaroo Joey 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Classification/ Classification: IIa Règle/ Rule: 2
672055	Tubulure pour pompe Kangaroo Epump, anti-écoulement libre, 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Classification/ Classification: IIa Règle/ Rule: 2
673656	Tubulure pour pompe Kangaroo Epump, anti-écoulement libre, 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Classification/ Classification: IIa Règle/ Rule: 2
673662	ePUMP INT.1000 mL, ALIMENTATION ET RINÇAGE NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2
668104	Kit d'alimentation et de rinçage Kangaroo Joey 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Classification/ Classification: IIa Règle/ Rule: 2
776150	Tubulure de recertification avec burette pour pompe Kangaroo Epump et Joey, 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777056	Tubulure avec burette pour pompe Kangaroo Epump, 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777064	Tubulure pour pompe Kangaroo ePump, 500 mL	063014000000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2

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Liste de référence produit <i>Product Code List</i>				
	Kangaroo ePump Set 500mL			
777106	Tubulure pour pompe Kangaroo ePump, 1000 mL Kangaroo ePump Set 1000mL	06301400000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777163	Tubulure pour pompe Kangaroo ePump, 1600 mL Kangaroo ePump Set 1600mL	06301400000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777401	Jeu de perforateur ENPlus Kangaroo ePump Kangaroo ePump ENPlus Spike Set	06301400000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777402	Jeu de perforateur Dual ENPlus Kangaroo ePump Kangaroo ePump Dual ENPlus Spike Set	06301400000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777403	Jeu 3 en 1 ENPlus Kangaroo ePump Kangaroo ePump ENPlus 3-in-1 Set	06301400000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777405	Poche d'alimentation et de rinçage avec perforateur ENPlus Kangaroo ePump, 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	06301400000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777406	Poche d'alimentation et de rinçage 3 en 1 ENPlus Kangaroo ePump, 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	06301400000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777407	Tubulure avec perforateur ENPlus pour la nutrition et perforateur avec prise d'air pour le rinçage de la pompe Kangaroo ePump Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	06301400000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2

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Liste de référence produit
Product Code List

777408	Tubulure d'alimentation et de rinçage 3 en 1 ENPlus Kangaroo ePump Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set	063014000000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777501	Jeu de perforateur ENPlus Kangaroo Joey Kangaroo Joey ENPlus Spike Set	063014000000000000001776U	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777502	Jeu de perforateur Dual ENPlus Kangaroo Joey Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777503	Jeu 3 en 1 ENPlus Kangaroo Joey Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777505	Poche d'alimentation et de rinçage avec perforateur ENPlus Kangaroo Joey, 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Classification/ Classification: IIa Règle/ Rule: 2
777506	Poche d'alimentation et de rinçage ENPlus 3 en 1 Kangaroo Joey Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Classification/ Classification: IIa Règle/ Rule: 2
778104	Poche d'alimentation et de rinçage Kangaroo ePump, 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2
778161	Poche d'alimentation et de rinçage Kangaroo ePump, 1600 mL/1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Classification/ Classification: IIa Règle/ Rule: 2
1814717995	Adaptateur 3 en 1 Kangaroo Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Classification/ Classification: IIa Règle/ Rule: 2

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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>	RE00184096
Technische Dokumentennummer <i>Technical Documentation Number</i>	RE00167844
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>	Beutel und Behälter für enterale Ernährung (einschließlich über Pumpe) – Einmalgebrauch Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
Grundlegende UDI-DI <i>Basic UDI-DI</i>	Siehe Anhang I/ Refer to Attachment 1
EMDN	Siehe Anhang I/ Refer to Attachment 1
Produktcode, Handelsname und Beschreibung <i>Product Code, Trade Name and Description</i>	Siehe Anhang I/ Refer to Attachment 1
Verwendungszweck <i>Intended Purpose</i>	Die Kangaroo Pumpensets zur enteralen Ernährung sind zur Verwendung bei Patienten bestimmt, die eine enterale Ernährung und/oder eine enterale Flüssigkeitszufuhr benötigen, welche durch eine enterale Ernährungspumpe und ein Pumpenset durchgeführt werden kann. Die Pumpen- und Ernährungssets sind für den Einsatz in wechselnden, akuten und häuslichen Pflegeeinrichtungen von Benutzern (Laien bis hin zu

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KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

	<p>Ärzten) vorgesehen. Der Zweck dieser Geräte besteht darin, Patienten mit intaktem Gastrointestinaltrakt enterale Nahrung in kontrollierter Geschwindigkeit zuzuführen.</p> <p>Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.</p>
Klassifizierung und Richtlinie <i>Classification and Rule</i>	Siehe Anhang I/ Refer to Attachment 1
Allgemeine Spezifikationen <i>Common Specifications</i>	Nicht zutreffend (N/A)
Gegebenenfalls anwendbare Rechtsvorschriften der Gewerkschaft hinzufügen <i>Where appropriate, add applicable Union legislation</i>	Nicht zutreffend (N/A)
Konformitätsbewertung <i>Conformity Assessment</i>	Anhang IX Kapitel I und III/ Annex IX Chapters I and III

UNTERSCHRIFTSABSCHNITT SIGNATURE SECTION

Diese EU-Konformitätserklärung wird für und im Namen und unter der alleinigen Verantwortung des oben angegebenen rechtmäßigen Herstellers ausgestellt.	
Ausstellungsort <i>Place of Issue</i>	Waukegan, IL 60085 USA
Unterschrift /Date <i>Signature/Date</i>	<p>Electronically signed by: Zafirios Gourgouliatos Reason: Approved Date: Nov 27, 2024 11:37 PST</p>
Name und Funktion <i>Name and Function</i>	<p>Zafirios Gourgouliatos Regulatory Affairs Zulassungsangelegenheiten</p>

ANHANG I ATTACHMENT I

Produktcodeliste Product Code List				
Produktcode Product Code	Handelsname und Beschreibung	Grundlegende UDI-DI Basic UDI-DI	EMDN	Klassifizierung und Richtlinie

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Produktcodeliste <i>Product Code List</i>				
	<i>Trade Name and Description</i>			<i>Classification and Rule</i>
666064	Kangaroo Joey Set 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
666106	Kangaroo Joey Set 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
672055	Kangaroo ePump Set Anti-Free Flow 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
673656	Kangaroo ePump Set Anti-Free Flow 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
673662	ePUMP INT. 1000 mL NAHRUNG/SPÜLUNG NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
668104	Kangaroo Joey Nahrungs-/Spülset 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
776150	Kangaroo ePump und Joey Büretten-Rezertifizierungsset 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777056	Känguru ePump Büretten-Set 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777064	Känguru ePump Set 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2

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Produktcodeliste <i>Product Code List</i>				
777106	Känguru ePump Set 1000 mL Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777163	Känguru ePump Set 1600 mL Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777401	Kangaroo ePump ENPlus Spike-Set Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777402	Kangaroo ePump Dual ENPlus Spike-Set Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777403	Kangaroo ePump ENPlus 3-in-1-Set Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777405	Kangaroo ePump ENPlus Spike-Nahrungs- und -Spülbeutel 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777406	Kangaroo ePump ENPlus 3-in-1-Nahrungs- und -Spülbeutel 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777407	Kangaroo ePump ENPlus Spike-Set zur Ernährungsverabreichung und Vented Spike-Spülset Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777408	Kangaroo ePump ENPlus 3-in-1-Set zur Ernährungsverabreichung und Spülung Kangaroo ePump ENPlus 3-in-1	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2


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Produktcodeliste <i>Product Code List</i>				
	Feed and Flush Set			
777501	Kangaroo Joey ENPlus Spike-Set Kangaroo Joey ENPlus Spike Set	063014000000000000001776U	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777502	Kangaroo Joey Dual ENPlus Spike-Set Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777503	Kangaroo Joey ENPlus 3-in-1-Set Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777505	Kangaroo Joey ENPlus Spike-Nahrungs- und -Spülbeutel 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
777506	Kangaroo Joey ENPlus 3-in-1-Nahrungs- und -Spülbeutel Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
778104	Kangaroo ePump Nahrungs- und Spülbeutel 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
778161	Kangaroo ePump Nahrungs- und Spülbeutel 1600 mL / 1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2
1814717995	Kangaroo 3-in-1-Adapter Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Klasse/ Classification: IIa Richtlinie/ Rule: 2

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GREEK

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ
DECLARATION OF CONFORMITY

 <p>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.</p>	
Αριθμός δήλωσης συμμόρφωσης <i>Declaration of Conformity Number</i>	RE00184096
Αριθμός τεχνικού φακέλου <i>Technical Documentation Number</i>	RE00167844
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>	Ασκοί και περιέκτες εντερικής σίτισης (συμπεριλαμβανομένων εκείνων μέσω αντλίας), μίας χρήσης Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
Βασικό UDI-DI <i>Basic UDI-DI</i>	Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1
EMDN	Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1
Κωδικός προϊόντος, εμπορική επωνυμία και περιγραφή <i>Product Code, Trade Name and Description</i>	Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1
Προοριζόμενος σκοπός <i>Intended Purpose</i>	Τα σετ αντλίας εντερικής σίτισης Kangaroo προορίζονται για χρήση σε ασθενείς με οποιαδήποτε πάθηση που απαιτεί εντερική σίτιση ή/και εντερική ενυδάτωση, η οποία μπορεί να επιτευχθεί μέσω αντλίας εντερικής σίτισης και σετ αντλίας. Τα σετ σίτισης με αντλία προορίζονται για χρήση σε εναλλακτικό περιβάλλον, καθώς και περιβάλλον νοσοκομειακής και οικιακής φροντίδας, τόσο από απλούς χρήστες όσο και

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ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ
DECLARATION OF CONFORMITY

	<p>από κλινικούς ιατρούς. Σκοπός αυτού του προϊόντος είναι η χορήγηση εντερικής διατροφής με ελεγχόμενο ρυθμό σε ασθενείς με άθικτη γαστρεντερική οδό.</p> <p>Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.</p>
Ταξινόμηση και κανόνας <i>Classification and Rule</i>	Ανατρέξτε στο Προσάρτημα I/ Refer to Attachment 1
Κοινές προδιαγραφές <i>Common Specifications</i>	Δεν ισχύει (N/A)
Όπου αρμόζει, προσθέστε την εφαρμοστέα νομοθεσία της Ένωσης <i>Where appropriate, add applicable Union legislation</i>	Δεν ισχύει (N/A)
Αξιολόγηση της συμμόρφωσης <i>Conformity Assessment</i>	Παράρτημα IX Κεφάλαια I και III/ Annex IX Chapters I and III

ΕΝΟΤΗΤΑ ΥΠΟΓΡΑΦΗΣ
SIGNATURE SECTION

Η παρούσα Δήλωση συμμόρφωσης ΕΕ εκδίδεται στο όνομα και για λογαριασμό και με την αποκλειστική ευθύνη του Νόμιμου κατασκευαστή που ταυτοποιείται παραπάνω.	
Τόπος έκδοσης <i>Place of Issue</i>	Waukegan, IL 60085 USA
Υπογραφή/Ημερομ <i>Signature/Date</i>	Electronically signed by: Zafirios Gourgouliatos Reason: Approved Date: Nov 27, 2024 11:37 PST
Όνομα και λειτουργία <i>Name and Function</i>	Zafirios Gourgouliatos Regulatory Affairs Ρυθμιστικές υποθέσεις

ΠΡΟΣΑΡΤΗΜΑ I
ATTACHMENT I

Κατάλογος κωδικών προϊόντος
Product Code List

Κωδικός προϊόντος <i>Product Code</i>	Εμπορική επωνυμία και περιγραφή <i>Trade Name and Description</i>	Βασικό UDI-DI <i>Basic UDI-DI</i>	EMDN	Ταξινόμηση και κανόνας <i>Classification</i>
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Κατάλογος κωδικών προϊόντος
Product Code List

				<i>and Rule</i>
666064	Σετ Kangaroo Joey 500 mL Kangaroo Joey Set 500mL	06301400000000000001776U	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
666106	Σετ Kangaroo Joey 1000 mL Kangaroo Joey Set 1000mL	06301400000000000001776U	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
672055	Σετ Kangaroo Epump διακοπής της ελεύθερης ροής 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	06301400000000000004997M	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
673656	Σετ Epump Kangaroo διακοπής της ελεύθερης ροής 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	06301400000000000004997M	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
673662	ΣΙΤΙΣΗ ΚΑΙ ΕΚΠΛΥΣΗ ePUMP INT. 1000 mL NS ePUMP INT.1000mL FEED & FLUSH NS	06301400000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
668104	Σετ σίτισης και έκπλυσης Kangaroo Joey 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	06301400000000000001776U	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
776150	Σετ επαναπιστοποίησης προχοϊδας Kangaroo Epump και Joey 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	06301400000000000001806H	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777056	Σετ επαναπιστοποίησης προχοϊδας 100 mL Kangaroo ePump Burette Set 100mL	06301400000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777064	Σετ Kangaroo Epump 500 mL Kangaroo ePump Set 500mL	06301400000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2

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Κατάλογος κωδικών προϊόντος
Product Code List

777106	Σετ Kangaroo Epump 1000 mL Kangaroo ePump Set 1000mL	06301400000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777163	Σετ Kangaroo Epump 1600 mL Kangaroo ePump Set 1600mL	06301400000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777401	Σετ ακίδας ENPlus Kangaroo ePump Kangaroo ePump ENPlus Spike Set	06301400000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777402	Σετ διπλής ακίδας ENPlus Kangaroo ePump Kangaroo ePump Dual ENPlus Spike Set	06301400000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777403	Σετ 3 σε 1 ENPlus Kangaroo ePump Kangaroo ePump ENPlus 3-in-1 Set	06301400000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777405	Ασκός σίτισης και έκπλυσης ακίδας ENPlus Kangaroo ePump 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	06301400000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777406	Ασκός σίτισης και έκπλυσης 3 σε 1 ENPlus Kangaroo ePump 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	06301400000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777407	Σετ έκπλυσης εξαεριζόμενης ακίδας και σίτισης ακίδας ENPlus Kangaroo ePump Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	06301400000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777408	Σετ σίτισης και έκπλυσης 3 σε 1 ENPlus Kangaroo ePump Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set	06301400000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2

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Κατάλογος κωδικών προϊόντος
Product Code List

777501	Σετ ακίδας ENPlus Kangaroo Joey Kangaroo Joey ENPlus Spike Set	063014000000000000001776U	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777502	Σετ διπλής ακίδας ENPlus Kangaroo Joey Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777503	Σετ 3 σε 1 ENPlus Kangaroo Joey Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777505	Ασκός σίτισης και έκπλυσης ακίδας ENPlus Kangaroo Joey 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
777506	Ασκός σίτισης και έκπλυσης 3 σε 1 ENPlus Kangaroo ePump Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
778104	Ασκός σίτισης και έκπλυσης Kangaroo ePump 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
778161	Ασκός σίτισης και έκπλυσης Kangaroo ePump 1600 mL / 1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2
1814717995	Προσαρμογέας 3 σε 1 Kangaroo Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Κατηγορία/ Classification: IIa Κανόνας/ Rule: 2

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ITALIAN

DICHIARAZIONE DI CONFORMITÀ DECLARATION OF CONFORMITY

 MDR: Noi sottoscritti, Cardinal Health 200 LLC, dichiariamo che i prodotti relativi alla presente Dichiarazione di conformità UE sono conformi alle disposizioni del Regolamento sui dispositivi medici (UE) 2017/745.	
Numero della dichiarazione di conformità <i>Declaration of Conformity Number</i>	RE00184096
Numero di documentazione tecnica <i>Technical Documentation Number</i>	RE00167844
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>	Sacchetti e contenitori per la nutrizione enterale (compresi quelli tramite pompa) monouso Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
UDI-DI di base <i>Basic UDI-DI</i>	Consultare l'Allegato I/ Refer to Attachment 1
EMDN	Consultare l'Allegato I/ Refer to Attachment 1
Codice prodotto, denominazione commerciale e descrizione <i>Product Code, Trade Name and Description</i>	Consultare l'Allegato I/ Refer to Attachment 1
Destinazione d'uso <i>Intended Purpose</i>	I set pompa per nutrizione enterale Kangaroo sono destinati all'uso in pazienti per qualsiasi condizione che richieda la nutrizione enterale e/o l'idratazione enterale, che possono essere effettuate mediante una pompa per nutrizione enterale e un set pompa. La pompa e i set per infusione sono destinati all'uso in contesti alternativi di ricovero, unità di terapia intensiva e di assistenza domiciliare da parte di utilizzatori che vanno da persone

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DICHIARAZIONE DI CONFORMITÀ
DECLARATION OF CONFORMITY

	<p>non esperte a medici. Lo scopo di questo dispositivo è quello di somministrare la nutrizione enterale a una velocità controllata ai pazienti che hanno un apparato gastrointestinale intatto.</p> <p>Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.</p>
Classificazione e regola <i>Classification and Rule</i>	Consultare l'Allegato I/ Refer to Attachment 1
Specifiche comuni <i>Common Specifications</i>	Non applicabile (N/A)
Ove necessario, aggiungere la legislazione pertinente dell'Unione <i>Where appropriate, add applicable Union legislation</i>	Non applicabile (N/A)
Valutazione della conformità <i>Conformity Assessment</i>	Allegato IX, Capitoli I e III/ Annex IX Chapters I and III

SEZIONE FIRMA
SIGNATURE SECTION

La presente Dichiarazione di conformità UE è stata prodotta per, a nome e sotto esclusiva responsabilità del fabbricante legale sopra indicato.	
Luogo di rilascio <i>Place of Issue</i>	Waukegan, IL 60085 USA
Firma/Data <i>Signature/Date</i>	<p>Electronically signed by: Zafirios Gourgouliatos Reason: Approved Date: Nov 27, 2024 11:37 PST</p>
Nome e mansion <i>Name and Function</i>	Zafirios Gourgouliatos Regulatory Affairs Affari regolatori

ALLEGATO I
ATTACHMENT I

Elenco codice prodotto
Product Code List

Codice prodotto <i>Product Code</i>	Denominazione commerciale e descrizione <i>Trade Name and Description</i>	UDI-DI di base <i>Basic UDI-DI</i>	EMDN	Classificazione e regola <i>Classification</i>
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Elenco codice prodotto <i>Product Code List</i>				
				<i>and Rule</i>
666064	Set Joey Kangaroo 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Classe/ Classification: IIa Regola/ Rule: 2
666106	Set Joey Kangaroo 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Classe/ Classification: IIa Regola/ Rule: 2
672055	Set ePump Kangaroo, anti-flusso libero, 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Classe/ Classification: IIa Regola/ Rule: 2
673656	Set ePump Kangaroo, anti-flusso libero, 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Classe/ Classification: IIa Regola/ Rule: 2
673662	NUTRIZIONE E LAVAGGIO NS ePUMP INT. 1000 mL ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2
668104	Set di nutrizione e lavaggio Joey Kangaroo 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Classe/ Classification: IIa Regola/ Rule: 2
776150	Set ricertificazione burette Joey ed ePump Kangaroo, 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777056	Set di burette ePump Kangaroo 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777064	Set ePump Kangaroo 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777106	Set ePump Kangaroo 1000 mL	063014000000000000001736L	A080101	Classe/ Classification: IIa

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Elenco codice prodotto <i>Product Code List</i>				
	Kangaroo ePump Set 1000mL			Regola/ Rule: 2
777163	Set ePump Kangaroo 1600 mL Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777401	Set perforatore ENPlus ePump Kangaroo Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777402	Set perforatore ENPlus Kangaroo ePump Dual Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777403	Set ENPlus ePump Kangaroo 3 in 1 Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777405	Sacca di nutrizione e lavaggio con perforatore ENPlus ePump Kangaroo 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777406	Sacca di nutrizione e lavaggio ENPlus ePump Kangaroo 3 in 1 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777407	Set di lavaggio con perforatore con sfiato e nutrizionale con perforatore ePump ENPlus Kangaroo Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777408	Set 3 in 1 per nutrizione e lavaggio ePump ENPlus Kangaroo Kangaroo ePump ENPlus 3-in-1	063014000000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2


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Elenco codice prodotto <i>Product Code List</i>				
	Feed and Flush Set			
777501	Set perforatore ENPlus Joey Kangaroo Kangaroo Joey ENPlus Spike Set	06301400000000000001776U	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777502	Set perforatore doppio Joey ENPlus Kangaroo Kangaroo Joey Dual ENPlus Spike Set	06301400000000000001776U	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777503	Set ENPlus Joey Kangaroo 3 in 1 Kangaroo Joey ENPlus 3-in-1 Set	06301400000000000001776U	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777505	Sacca di nutrizione e lavaggio con perforatore ENPlus Joey Kangaroo 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	06301400000000000001776U	A080101	Classe/ Classification: IIa Regola/ Rule: 2
777506	Sacca nutrizionale/di lavaggio 3 in 1 Joey ENPlus Kangaroo Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	06301400000000000001776U	A080101	Classe/ Classification: IIa Regola/ Rule: 2
778104	Sacca di nutrizione e lavaggio ePump Kangaroo 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	06301400000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2
778161	Sacca di nutrizione e lavaggio ePump Kangaroo 1600 mL / 1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	06301400000000000001736L	A080101	Classe/ Classification: IIa Regola/ Rule: 2
1814717995	Adattatore Kangaroo 3 in 1 Kangaroo 3-in-1 Adapter	06301400000000000001706E	A080101	Classe/ Classification: IIa Regola/ Rule: 2

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NORWEGIAN

SAMSVARERKLÆRING DECLARATION OF CONFORMITY

 MDR: Vi, Cardinal Health 200 LLC, erklærer at produktene som dekkes i denne EU-samsvarserklæringen oppfyller bestemmelsene i forordningen om medisinsk utstyr (EU) 2017/745.	
Samsvarserklæringsnummer <i>Declaration of Conformity Number</i>	RE00184096
Teknisk dokumentasjonsnummer <i>Technical Documentation Number</i>	RE00167844
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>	Enterale ernæringsposer og -beholdere (inkludert de via pumpe), engangsbruk Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
Grunnleggende UDI-DI <i>Basic UDI-DI</i>	Se Tillegg I/ Refer to Attachment 1
EMDN	Se Tillegg I/ Refer to Attachment 1
Produktkode, handelsnavn og beskrivelse <i>Product Code, Trade Name and Description</i>	Se Tillegg I/ Refer to Attachment 1
Tiltenkt formal <i>Intended Purpose</i>	Kangaroo enteralt ernæringspumpesett er tiltenkt for bruk på pasienter med en tilstand som krever enteral ernæring og/eller enteral hydrering, noe som kan oppnås ved å ta i bruk en enteral ernæringspumpe og et pumpesett. Pumpen og matesettet er ment til alternativt, akutt og hjemmebruk av brukere som kan være alt fra legerpersoner til leger. Formålet med denne enheten er å kunne levere enteral ernæring i en

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SAMSVARSERKLÆRING
DECLARATION OF CONFORMITY

	kontrollert hastighet til pasienter med en intakt gastrointestinal kanal. Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.
Klassifisering og regel <i>Classification and Rule</i>	Se Tillegg I/ Refer to Attachment 1
Vanlige spesifikasjoner <i>Common Specifications</i>	Ikke relevant (N/A)
Legg til gjeldende EU-lovgivning der det er relevant <i>Where appropriate, add applicable Union legislation</i>	Ikke relevant (N/A)
Samsvarsvurdering <i>Conformity Assessment</i>	Tillegg IX, kapittel I og III/ Annex IX Chapters I and III

SIGNATURDEL
SIGNATURE SECTION

Denne EU-samsvarserklæringen utstedes for og på vegne av den ovenfor identifiserte lomessige produsenten, og utelukkende under dennes ansvar.	
Utstedelsessted <i>Place of Issue</i>	Waukegan, IL 60085 USA
Signatur/Dato <i>Signature/Date</i>	Electronically signed by: Zafirios Gourgouliatos Reason: Approved Date: Nov 27, 2024 11:37 PST
Navn og funksjon <i>Name and Function</i>	Zafirios Gourgouliatos Regulatory Affairs Juridisk avdeling

TILLEGG I
ATTACHMENT I

Produktkodeliste
Product Code List

Produktkode <i>Product Code</i>	Handelsnavn og beskrivelse <i>Trade Name and Description</i>	Grunnleggende UDI-DI <i>Basic UDI-DI</i>	EMDN	Klassifisering og regel <i>Classification and Rule</i>
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Produktkodeliste <i>Product Code List</i>				
666064	Kangaroo Joey-sett 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
666106	Kangaroo Joey-sett 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
672055	Kangaroo ePump-sett anti-fri strømning 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
673656	Kangaroo ePump-sett anti-fri strømning 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
673662	ePUMP INT.1000 mL MATING OG SPYLING NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
668104	Kangaroo Joey mate- og spylesett 1000 ml Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
776150	Kangaroo ePump og Joey Burette resertifiseringssett 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777056	Kangaroo ePump Burette sett 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777064	Kangaroo ePump-sett 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777106	Kangaroo ePump-sett 1000 mL Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2

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Produktkodeliste <i>Product Code List</i>				
777163	Kangaroo ePump-sett 1600 mL Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777401	Kangaroo ePump ENPlus spike-sett Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777402	Kangaroo ePump dobbelt ENPlus spike-sett Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777403	Kangaroo ePump ENPlus 3 i 1-sett Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777405	Kangaroo ePump ENPlus spike-ernærings- og skyllepose 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777406	Kangaroo ePump ENPlus 3 i 1 ernærings- og skyllepose 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777407	Kangaroo ePump ENPlus spike-ernæringssett og Vented spike-skyllesett Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777408	Kangaroo ePump ENPlus 3-i-1 ernærings- og skyllesett Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777501	Kangaroo Joey ENPlus spike-sett Kangaroo Joey ENPlus Spike Set	063014000000000000001776U	A080101	Klasse/ Classification: IIa Regel/ Rule: 2

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Produktkodeliste
Product Code List

777502	Kangaroo Joey dobbelt ENPlus spike-sett Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777503	Kangaroo Joey ENPlus 3 i 1-sett Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777505	Kangaroo Joey ENPlus spike-ernærings- og skyllepose 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
777506	Kangaroo Joey ENPlus 3-i-1 ernærings- og skyllepose Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
778104	Kangaroo ePump ernærings- og skyllepose 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
778161	Kangaroo ePump ernærings- og skyllepose 1600 mL / 1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Klasse/ Classification: IIa Regel/ Rule: 2
1814717995	Kangaroo 3-i-1-adapter Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Klasse/ Classification: IIa Regel/ Rule: 2

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POLISH

DEKLARACJA ZGODNOŚCI
DECLARATION OF CONFORMITY



CardinalHealth

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>	RE00184096
Numer dokumentacji technicznej <i>Technical Documentation Number</i>	RE00167844
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>	Worki i pojemniki do żywienia dojelitowego (w tym za pomocą pompy) jednorazowego użytku Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
Podstawowy unikalny identyfikator urządzenia UDI-DI <i>Basic UDI-DI</i>	Patrz Załącznik I/ Refer to Attachment 1
EMDN	Patrz Załącznik I/ Refer to Attachment 1
Kod produktu, nazwa handlowa i opis <i>Product Code, Trade Name and Description</i>	Patrz Załącznik I/ Refer to Attachment 1
Przeznaczenie <i>Intended Purpose</i>	Pompa do żywienia dojelitowego Kangaroo jest przeznaczona do stosowania u pacjentów, u których występują schorzenia wymagające żywienia dojelitowego, co można osiągnąć za pomocą pompy do żywienia dojelitowego i zestawu pompy. Pompa i zestaw do żywienia dojelitowego są przeznaczone do stosowania w środowisku alternatywnej, intensywnej lub domowej opieki medycznej przez różnych użytkowników, od osób

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DEKLARACJA ZGODNOŚCI
DECLARATION OF CONFORMITY

	<p>niedoświadczonych po lekarzy. Celem tego urządzenia jest dostarczanie żywienia dojelitowego z kontrolowaną szybkością pacjentom z nienaruszonym przewodem pokarmowym.</p> <p>Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.</p>
Klasyfikacja i reguła <i>Classification and Rule</i>	Patrz Załącznik I/ Refer to Attachment 1
Wspólne specyfikacje <i>Common Specifications</i>	Nie dotyczy (N/A)
W stosownych przypadkach dodać obowiązujące przepisy unijne <i>Where appropriate, add applicable Union legislation</i>	Nie dotyczy (N/A)
Ocena zgodności <i>Conformity Assessment</i>	Załącznik IX, rozdziały I i III/ Annex IX Chapters I and III

SEKCJA PODPISÓW
SIGNATURE SECTION

Niniejsza deklaracja zgodności UE została wydana w imieniu i na wyłączną odpowiedzialność legalnego producenta określonego powyżej.	
Miejsce wydania <i>Place of Issue</i>	Waukegan, IL 60085 USA
Podpis/Data <i>Signature/Date</i>	<p>Electronically signed by: Zafirios Gourgouliatos Reason: Approved Date: Nov 27, 2024 11:37 PST</p>
Imię i nazwisko oraz stanowisko <i>Name and Function</i>	<p>Zafirios Gourgouliatos Regulatory Affairs Dział spraw regulacyjnych</p>

ZAŁĄCZNIK 1
ATTACHMENT 1

Lista kodów produktu
Product Code List

Kod produktu <i>Product Code</i>	Nazwa handlowa i opis <i>Trade Name and Description</i>	Podstawowy unikalny identyfikator urządzenia UDI-DI	EMDN	Klasyfikacja i reguła <i>Classification</i>
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Lista kodów produktu <i>Product Code List</i>				
		<i>Basic UDI-DI</i>		<i>and Rule</i>
666064	Zestaw Kangaroo Joey 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
666106	Zestaw Kangaroo Joey 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
672055	Zestaw Kangaroo Epump zapobiegający swobodnemu przepływowi 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
673656	Zestaw Kangaroo Epump zapobiegający swobodnemu przepływowi 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
673662	ePUMP INT. 1000 mL FEED & FLUSH NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
668104	Zestaw do karmienia i płukania Kangaroo Joey 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
776150	Zestaw recertyfikacyjny biurety Kangaroo Epump i Joey 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777056	Zestaw biurety Kangaroo ePump 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777064	Zestaw Kangaroo ePump 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2

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Lista kodów produktu <i>Product Code List</i>				
777106	Zestaw Kangaroo ePump 1000 mL Kangaroo ePump Set 1000mL	06301400000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777163	Zestaw Kangaroo ePump 1600 mL Kangaroo ePump Set 1600mL	06301400000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777401	Zestaw kolca Kangaroo ePump ENPlus Kangaroo ePump ENPlus Spike Set	06301400000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777402	Zestaw kolca Kangaroo ePump Dual ENPlus Kangaroo ePump Dual ENPlus Spike Set	06301400000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777403	Zestaw 3 w 1 Kangaroo ePump ENPlus Kangaroo ePump ENPlus 3-in-1 Set	06301400000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777405	Worek do karmienia i płukania Kangaroo ePump ENPlus z kolcem 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	06301400000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777406	Worek do karmienia i płukania 3 w 1 Kangaroo ePump ENPlus 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	06301400000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777407	Zestaw do karmienia z nakłuwaczem i do płukania z nakłuwaczem z odpowietrznikiem Kangaroo ePump ENPlus Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	06301400000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777408	Zestaw do karmienia i płukania 3 w 1 Kangaroo ePump ENPlus	06301400000000000001736L	A080101	Klasa, Classification: IIa

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Lista kodów produktu <i>Product Code List</i>				
	Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set			Reguła/ Rule: 2
777501	Zestaw kolca Kangaroo Joey ENPlus Kangaroo Joey ENPlus Spike Set	063014000000000000001776U	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777502	Zestaw kolca Kangaroo Joey Dual ENPlus Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777503	Zestaw 3 w 1 Kangaroo Joey ENPlus Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777505	Worek do karmienia i płukania Kangaroo Joey ENPlus z kolcem 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
777506	Worek do karmienia i płukania 3 w 1 Kangaroo Joey ENPlus Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
778104	Worek do karmienia i płukania Kangaroo ePump 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
778161	Worek do karmienia i płukania Kangaroo ePump 1600 mL / 1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Klasa, Classification: IIa Reguła/ Rule: 2
1814717995	Adapter Kangaroo 3 w 1 Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Klasa, Classification: IIa Reguła/ Rule: 2

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PORTUGUESE

DECLARAÇÃO DE CONFORMIDADE DECLARATION OF CONFORMITY	
	MDR: Nos, Cardinal Health 200 LLC, declaramos que os produtos abrangidos por esta Declaração de Conformidade da UE cumprem a disposição do Regulamento relativo a dispositivos médicos (UE) 2017/745.
Número de Declaração de Conformidade <i>Declaration of Conformity Number</i>	RE00184096
Número de documentação técnica <i>Technical Documentation Number</i>	RE00167844
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>	Bolsas e frascos de alimentação enteral (inclusive aqueles que utilizam bombas) descartáveis Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
UDI-DI básico <i>Basic UDI-DI</i>	Consultar o Anexo I/ Refer to Attachment 1
EMDN	Consultar o Anexo I/ Refer to Attachment 1
Código, nome comercial e descrição do produto <i>Product Code, Trade Name and Description</i>	Consultar o Anexo I/ Refer to Attachment 1
Finalidade <i>Intended Purpose</i>	Os conjuntos de alimentação enteral Kangaroo são destinados ao uso em pacientes com qualquer condição que exija alimentação enteral e/ou hidratação enteral, que pode ser realizada por meio de uma bomba de alimentação enteral e conjunto da bomba. A bomba e os conjuntos de alimentação se destinam ao uso em ambientes de cuidados alternativos,

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DECLARAÇÃO DE CONFORMIDADE <i>DECLARATION OF CONFORMITY</i>	
	<p>agudos e domiciliares por usuários que variam de leigos a médicos. O objetivo deste dispositivo é fornecer nutrição enteral a uma taxa controlada para pacientes com trato gastrointestinal intacto.</p> <p>Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.</p>
Classificação e regra <i>Classification and Rule</i>	Consultar o Anexo I/ Refer to Attachment 1
Especificações comuns <i>Common Specifications</i>	Não aplicável (N/A)
Se for o caso, adicione a legislação aplicável ao nível da União <i>Where appropriate, add applicable Union legislation</i>	Não aplicável (N/A)
Avaliação de conformidade <i>Conformity Assessment</i>	Anexo IX, Capítulos I e III / Annex IX Chapters I and III

SECÇÃO DE ASSINATURA <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>	Electronically signed by: Zafrios Gourgouliatos Reason: Approved Date: Nov 27, 2024 11:37 PST
Nome e cargo <i>Name and Function</i>	Zafrios Gourgouliatos Regulatory Affairs Assuntos Regulamentares

ANEXO I
ATTACHMENT I

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</i>

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Lista de códigos dos produtos
Product Code List

				<i>and Rule</i>
666064	Conjunto Kangaroo Joey 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Classe/ Classification: IIa Regra/ Rule: 2
666106	Conjunto Kangaroo Joey 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Classe/ Classification: IIa Regra/ Rule: 2
672055	Conjunto de bomba eletrônica anti-fluxo livre Kangaroo 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Classe/ Classification: IIa Regra/ Rule: 2
673656	Conjunto de bomba eletrônica anti-fluxo livre Kangaroo 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Classe/ Classification: IIa Regra/ Rule: 2
673662	ePUMP INT.1000mL ALIMENTAÇÃO E DESCARGA NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2
668104	Conjunto de alimentação e descarga Kangaroo Joey 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Classe/ Classification: IIa Regra/ Rule: 2
776150	Conjunto de recertificação de bureta Kangaroo Epump e Joey 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777056	Conjunto de bureta Kangaroo ePump 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777064	Conjunto Kangaroo ePump 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2

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Lista de códigos dos produtos
Product Code List

777106	Conjunto Kangaroo ePump 1000 mL Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777163	Conjunto Kangaroo ePump 1600 mL Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777401	Conjunto de espigões Kangaroo ePump ENPlus Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777402	Conjunto de espigões Kangaroo ePump Dual ENPlus Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777403	Conjunto 3-em-1 Kangaroo ePump ENPlus Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777405	Saco de alimentação e descarga de espigões Kangaroo ePump ENPlus 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777406	Saco de alimentação e descarga 3- em-1 Kangaroo ePump ENPlus 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777407	Conjunto de alimentação com espigão e descarga ventilada com espigão Kangaroo ePump ENPlus Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777408	Conjunto de alimentação e descarga 3-em-1 Kangaroo ePump ENPlus	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2

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Lista de códigos dos produtos
Product Code List

	Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set			
777501	Conjunto de espigões Kangaroo Joey ENPlus Kangaroo Joey ENPlus Spike Set	063014000000000000001776U	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777502	Conjunto de espigões Kangaroo Joey Dual ENPlus Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777503	Conjunto 3-em-1 Kangaroo Joey ENPlus Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777505	Saco de alimentação e descarga de espigões Kangaroo Joey ENPlus 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Classe/ Classification: IIa Regra/ Rule: 2
777506	Saco de alimentação e descarga 3-em-1 Kangaroo Joey ENPlus Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Classe/ Classification: IIa Regra/ Rule: 2
778104	Saco de alimentação e descarga Kangaroo ePump 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2
778161	Saco de alimentação e descarga Kangaroo ePump 1600 mL / 1000mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Classe/ Classification: IIa Regra/ Rule: 2
1814717995	Adaptador 3 em 1 Kangaroo Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Classe/ Classification: IIa Regra/ Rule: 2

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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>	RE00184096
Număr documentație tehnică <i>Technical Documentation Number</i>	RE00167844
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>	Pungi și recipiente de nutriție enterală (inclusiv cele prin pompă) de unică folosință Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
UDI-DI de bază <i>Basic UDI-DI</i>	Consultați Anexa I/ Refer to Attachment 1
EMDN	Consultați Anexa I/ Refer to Attachment 1
Cod produs, Nume comercial și Descriere <i>Product Code, Trade Name and Description</i>	Consultați Anexa I/ Refer to Attachment 1
Destinația utilizării <i>Intended Purpose</i>	Seturile de pompe de nutriție enterală Kangaroo sunt destinate utilizării la pacienții cu orice afecțiune care necesită hrănire enterală și/sau hidratare enterală, care pot fi realizate prin intermediul unei pompe de hrănire enterală și al unui set de pompe. Pompa și seturile de alimentare sunt destinate utilizării în medii de îngrijire alternativă, acută și la domiciliu de către utilizatori, atât nespecialiști, cât și clinicieni. Scopul acestui

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DECLARAȚIE DE CONFORMITATE <i>DECLARATION OF CONFORMITY</i>	
	dispozitiv este de a furniza nutriție enterală cu viteză controlată pacienților care au un tract gastrointestinal intact. Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.
Clasificare și regulă <i>Classification and Rule</i>	Consultați Anexa I/ Refer to Attachment 1
Specificații comune <i>Common Specifications</i>	Nu este cazul (N/A)
Când este cazul, adăugați legislația aplicabilă din Uniune <i>Where appropriate, add applicable Union legislation</i>	Nu este cazul (N/A)
Evaluarea de conformitate <i>Conformity Assessment</i>	Anexa IX, Capitolele I și III/ Annex IX Chapters I and III

SECȚIUNEA DE SEMNĂTURI <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>	Electronically signed by: Zafirios Gourgouliatos Reason: Approved Date: Nov 27, 2024 11:37 PST
Nume și funcție <i>Name and Function</i>	Zafirios Gourgouliatos 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>

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Listă cu Coduri de produse <i>Product Code List</i>				
666064	Set Kangaroo Joey 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
666106	Set Kangaroo Joey 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
672055	Set Kangaroo Epump anti-flux liber 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
673656	Set Kangaroo Epump anti-flux liber 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
673662	ePUMP INT. 1000 mL FEED & FLUSH NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
668104	Set Kangaroo Joey Feed and Flush 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
776150	Set de recertificare Joey Burette și Kangaroo Epump 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777056	Set Kangaroo ePump Burette 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777064	Set Kangaroo ePump 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777106	Set Kangaroo ePump 1000 mL Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2

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Listă cu Coduri de produse <i>Product Code List</i>				
777163	Set Kangaroo ePump 1600 mL Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777401	Set de administrare ENPlus Kangaroo ePump Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777402	Set de administrare ENPlus Kangaroo ePump Dual Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777403	Set 3 în 1 Kangaroo ePump ENPlus Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777405	Pungă de spălare și tub perfuzor Kangaroo ePump ENPlus 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777406	Pungă de spălare și hrănire 3 în 1 Kangaroo ePump ENPlus 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777407	Set de spălare cu tub perfuzor cu aerisire și tub perfuzor Kangaroo ePump ENPlus Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777408	Set de spălare și hrănire 3 în 1 Kangaroo ePump ENPlus Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777501	Set de administrare ENPlus Kangaroo Joey	063014000000000000001776U	A080101	Clasă/ Class: IIa Regulă/ Rule: 2


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Listă cu Coduri de produse <i>Product Code List</i>				
	Kangaroo Joey ENPlus Spike Set			
777502	Set de administrare ENPlus Kangaroo Joey Dual Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777503	Set 3 în 1 Kangaroo Joey ENPlus Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777505	Pungă de spălare și tub perfuzor Kangaroo Joey ENPlus 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
777506	Pungă de spălare și hrănire 3 în 1 Kangaroo Joey ENPlus Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
778104	Pungă de spălare și hrănire Kangaroo ePump 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
778161	Pungă de spălare și hrănire Kangaroo ePump 1600 mL /1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Clasă/ Class: IIa Regulă/ Rule: 2
1814717995	Adaptor 3 în 1 Kangaroo Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Clasă/ Class: IIa Regulă/ Rule: 2

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SLOVAK

VYHLÁSENIE O ZHODE
DECLARATION OF CONFORMITY

 CardinalHealth		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>	RE00184096	
Číslo technickej dokumentácie <i>Technical Documentation Number</i>	RE00167844	
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>	Vaky a nádoby na enterálnu výživu (vrátane tých, ktoré sa používajú prostredníctvom pumpy) na jedno použitie Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use	
Základné UDI-DI <i>Basic UDI-DI</i>	Pozrite si Prílohu I/ Refer to Attachment 1	
EMDN	Pozrite si Prílohu I/ Refer to Attachment 1	
Kód výrobku, obchodný názov a popis <i>Product Code, Trade Name and Description</i>	Pozrite si Prílohu I/ Refer to Attachment 1	
Zamýšľaný účel <i>Intended Purpose</i>	Súpravy pumpy na enterálnu výživu Kangaroo sú určené na použitie u pacientov s akýmkoľvek stavom vyžadujúcim enterálne podávanie výživy a/alebo enterálnu hydratáciu, čo je možné dosiahnuť pomocou pumpy na enterálne podávanie výživy a súpravy pumpy. Súpravy pumpy na podávanie výživy sú určené na použitie v zariadeniach alternatívnej, akútnej a domácej starostlivosti používateľmi od laikov až po lekárov. Účelom tejto pomôcky je dodávať enterálnu výživu kontrolovanou rýchlosťou pacientom, ktorí majú neporušený gastrointestinálny trakt.	

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VYHLÁSENIE O ZHODE
DECLARATION OF CONFORMITY

	Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.
Klasifikácia a pravidlo <i>Classification and Rule</i>	Pozrite si Prílohu I/ Refer to Attachment 1
Bežné špecifikácie <i>Common Specifications</i>	Nevzťahuje sa (N/A)
V prípade potreby doplňte príslušné právne predpisy Únie <i>Where appropriate, add applicable Union legislation</i>	Nevzťahuje sa (N/A)
Posúdenie zhody <i>Conformity Assessment</i>	Príloha IX, kapitoly I a III/ Annex IX Chapters I and III

PODPISOVÁ SEKCIA SIGNATURE SECTION	
Toto vyhlásenie o zhode EÚ sa vydáva pre zákonného výrobcu, v jeho mene a na jeho výhradnú zodpovednosť.	
Miesto vydania <i>Place of Issue</i>	Waukegan, IL 60085 USA
Podpis/ Dátum <i>Signature/Date</i>	Electronically signed by: Zafirios Gourgouliatos Reason: Approved Date: Nov 27, 2024 11:37 PST
Meno a pozícia <i>Name and Function</i>	Zafirios Gourgouliatos Regulatory Affairs Regulačné záležitosti

PRÍLOHU I
ATTACHMENT I

Zoznam kódov výrobkov Product Code List				
Kód výrobku <i>Product Code</i>	Obchodný názov a popis <i>Trade Name and Description</i>	Základné UDI-DI <i>Basic UDI-DI</i>	EMDN	Klasifikácia a pravidlo <i>Classification and Rule</i>
666064	Súprava Kangaroo Joey 500 mL Kangaroo Joey Set 500mL	06301400000000000001776U	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2

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Zoznam kódov výrobkov <i>Product Code List</i>				
666106	Súprava Kangaroo Joey 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
672055	Súprava Kangaroo Epump s ochranou proti voľnému prietoku 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
673656	Súprava Kangaroo Epump s ochranou proti voľnému prietoku 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
673662	ePUMP INT.1000 mL VÝŽIVA A PREPLACH NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
668104	Súprava na podávanie výživy a preplachovanie Kangaroo Joey 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
776150	Recertifikačná súprava Kangaroo Epump a Joey Burette 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777056	Súprava Kangaroo ePump Burette 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777064	Súprava Kangaroo ePump 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777106	Súprava Kangaroo ePump 1000 mL Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2

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Zoznam kódov výrobkov <i>Product Code List</i>				
777163	Súprava Kangaroo ePump 1600 mL Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777401	Súprava prepichovacieho hrotu Kangaroo ePump ENPlus Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777402	Súprava prepichovacieho hrotu Kangaroo ePump Dual ENPlus Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777403	Súprava 3v1 Kangaroo ePump ENPlus Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777405	Podávací a preplachovací vak Kangaroo ePump ENPlus Spike 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777406	Podávací a preplachovací vak 3v1 Kangaroo ePump ENPlus 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777407	Súprava na podávanie a preplachovanie odvetraného prepichovacieho hrotu Kangaroo ePump ENPlus Spike Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777408	Súprava 3v1 na podávanie a preplachovanie Kangaroo ePump ENPlus Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2


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Zoznam kódov výrobkov <i>Product Code List</i>				
777501	Súprava prepichovacieho hrotu Kangaroo Joey ENPlus Kangaroo Joey ENPlus Spike Set	063014000000000000001776U	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777502	Súprava prepichovacieho hrotu Kangaroo Joey Dual ENPlus Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777503	Súprava 3v1 Kangaroo Joey ENPlus Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777505	Podávací a preplachovací vak Kangaroo Joey ENPlus Spike 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
777506	Podávací a preplachovací vak 3v1 Kangaroo Joey ENPlus Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
778104	Podávací a preplachovací vak Kangaroo ePump 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
778161	Podávací a preplachovací vak Kangaroo ePump 1600 mL /1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2
1814717995	Adaptér 3v1 Kangaroo Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Trieda/ Class: IIa Pravidlo/ Rule: 2

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SPANISH

DECLARACIÓN DE CONFORMIDAD DECLARATION OF CONFORMITY

 CardinalHealth	MDR: Nosotros, Cardinal Health 200 LLC, declaramos que los productos contemplados en la presente Declaración de conformidad de la UE cumplen con la disposición del Reglamento sobre productos sanitarios (UE) 2017/745.
Número de declaración de conformidad <i>Declaration of Conformity Number</i>	RE00184096
Número de documentación técnica <i>Technical Documentation Number</i>	RE00167844
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>	Bolsas y recipientes de alimentación enteral (incluida la que se realiza mediante bomba) de un solo uso Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
UDI-DI básico <i>Basic UDI-DI</i>	Consulte el Archivo adjunto I/ Refer to Attachment 1
EMDN	Consulte el Archivo adjunto I/ Refer to Attachment 1
Código del producto, nombre comercial y descripción <i>Product Code, Trade Name and Description</i>	Consulte el Archivo adjunto I/ Refer to Attachment 1
Propósito <i>Intended Purpose</i>	Los conjuntos de bomba de alimentación enteral están indicados para usarse en pacientes con una afección que requiera alimentación o hidratación enterales, que pueda suministrarse por medio de una bomba de alimentación enteral y un conjunto de bomba. Los conjuntos de bombeo y alimentación están indicados para su utilización en entornos alternos, agudos y de atención domiciliaria por usuarios diversos, desde legos hasta

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DECLARACIÓN DE CONFORMIDAD <i>DECLARATION OF CONFORMITY</i>	
	<p>médicos. La finalidad de este dispositivo es suministrar nutrición enteral a un ritmo controlado a pacientes que tienen el tracto gastrointestinal intacto.</p> <p>Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.</p>
Clasificación y regla <i>Classification and Rule</i>	Consulte el Archivo adjunto I/ Refer to Attachment 1
Especificaciones comunes <i>Common Specifications</i>	No corresponde (N/A)
Cuando proceda, añada la legislación de la Unión Europea aplicable <i>Where appropriate, add applicable Union legislation</i>	No corresponde (N/A)
Evaluación de conformidad <i>Conformity Assessment</i>	Anexo IX capítulos I y III/ Annex IX Chapters I and III

SECCIÓN DE FIRMA <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>	<p>Electronically signed by: Zafirios Gourgouliatos Reason: Approved Date: Nov 27, 2024 11:37 PST</p>
Nombre y función <i>Name and Function</i>	Zafirios Gourgouliatos Regulatory Affairs Asuntos normativos

ARCHIVO ADJUNTO I
ATTACHMENT I

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>

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Lista de códigos del product <i>Product Code List</i>				
666064	Conjunto Kangaroo Joey, 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Clase/ Class: IIa Regla/ Rule: 2
666106	Conjunto Kangaroo Joey, 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Clase/ Class: IIa Regla/ Rule: 2
672055	Conjunto Kangaroo ePump, antiflujo libre, 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Clase/ Class: IIa Regla/ Rule: 2
673656	Conjunto Kangaroo ePump, antiflujo libre, 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Clase/ Class: IIa Regla/ Rule: 2
673662	ePUMP INT.1000mL ALIMENTACIÓN Y LAVADO NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2
668104	Conjunto Kangaroo Joey, alimentación y lavado, 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Clase/ Class: IIa Regla/ Rule: 2
776150	Conjunto de recertificación de bureta Kangaroo ePump y Joey, 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Clase/ Class: IIa Regla/ Rule: 2
777056	Juego de buretas Kangaroo ePump, 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2
777064	Conjunto Kangaroo ePump, 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2

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Lista de códigos del product
Product Code List

777106	Conjunto Kangaroo ePump, 1000 mL Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2
777163	Conjunto Kangaroo ePump, 1600 mL Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2
777401	Kit de boquillas ENPlus Kangaroo ePump Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2
777402	Kit de boquillas doble ENPlus Kangaroo ePump Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2
777403	Kit 3 en 1 ENPlus Kangaroo ePump Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2
777405	Bolsa de hidratación y alimentación con boquilla ENPlus Kangaroo ePump, 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2
777406	Bolsa de hidratación y alimentación 3 en 1 ENPlus Kangaroo ePump, 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2
777407	Conjunto de alimentación con boquilla e hidratación con boquilla con vía de aire ENPlus Kangaroo ePump Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2
777408	Conjunto 3 en 1 de alimentación e hidratación ENPlus Kangaroo	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2

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Lista de códigos del product
Product Code List

	ePump Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set			
777501	Kit de boquillas ENPlus Kangaroo Joey Kangaroo Joey ENPlus Spike Set	063014000000000000001776U	A080101	Clase/ Class: IIa Regla/ Rule: 2
777502	Kit de boquillas ENPlus doble Kangaroo Joey Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Clase/ Class: IIa Regla/ Rule: 2
777503	Kit 3 en 1 ENPlus Kangaroo Joey Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Clase/ Class: IIa Regla/ Rule: 2
777505	Bolsa de hidratación y alimentación con boquilla ENPlus Kangaroo Joey, 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Clase/ Class: IIa Regla/ Rule: 2
777506	Bolsa de hidratación y alimentación 3 en 1 ENPlus Kangaroo Joey Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Clase/ Class: IIa Regla/ Rule: 2
778104	Bolsa de hidratación y alimentación Kangaroo ePump, 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2
778161	Bolsa de hidratación y alimentación Kangaroo ePump, 1600 mL / 1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Clase/ Class: IIa Regla/ Rule: 2
1814717995	Adaptador 3 en 1 Kangaroo Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Clase/ Class: IIa Regla/ Rule: 2

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SWEDISH

FÖRSÄKRAN OM ÖVERENSSTÄMMELSE DECLARATION OF CONFORMITY

 CardinalHealth	MDR: Vi, Cardinal Health 200 LLC, försäkrar härmed att produkterna som omfattas av denna EU-försäkran om överensstämmelse uppfyller bestämmelserna om medicintekniska produkter i förordning (EU) 2017/745.
Nummer på försäkran om överensstämmelse <i>Declaration of Conformity Number</i>	RE00184096
Nummer på teknisk dokumentation <i>Technical Documentation Number</i>	RE00167844
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>	Enterala matningspåsar och behållare (inklusive dem via pump), engångsbruk Enteral Feeding Bags and Containers (Including Those Via Pump), Single-Use
Grundläggande UDI-DI <i>Basic UDI-DI</i>	Medföljande dokument I/ Refer to Attachment 1
EMDN	Medföljande dokument I/ Refer to Attachment 1
Produktkod, handelsnamn och beskrivning <i>Product Code, Trade Name and Description</i>	Medföljande dokument I/ Refer to Attachment 1
Avsedd användning <i>Intended Purpose</i>	Kangaroo enterala matningspumpset är avsedda för användning på patienter med ett tillstånd som kräver sondmatning och/eller epiteliseringshydrering, vilket kan uppnås med hjälp av ett pump- och matningsset. Pump- och matningsseten är avsedda att användas i alternativa, akuta och hemsjukvårdsmiljöer av användare allt från lekmän

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FÖRSÄKRAN OM ÖVERENSSTÄMMELSE <i>DECLARATION OF CONFORMITY</i>	
	till kliniker. Syftet med denna produkt är att tillföra sondnäring i en kontrollerad hastighet till patienter som har en intakt mag-tarmkanal. Kangaroo Enteral Feeding Pump Sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to patients who have an intact gastrointestinal tract.
Klassificering och regel <i>Classification and Rule</i>	Medföljande dokument I/ Refer to Attachment 1
Gemensamma specifikationer <i>Common Specifications</i>	Ej tillämpligt (N/A)
Lägg till tillämplig EU-lagstiftning <i>Where appropriate, add applicable Union legislation</i>	Ej tillämpligt (N/A)
Bedömning av överensstämmelse <i>Conformity Assessment</i>	Bilaga IX kapitel I och III/ Annex IX Chapters I and III

SEKTION FÖR UNDERSKRIFT <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/ Da <i>Signature/Date</i>	Electronically signed by: Zafirios Gourgouliatos Reason: Approved Date: Nov 27, 2024 11:37 PST
Namn och function <i>Name and Function</i>	Zafirios Gourgouliatos Regulatory Affairs Myndighetsärenden

DOKUMENT I
ATTACHMENT I

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>

DOCUMENT NO:	RE00184096	REVISION:	1
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Lista de códigos del product
Product Code List

666064	Kangaroo Joey-set 500 mL Kangaroo Joey Set 500mL	063014000000000000001776U	A080101	Klass/ Class: IIa Regel/ Rule: 2
666106	Kangaroo Joey-set 1000 mL Kangaroo Joey Set 1000mL	063014000000000000001776U	A080101	Klass/ Class: IIa Regel/ Rule: 2
672055	Kangaroo Epump-set antifritt flöde 500 mL Kangaroo Epump Set Anti-free Flow 500 mL	063014000000000000004997M	A080101	Klass/ Class: IIa Regel/ Rule: 2
673656	Kangaroo Epump-set antifritt flöde 1000 mL Kangaroo Epump Set Anti-free Flow 1000 mL	063014000000000000004997M	A080101	Klass/ Class: IIa Regel/ Rule: 2
673662	ePUMP INT.1000 mL TILLFÖRSEL OCH SPOLNING NS ePUMP INT.1000mL FEED & FLUSH NS	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
668104	Kangaroo Joey tillförsel- och spolningsset 1000 mL Kangaroo Joey Feed and Flush Set 1000mL	063014000000000000001776U	A080101	Klass/ Class: IIa Regel/ Rule: 2
776150	Kangaroo Epump and Joey Burette omcertifieringsset 100 mL Kangaroo Epump and Joey Burette Recertification Set 100 mL	063014000000000000001806H	A080101	Klass/ Class: IIa Regel/ Rule: 2
777056	Kangaroo ePump Burette-set 100 mL Kangaroo ePump Burette Set 100mL	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
777064	Kangaroo ePump-set 500 mL Kangaroo ePump Set 500mL	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
777106	Kangaroo ePump-set 1000 mL Kangaroo ePump Set 1000mL	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2

DOCUMENT NO:	RE00184096	REVISION:	1
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Lista de códigos del product
Product Code List

777163	Kangaroo ePump-set 1600 mL Kangaroo ePump Set 1600mL	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
777401	Kangaroo ePump ENPlus-set med kanyler Kangaroo ePump ENPlus Spike Set	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
777402	Kangaroo ePump Dual ENPlus-set med kanyler Kangaroo ePump Dual ENPlus Spike Set	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
777403	Kangaroo ePump ENPlus 3-i-1-set Kangaroo ePump ENPlus 3-in-1 Set	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
777405	Kangaroo ePump ENPlus-kanyl med påse för tillförsel och spolning 1000 mL Kangaroo ePump ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
777406	Kangaroo ePump ENPlus 3-i-1 med påse för tillförsel och spolning 1000 mL Kangaroo ePump ENPlus 3-in-1 Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
777407	Kangaroo ventilförsedd ePump ENPlus-kanyl med påse för tillförsel och spolning Kangaroo ePump ENPlus Spike Feed and Vented Spike Flush Set	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
777408	Kangaroo ePump ENPlus 3-i-1-set med påse för tillförsel och spolning Kangaroo ePump ENPlus 3-in-1 Feed and Flush Set	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
777501	Kangaroo Joey ENPlus-set med kanyler	063014000000000000001776U	A080101	Klass/ Class: IIa Regel/ Rule: 2

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Lista de códigos del product
Product Code List

	Kangaroo Joey ENPlus Spike Set			
777502	Kangaroo Joey Dual ENPlus-set med kanyler Kangaroo Joey Dual ENPlus Spike Set	063014000000000000001776U	A080101	Klass/ Class: IIa Regel/ Rule: 2
777503	Kangaroo Joey ENPlus 3-i-1-set Kangaroo Joey ENPlus 3-in-1 Set	063014000000000000001776U	A080101	Klass/ Class: IIa Regel/ Rule: 2
777505	Kangaroo Joey ENPlus-kanyl med påse för tillförsel och spolning 1000 mL Kangaroo Joey ENPlus Spike Feed and Flush Bag 1000mL	063014000000000000001776U	A080101	Klass/ Class: IIa Regel/ Rule: 2
777506	Kangaroo Joey ENPlus 3-i-1 med påse för tillförsel och spolning Kangaroo Joey ENPlus 3-in-1 Feed and Flush Bag	063014000000000000001776U	A080101	Klass/ Class: IIa Regel/ Rule: 2
778104	Kangaroo ePump med påse för tillförsel och spolning 1000 mL Kangaroo ePump Feed and Flush Bag 1000mL	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
778161	Kangaroo ePump med påse för tillförsel och spolning 1600 ml/1000 mL Kangaroo ePump Feed and Flush Bag 1600mL / 1000mL	063014000000000000001736L	A080101	Klass/ Class: IIa Regel/ Rule: 2
1814717995	Kangaroo 3-i-1-adapter Kangaroo 3-in-1 Adapter	063014000000000000001706E	A080101	Klass/ Class: IIa Regel/ Rule: 2







RE00184096

Final Audit Report

2024-11-27

Created:	2024-11-27
By:	Jonathan Hills (jonathan.hills@cardinalhealth.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAOM2Z6aw0Fjj7hndgjl7C9NvgXbbQfmAp

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Approved (Signature 17)
Approved (Signature 16)
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Approved (Signature 5)
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Approved (Signature 8)
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Approved (Signature 10)
Approved (Signature 13)
Approved (Signature 14)
Approved (Signature 15)
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