



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EC-certificate No. G10
037258 0012 Rev.01 and Expiration Date 2026-03-09
issued by Notified Body TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

Enteral Giving Sets and Accessories

Refer to attachment
(Product name)

Refer to attachment
(article number)

Device classification according to Annex VIII, clause 4.2, rule 2

Class IIa - IIb

We

**Fresenius Kabi AG, Else-Kröner-Str. 1
61352 Bad Homburg, Germany**
Single Registration Number (SRN): DE-MF-000009273

manufacturer of the above products, hereby declare under our sole responsibility for this Declaration of Conformity that the referenced products comply with all relevant provisions of the Medical Device Regulation 2017/745 and any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity. The products comply with the general safety and performance requirements of Annex I, further applicable standards and/or other normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.

Bad Hersfeld 17.02.2023 Britta Heyne, Senior Manager Regulatory Affairs i.V. B. Heyne
Place and date of issue/ Name (printed letters), position and signature of authorized person/

Valid starting with the original date of the document until product change



Attachment to EU DECLARATION OF CONFORMITY

Enteral Giving Sets and Accessories

Intended Purpose:
Enteral pump giving set for tube feeding

Basic UDI:
42502737NEN60312a000000H4

EMDN code:
A030103

| Article Number | Product Name |
|-----------------------|---|
| 7751910 | Amika Pump Set TwoLine Easybag, universal, ENFit |
| 7751924 | Applix Smart/Vision Varioline, ENFit |
| 7751926 | Applix Smart/Vision Varioline Comfort, ENFit |
| 7751943 | Applix Smart/Vision Pump Set EasyBag, universal, ENFit |
| 7751944 | Applix Smart/Vision Pump Set EasyBag with cover, universal, ENFit |
| 7751946 | Applix Smart/Vision Pump Set Varioline, universal, ENFit |
| 7751947 | Applix Smart/Vision Pump Set TwoLine EasyBag, universal, ENFit |
| 7751948 | Applix Smart/Vision Pump Set Varioline Comfort, universal, ENFit |
| 7751949 | Applix Smart/Vision Pump Set EasyBag mobile, universal, ENFit |
| 7751998 | Amika Pump Set Varioline Comfort, universal, ENFit + |
| 7751999 | Amika Pump Set EasyBag mobile, universal, ENFit |
| 7752085T | Amika Pump Set EasyBag, universal, ENFit |