

**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 die Produkte**Nutrifix® ENFit® Set**Überleitgerät mit ENFit® Konnektor für die
enterale SchwerkraftapplikationBasis UDI-DI: 403923900000263834
(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 Is**Benannte Stelle**TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**gemäß gültigem EU Zertifikat
(Nr. G11 012974 0626)hereby declare in our own responsibility
that the products**Nutrifix® ENFit® Set**

Enteral Gravity Set with ENFit® connector

Basic UDI-DI: 403923900000263834
(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 Is**Notified Body**TÜV SÜD Product Service GmbH
Identification number 0123**Valid until**according to our valid EU Certificate
(No. G11 012974 0626)

Anlage I / Attachment I**Basic UDI-DI: 40392390000263834****Art.-Nr. / Art. No. Produktname / Product name**

9240627 Nutrifix® ENFit® Set

9240620 Nutrifix® ENFit® Set

Klasse / Class

Is

Is

Document amendment information

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

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