Konformitätserklärung
Declaration of Conformity

Wir | We

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201

erklären in eigener Verantwortung, dass das/die Produkt/e

hereby declare in our own responsibility that the product/s

Barcode Image Reader SP
Battery-Pack SP (NiMH) incl. pin
Battery-Pack SP (Li-Ion) incl. pin and WiFi
Battery-Pack SP (NiMH)
Syringe Anti Removal Cap PSP
Drop Sensor SP
Combi Lead SP 12V
Combi Lead SP 12V XL
Connection Lead SP 12V
Connection Lead for Staff Call SP
PCA Lockbox
Space PCA-Kit
Pole Clamp SP
Power Supply SP EU III
Power Supply SP GB III
Power Supply SP US III
Power Supply SP AU III
Power Supply SP ZA III
Power Supply SP CN III
Power Supply SP DK III
Power Supply SP BR III
Power Supply SP KR III
Power Supply SP EU III, 3,0 m
Short Stand SP
fm mobil

Zubehör für Space Infusionspumpen
(Artikelnummern und Basis UDI-DI siehe Anlage I)

Accessories for Space infusion pumps
(article numbers and Basic UDI-DI see attachment I)

mit den Anforderungen der Medizinprodukte Verordnung (EU) 2017/745 übereinstimmt/übereinstimmen

is/are in conformity with the requirements of the Medical Device Regulation (EU) 2017/745

Konformitätsbewertungsverfahren
nach Artikel 52 Absatz 7 der oben genannten Verordnung

Conformity Assessment Procedure
according to article 52 section 7 of the Regulation named above

Effective

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Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse I

Des Weiteren erklären wir in eigener Verantwortung, dass die von der Basis UDI-DIs:
403923900000024927
40392390000000230ZF
40392390000000227ZS
40392390000000231ZH
403923900000024825
erfassten Medizinprodukte die Anforderung zu folgender EU Richtlinie

Richtlinie 2011/65/EU

des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten

erfüllen

Darüber hinaus erfüllt der **Artikel 8713182A Battery-Pack SP (Li-Ion) incl. pin and WiFi** die Anforderungen der folgenden EU-Richtlinie

Richtlinie 2014/53/EU

des Europäischen Parlaments und des Rates vom 16. April 2014 über die Harmonisierung der Rechtsvorschriften der Mitgliedstaaten über die Bereitstellung von Funkanlagen auf dem Markt und zur Aufhebung der Richtlinie 1999/5/EG

Gültig bis
gemäß gültigem ISO Zertifikat
Q5 012974 0590

Classification
according to annex VIII of the Regulation named above
Class I

Furthermore, we declare in our own responsibility that the medical devices covered by Basic UDI-Dis:
403923900000024927
40392390000000230ZF
40392390000000227ZS
40392390000000231ZH
403923900000024825
meet the requirements of the following EU Directive

Directive 2011/65/EU

of the European Parliament and of the Council of 8th June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

In addition, **article 8713182A Battery-Pack SP (Li-Ion) incl. pin and WiFi** meets the requirements of the following EU Directive

Directive 2014/53/EU

of the European Parliament and of the Council of 16th April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

Valid until
according to our valid ISO Certificate
Q5 012974 0590

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Anlage I / Attachment I

Basic UDI-DI 403923900000024927

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8713241	Barcode Image Reader SP	I

Basic UDI-DI 4039239000000230ZF

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8713180A	Battery-Pack SP (NiMH) incl. pin	I
8713182A	Battery-Pack SP (Li-Ion) incl. pin and WiFi	I

Basic UDI-DI 4039239000000232ZK

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8713556	Syringe Anti Removal Cap PSP	I

Basic UDI-DI 4039239000000229ZW

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8713175	Drop Sensor SP	I

Basic UDI-DI 4039239000000227ZS

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8713133	Combi Lead SP 12V	I
8713134	Combi Lead SP 12V XL	I
8713231	Connection Lead SP 12V	I
8713232	Connection Lead for Staff Call SP	I

Basic UDI-DI 4039239000000251ZP

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8713557	PCA Lockbox	I

Basic UDI-DI 4039239000000231ZH

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8713554	Space PCA-Kit	I

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Basic UDI-DI 4039239000000226ZQ

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8713130	Pole Clamp SP	I

Basic UDI-DI 403923900000024825

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8713110D	Power Supply SP EU III	I
8713111D	Power Supply SP GB III	I
8713112D	Power Supply SP US III	I
8713113D	Power Supply SP AU III	I
8713115D	Power Supply SP ZA III	I
8713117D	Power Supply SP CN III	I
8713118D	Power Supply SP DK III	I
8713119D	Power Supply SP BR III	I
8713120D	Power Supply SP KR III	I
8713123D	Power Supply SP EU III, 3,0 m	I

Basic UDI-DI 4039239000000228ZU

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8713135	Short Stand SP	I
8721106	fm mobil	I

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Document amendment information

Version	Description of the changes
1.0	Initial version of document.
2.0	Adaption of validity.
3.0	Adaption of validity.
4.0	Deletion of 8713180 Battery-Pack SP (NiMH) – End of Life

Effective

Title: Declaration of Conformity - 170-100 - Accessories for Space Infusion Pumps - MDR Initiator: Jessica ? Walda

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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