

## 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**

**Effective**

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**  
gemäß gültigem ISO Zertifikat  
Q5 012974 0590

of the European Parliament and  
of the Council of 8<sup>th</sup> 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 16<sup>th</sup> 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**  
according to our valid ISO Certificate  
Q5 012974 0590

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

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

**Basic UDI-DI 40392390000024452P**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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**

<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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