



SpaceStation MRI

**System Declaration
Article 12
93/42/EEC**

System Declaration according to Article 12 93/42/EEC for B.Braun automated infusion system SpaceStation MRI

We

**MIPM MAMMENDORFER INSTITUT
FÜR PHYSIK UND MEDIZIN GMBH**
Oskar-von-Miller Str. 6
82291 Mammendorf
GERMANY

As

OEM manufacturer of B.Braun Melsungen AG/Germany

declare that the following product

**SpaceStation MRI
automated infusion system**

manufactured by:

MIPM Mammendorfer Institut für Physik und Medizin GmbH
(OEM manufacturer of B.Braun Melsungen AG/Germany)

in combination with the use of the MRI systems

manufactured by:

Siemens Healthcare GmbH
Henkestraße 127
91052 Erlangen, Germany

Seq. no.	MR System or option (type designation)	
1	MAGNETOM Prisma	(3 Tesla)
2	MAGNETOM Spectra	(3 Tesla)
3	MAGNETOM Skyra	(3 Tesla)
4	MAGNETOM Verio	(3 Tesla)
5	MAGNETOM Biograph mMr	(3 Tesla)
6	MAGNETOM Trio	(3 Tesla)
7	MAGNETOM Aera	(1.5 Tesla)
8	MAGNETOM Amira	(1.5 Tesla)
9	MAGNETOM ESSENZA	(1.5 Tesla)
10	MAGNETOM Avanto	(1.5 Tesla)
11	MAGNETOM Espree	(1.5 Tesla)
12	MAGNETOM Symphony	(1.5 Tesla)
13	MAGNETOM Vida	(3 Tesla)



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14	MAGNETOM Sempra	(1,5 Tesla)
15	MAGNETOM Sola	(1,5 Tesla)
16	MAGNETOM Altea	(1,5 Tesla)
17	MAGNETOM Lumina	(3 Tesla)

manufactured by: Philips Medical Systems Nederlands B.V.
Veenpluis 4-6
5684 PC Best, Netherlands

Seq. no.	MR System or option (type designation)	
1	Achieva	(3 Tesla)
2	Ingenia	(3 Tesla)
3	Achieva	(1.5 Tesla)
4	Ingenia	(1.5 Tesla)

have been verified to be mutually compatible in accordance with the manufacturers instructions.

All relevant information can be found in the accompanying documentation.

Testing activities are subject to internal control and inspection.

Mammendorf, 10. January 2019

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Hans Schwaiger (Quality Assurance and Regulatory Affairs Manager)