

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

**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)

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

Konformitätsbewertungsverfahren
nach Artikel 52 Absatz 7 der oben genannten
Verordnung

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**

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

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

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

Klassifizierung

gemäß Anhang VIII der oben genannten
Verordnung
Klasse I

**Des Weiteren erklären wir in
eigener Verantwortung, dass die von der
Basis UDI-Dis:**

**40392390000024927
403923900000230ZF
403923900000227ZS
403923900000231ZH
40392390000024825**

**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:
40392390000024927
403923900000230ZF
403923900000227ZS
403923900000231ZH
40392390000024825**

**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

Anlage I / Attachment I**Basic UDI-DI 40392390000024927**

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

Basic UDI-DI 403923900000230ZF

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

Basic UDI-DI 403923900000232ZK

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

Basic UDI-DI 403923900000229ZW

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

Basic UDI-DI 403923900000227ZS

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

Basic UDI-DI 403923900000251ZP

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

Basic UDI-DI 403923900000231ZH

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

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

Document amendment information

Version	Description of the changes
1.0	Initial version of document.
2.0	Adaption of validity.
3.0	Adaption of validity.

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