FRESENIUS KABI

EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to
EU-certificate No. G11 037258 0015 Rev. 01 and Expiration Date 2027-07-31
issued by Notified Body (e.g. 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 Is

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.

Nanchang/09.10.2024	Xin Luo, Manager Regulatory Affairs
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

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Attachment to EU DECLARATION OF CONFORMITY

Enteral Giving Sets and Accessories

Basic UDI:
42502737NEN60321s000000SS

Article Number	Product Name
7751857	Applix VarioLine Adaptor, ENPlus
7751936	GraviSet EasyBag, ENFit
7751937	GraviSet Varioline, ENFit
7751938	GraviSet Bag, ENFit
7751939	GraviSet EasyBag with cover, ENFit
7751952	GraviSet EasyBag, universal, ENFit
7751953	GraviSet Varioline, universal, ENFit
7751954	GraviSet Bag, universal, ENFit
7751955	GraviSet EasyBag with cover, universal, ENFit
7989923	Easy Bottle Adaptor Gravity, ENPlus
M44310094	GraviSet Varioline with cover, ENFit