

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

**SpaceStation
SpaceStation with SpaceCom
SpaceCover comfort
SpaceCover standard
SpaceCom
WIRELESS LAN USB-STICK
Extension Lead SP 60cm
Extension Lead SP 120cm
RS232 Cross-over cable SP
RS232 Connector-Converter SP
Extension Lead SP 10m
Extension Lead SP 15m**

Ordnungssystem und Zubehör für Space
Infusionspumpen
(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 oben genannte/s
Medizinprodukt/e die Anforderung zu
folgender EU Richtlinie**

Richtlinie 2011/65/EU

hereby declare in our own responsibility
that the product/s

**SpaceStation
SpaceStation with SpaceCom
SpaceCover comfort
SpaceCover standard
SpaceCom
WIRELESS LAN USB-STICK
Extension Lead SP 60cm
Extension Lead SP 120cm
RS232 Cross-over cable SP
RS232 Connector-Converter SP
Extension Lead SP 10m
Extension Lead SP 15m**

Rack system and accessories for Space infusion
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 above-mentioned
medical device/s meet/s the requirements of
the following EU Directive**

Directive 2011/65/EU

des Europäischen Parlaments
und des Rates vom 8. Juni 2011
zur Beschränkung der Verwendung bestimmter
gefährlicher Stoffe in Elektro- und
Elektronikgeräten

erfüllen

Darüber hinaus erfüllt der
Artikel 8713185U WIRELESS LAN USB-STICK
die Anforderungen der folgenden EU-Richtlinie

Richtlinie 2014/53/EU

des Europäischen Parlaments und des Rates
vom 16. April 2014 über die Harmonisierung der
Rechtsvorschriften der Mitgliedstaaten über die
Bereitstellung von Funkanlagen auf dem Markt
und zur Aufhebung der Richtlinie 1999/5/EG

Gültig bis
2024-10-19

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
electronic equipment.

In addition,
article 8713185U WIRELESS LAN USB-STICK
meets the requirements of the following EU
Directive

Directive 2014/53/EU

of the European Parliament and of the Council
of 16th April 2014 on the harmonisation of the
laws of the Member States relating to the
making available on the market of radio
equipment and repealing Directive 1999/5/EC

Valid until
2024-10-19

Anlage I / Attachment I**Basic UDI-DI 403923900000225ZN**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8713140	SpaceStation	
8713142	SpaceStation with SpaceCom	
8713145	SpaceCover comfort	
8713147	SpaceCover standard	
8713160	SpaceCom	
8713185U	WIRELESS LAN USB-STICK	

Basic UDI-DI 40392390000024452P

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8713210	Extension Lead SP 60cm	
8713215	Extension Lead SP 120cm	
8713237	RS232 Cross-over cable SP	
8713238	RS232 Connector-Converter SP	
8713315	Extension Lead SP 10m	
8713415	Extension Lead SP 15m	

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, 16:26 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, 16:40 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Heil, Juergen (heiljrde)
Title: VP Quality Management HC
Date: Thursday, 21 October 2021, 12:02 W. Europe Daylight Time
Meaning: Approve Document
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