

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

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

Gültig bis
2021-10-20

hereby declare in our own responsibility
that the product/s

Connection lead 12V Space^{plus} 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.

Valid until
2021-10-20

Effective

Anlage I / Attachment I**Basic UDI-DI 4039239000000254ZV****Art.-Nr. / Art. No. Produktname / Product name**

871923112 Connection lead 12V

Klasse / Class

I

Basic UDI-DI 4039239000000245ZU**Art.-Nr. / Art. No. Produktname / Product name**8719165 Space^{plus} Pump clamp**Klasse / Class**

I

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 403923900000245ZU

Title: Declaration of Conformity - 170-101 - Accessories for Space plus Infusion Pumps - MDR Initiator: Anna Heil

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