

## 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

**Space<sup>plus</sup> Station with Pole Clamp  
Space<sup>plus</sup> Station w/o Pole Clamp  
Space<sup>plus</sup> Cover  
Station Carry Handle**  
Ordnungssystem und Zubehör für Space<sup>plus</sup>  
Infusionspumpen  
Basis UDI-DI: 4039239000000243ZQ  
(Artikelnummern 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 oben genannte  
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

hereby declare in our own responsibility  
that the product/s

**Space<sup>plus</sup> Station with Pole Clamp  
Space<sup>plus</sup> Station w/o Pole Clamp  
Space<sup>plus</sup> Cover  
Station Carry Handle**  
Rack system and accessories for Space<sup>plus</sup>  
infusion pumps  
Basic UDI-DI: 4039239000000243ZQ  
(article numbers 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 above-mentioned  
medical devices 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

**Effective**

Elektronikgeräten

**erfüllen**

**Gültig bis**  
2021-10-20

electronic equipment.

**Valid until**  
2021-10-20

**Anlage I / Attachment I****Basic UDI-DI 4039239000000243ZQ**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
8719141	Space <sup>plus</sup> Station with Pole Clamp	
8719142	Space <sup>plus</sup> Station w/o Pole Clamp	
8719145	Space <sup>plus</sup> Cover	
8717143	Station Carry Handle	

**Document amendment information**

<b>Version</b>	<b>Description of the changes</b>
1.0	Initial version of document.

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