

Konformitätserklärung Declaration of Conformity

Wir

We

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-00000201

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

Connection lead 12V
Space^{plus} Pump clamp
Space^{plus} 45° Pump clamp
Zubehör für Space^{plus} 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

Klassifizierung
gemäß Anhang VIII der oben genannten
Verordnung
Klasse I

**Des Weiteren erklären wir in eigener
Verantwortung, dass die von der
Basis UDI-DI 403923900000254ZV 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

hereby declare in our own responsibility
that the product/s

Connection lead 12V
Space^{plus} Pump clamp
Space^{plus} 45° Pump clamp
Accessories for Space^{plus} 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

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-DI 403923900000254ZV
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.

Effective

Gültig bis
gemäß gültigem ISO Zertifikat
Q5 012974 0590

Valid until
according to our valid ISO Certificate
Q5 012974 0590

Anlage I / Attachment I**Basic UDI-DI 4039239000000254ZV**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
871923112	Connection lead 12V	

Basic UDI-DI 4039239000000245ZU

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8719165	Space ^{plus} Pump clamp	
8719166	Space ^{plus} 45° Pump clamp	

Document amendment information

Version	Description of the changes
1.0	Initial version of document.
2.0	Correction of the applicability of Directive 2011/65/EU -> Directive 2011/65/EU is not applicable for products covered by Basic UDI-DI 4039239000000245ZU
3.0	Adaption of validity.
4.0	Addition of Space ^{plus} 45° Pump clamp (art. no. 8719166) Adaption of validity.

Title: Declaration of Conformity - 170-101 - Accessories for Spaceplus Infusion Pumps - MDR Initiator: Malte Loh

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

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

UserName: Loh, Malte (lohmatde)
Title: HC-RA-DE08 Senior Manager Regulatory Affairs
Date: Friday, 26 January 2024, 16:35 W. Europe Daylight Time
Meaning: Approve Document

UserName: Arico, Mareike (sommrde)
Title: HC-QM - Head of QM active MD/ Head of Regulatory Affairs CoE AIS
Date: Friday, 26 January 2024, 20:45 W. Europe Daylight Time
Meaning: Approve Document
