

**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 8th June 2011

gefährlicher Stoffe in Elektro- und
Elektronikgeräten

erfüllen

Gültig bis
2024-10-19

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

Valid until
2024-10-19

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

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
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

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

Basic UDI-DI 403923900000224ZL

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

Document amendment information

Version	Description of the changes
1.0	Initial version of document.
2.0	Adaption of validity.

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

UserName: Heil, Anna (heilaade)
Title: Junior Manager Regulatory Affairs
Date: Wednesday, 20 October 2021, 16:32 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Arico, Mareike (sommrde)
Title: Head of QM active MD/ Head of Regulatory Affairs CoE AIS
Date: Wednesday, 20 October 2021, 16:43 W. Europe Daylight Time
Meaning: Approve Document

UserName: Heil, Juergen (heiljrde)
Title: VP Quality Management HC
Date: Thursday, 21 October 2021, 12:04 W. Europe Daylight Time
Meaning: Approve Document
