

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

**Connection lead for potential equalization
MFC-RS 232 Interface lead
MFC 12V-Connection lead
MFC Connection Lead for Staff Call
Universal adapter for drip sensor
Zubehör für Infusomat® P / fmS
(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 die von der
Basis UDI-DI 403923900000250ZM
erfassten Medizinprodukte 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

erfüllen

hereby declare in our own responsibility
that the product/s

**Connection lead for potential equalization
MFC-RS 232 Interface lead
MFC 12V-Connection lead
MFC Connection Lead for Staff Call
Universal adapter for drip sensor
Accessories for Infusomat® P / fmS
(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 medical devices
covered by
Basic UDI-DI 403923900000250ZM
meet 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.

Effective

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 403923900000250ZM**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8701628	Connection lead for potential equalization	
8711661	MFC-RS 232 Interface lead	
8711674	MFC 12V-Connection lead	
8711682	MFC Connection Lead for Staff Call	

Basic UDI-DI 403923900000237ZV

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8711747	Universal adapter for drip sensor	

Document amendment information

Version	Description of the changes
1.0	Initial version of document.
2.0	Adaption of validity.
3.0	Adaption of validity.

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