

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**erklären in eigener Verantwortung,
dass das/die Produkt/ehereby declare in our own responsibility
that the product/s**SpaceStation MRI**Infusionspumpen-Managementeinheit
(Artikelnummern siehe Anlage I)**SpaceStation MRI**Infusion pump management unit
(article numbers see Attachment I)mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

is/are in compliance with the following directive

Richtlinie 93/42/EWG des Rates vom
14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EGCouncil Directive 93/42/EEC of
14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC**Konformitätsbewertungsverfahren**
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie**Conformity Assessment Procedure**
according to annex II (excluding section 4)
of the Council Directive named above**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIb**Classification**
according to annex IX of the
Council Directive named above
Class IIb**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Notified Body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Datum der ersten CE-Kennzeichnung**
2004-06**Date of first CE-marking**
2004-06**Gültig bis**
2024-05-26**Valid until**
2024-05-26

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Anlage I / Attachment I

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description	Klasse / Class
8713152	SpaceStation MRI	IIb

Effective

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Amendment Information

Version	Description of the change
1.0	Initial Version. Replaces DoC 39.05.705. Changed validity. New electronic format.

Effective

Title: Declaration of Conformity 170-002 SpaceStation MRI Initiator: Jessica ? Walda

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

UserName: Walda, Jessica (gorojede)
Title: HC-RA-DE08 Manager Regulatory Affairs
Date: Monday, 03 February 2020, 14:57 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Trottier, Ullrich (trolulde)
Title: HC-RA-DE08W Director Regulatory Affairs CoE AIS
Date: Tuesday, 04 February 2020, 08:22 W. Europe Daylight Time
Meaning: Approve Document

UserName: Heil, Juergen (heiljrde)
Title: VP Quality Management HC
Date: Friday, 14 February 2020, 08:09 W. Europe Daylight Time
Meaning: Approve Document
