

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**erklären in eigener Verantwortung,
dass das Produkt**Enteroport® plus**Pumpe zur enteralen Ernährung
(Artikelnummern siehe Anlage I)Aktives Medizinprodukt zur enteralen
Ernährungstherapiemit den Anforderungen der folgenden Richtlinie
übereinstimmtRichtlinie 93/42/EWG des Rates vom
14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München / Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**
2016-01**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product**Enteroport® plus**Enteral feeding pump
(article numbers see attachment I)Active medical device for delivery of enteral
nutrition

is in compliance with the following directive

Council Directive 93/42/EEC of
14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**
according to annex II (excluding section 4)
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class IIa**Notified Body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München / Germany
Identification number 0123**Date of first CE-marking**
2016-01**Valid until**
2024-05-26

Anlage I / Attachment I

| Art.-Nr. / Art. No. | Artikelbezeichnung / Article description | Klasse / Class |
|--------------------------------|---|---------------------------|
| 8710355 | Enteroport® plus | Ila |

Amendment Information

| Version | Description of the changes |
|----------------|-----------------------------------|
| 1.0 | Initial version. |
| 2.0 | New electronic format. |

Title: Declaration of Conformity 238-002 Enteroport plus 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: Thursday, 05 December 2019, 10:20 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Trottier, Ullrich (trolulde)
Title: HC-RA-DE08W Director Regulatory Affairs CoE AIS
Date: Thursday, 05 December 2019, 11:36 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Heil, Juergen (heiljrde)
Title: VP Quality Management HC
Date: Tuesday, 10 December 2019, 13:38 W. Europe Daylight Time
Meaning: Approve Document
=====