

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

**Space^{plus} Station with Pole Clamp
Space^{plus} Station w/o Pole Clamp
Space^{plus} Cover
Station Carry Handle**
Ordnungssystem und Zubehör für Space^{plus}
Infusionspumpen
Basis UDI-DI: 403923900000243ZQ
(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^{plus} Station with Pole Clamp
Space^{plus} Station w/o Pole Clamp
Space^{plus} Cover
Station Carry Handle**
Rack system and accessories for Space^{plus}
infusion pumps
Basic UDI-DI: 403923900000243ZQ
(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 8th June 2011
on the restriction of the use of certain
hazardous substances in electrical and

Effective

Elektronikgeräten

erfüllen

Gültig bis
gemäß gültigem ISO Zertifikat
Q5 012974 0590

electronic equipment.

Valid until
according to our valid ISO Certificate
Q5 012974 0590

Anlage I / Attachment I**Basic UDI-DI 403923900000243ZQ**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8719141	Space ^{plus} Station with Pole Clamp	
8719142	Space ^{plus} Station w/o Pole Clamp	
8719145	Space ^{plus} Cover	
8717143	Station Carry Handle	

Document amendment information

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

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