

## 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<sup>plus</sup> Pump clamp  
Space<sup>plus</sup> 45° Pump clamp  
Space<sup>plus</sup> PCA Button**

Zubehör für Space<sup>plus</sup> 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 / 403923900000246ZW  
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<sup>plus</sup> Pump clamp  
Space<sup>plus</sup> 45° Pump clamp  
Space<sup>plus</sup> PCA Button**

Accessories for Space<sup>plus</sup> 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 / 403923900000246ZW  
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.

**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**

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

**Basic UDI-DI 4039239000000245ZU**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
8719165	Space <sup>plus</sup> Pump clamp	
8719166	Space <sup>plus</sup> 45° Pump clamp	

**Basic UDI-DI 4039239000000246ZW**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
8719554	Space <sup>plus</sup> PCA Button	

**Document amendment information**

<b>Version</b>	<b>Description of the changes</b>
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 <sup>plus</sup> 45° Pump clamp (art. no. 8719166) Adaption of validity.
5.0	Addition of Space <sup>plus</sup> PCA Button (Art.No. 8719554).

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:

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