

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
2024-10-19

electronic equipment.

Valid until
2024-10-19

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.

Title: Declaration of Conformity - 170-007 - Space plus Station and Accessories - MDR Initiator: Anna Heil

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, 16:27 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
=====