

**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} MRI Station
Space^{plus} MRI Station with Trolley**
Infusionspumpen-Managementeinheit
Basis UDI-DI: 40392390000025624
(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/s
Medizinprodukt/e 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
Elektronikgeräten**erfüllt**hereby declare in our own responsibility
that the product/s**Space^{plus} MRI Station
Space^{plus} MRI Station with Trolley**
Infusion pump management unit
Basis UDI-DI: 40392390000025624
(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 device/s meet/s 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
electronic equipment.

Gültig bis
gemäß gültigem
ISO Zertifikat Q5 012974 0590

Valid until
according to our valid ISO Certificate
Q5 012974 0590

Anlage I / Attachment I**Basic UDI-DI 403923900000025624**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8719152	Space ^{plus} MRI Station with trolley	
8719155	Space ^{plus} MRI Station	

Document amendment information

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

UserName: Loh, Malte (lohmatde)
Title: HC-RA-DE08 Senior Manager Regulatory Affairs
Date: Thursday, 29 June 2023, 15:44 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Loh, Malte (lohmatde)
Title: HC-RA-DE08 Senior Manager Regulatory Affairs
Date: Thursday, 29 June 2023, 15:54 W. Europe Daylight Time
Meaning: Approve Document

UserName: Arico, Mareike (sommrde)
Title: Head of QM active MD/ Head of Regulatory Affairs CoE AIS
Date: Thursday, 29 June 2023, 18:09 W. Europe Daylight Time
Meaning: Approve Document
