

**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**Power Supply Enteroport Plus EU  
Power Supply Enteroport Plus UK  
Power Supply Enteroport Plus US/JP  
Power Supply Enteroport Plus BR  
Power Supply Enteroport Plus AU  
Pole Clamp (rotatable)****Short Stand for Pole Clamp**Zubehör für Enteroport® plus enterale  
Ernährungspumpen

(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 40392390000024723  
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 bestimmterhereby declare in our own responsibility  
that the product/s**Power Supply Enteroport Plus EU  
Power Supply Enteroport Plus UK  
Power Supply Enteroport Plus US/JP  
Power Supply Enteroport Plus BR  
Power Supply Enteroport Plus AU  
Pole Clamp (rotatable)****Short Stand for Pole Clamp**Accessories for Enteroport® plus enteral nutrition  
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 40392390000024723  
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

gefährlicher Stoffe in Elektro- und  
Elektronikgeräten

**erfüllen**

**Gültig bis**  
gemäß gültigem ISO Zertifikat  
Q5 012974 0590

on the restriction of the use of certain  
hazardous substances in electrical and  
electronic equipment.

**Valid until**  
according to our valid ISO Certificate  
Q5 012974 0590

**Anlage I / Attachment I****Basic UDI-DI 40392390000024723**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
8710360	Power Supply Enteroport Plus EU	
8710361	Power Supply Enteroport Plus UK	
8710362	Power Supply Enteroport Plus US/JP	
8710363	Power Supply Enteroport Plus BR	
8710364	Power Supply Enteroport Plus AU	

**Basic UDI-DI 403923900000223ZJ**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
8721061	Pole Clamp (rotatable)	

**Basic UDI-DI 403923900000224ZL**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
8721670	Short Stand for Pole Clamp	

**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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