Konformitätserklärung
Declaration of Conformity

Wir | We

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201

erklären in eigener Verantwortung, dass die Produkte

Enteroport® ENFit® Set
Enterales Pumpenset mit ENFit®-Konnektor

Basis UDI-DI: 403923900000263732
(Artikelnummern siehe Anlage I)

mit den Anforderungen der Medizinprodukte Verordnung (EU) 2017/745 übereinstimmen

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

Klassifizierung
Gemäß Anhang VIII der oben genannten Verordnung
Klasse IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis
gemäß gültigem EU Zertifikat
(Nr. G10 012974 0611)

hereby declare in our own responsibility that the products

Enteroport® ENFit® Set
Enteral pump set with ENFit® connector

Basic UDI-DI: 403923900000263732
(article numbers see attachment I)

are in conformity with the requirements of the Medical Device Regulation (EU) 2017/745

Conformity Assessment Procedure
according to annex IX
of the Regulation named above

Classification
According to annex VIII of the Regulation named above
Class IIa

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Valid until
according to our valid EU Certificate
(No. G10 012974 0611)

Effective

Anlage I / Attachment I

Basic UDI-DI: 403923900000263732

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8721739	Enteroport® ENFit® Set	IIa
8721738	Enteroport® ENFit® Set	IIa

Effective

Document amendment information

Version	Description of the changes
1.0	Initial version under 2017/745 MDR

Effective

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

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