

## 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:**

**403923900000024927  
4039239000000230ZF  
4039239000000227ZS  
4039239000000231ZH  
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  
4039239000000230ZF  
4039239000000227ZS  
4039239000000231ZH  
403923900000024825**

**meet the requirements of the following EU  
Directive**

**Directive 2011/65/EU**

of the European Parliament and  
of the Council of 8<sup>th</sup> 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 16<sup>th</sup> 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**

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

**Basic UDI-DI 403923900000230ZF**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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**

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

**Basic UDI-DI 403923900000229ZW**

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

**Basic UDI-DI 403923900000227ZS**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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**

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

**Basic UDI-DI 403923900000231ZH**

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

**Basic UDI-DI 4039239000000226ZQ**

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

**Basic UDI-DI 403923900000024825**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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**

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

**Document amendment information**

<b>Version</b>	<b>Description of the changes</b>
1.0	Initial version of document.
2.0	Adaption of validity.
3.0	Adaption of validity.

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

UserName: Heil, Anna (heilaade)  
Title: Manager Regulatory Affairs  
Date: Monday, 22 January 2024, 10:47 W. Europe Daylight Time  
Meaning: Document signed as Author

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UserName: Arico, Mareike (sommrde)  
Title: HC-QM - Head of QM active MD/ Head of Regulatory Affairs CoE AIS  
Date: Tuesday, 23 January 2024, 16:10 W. Europe Daylight Time  
Meaning: Approve Document

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UserName: Loh, Malte (lohmatde)  
Title: HC-RA-DE08 Senior Manager Regulatory Affairs  
Date: Friday, 26 January 2024, 16:25 W. Europe Daylight Time  
Meaning: Approve Document

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**Effective**