



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.

Ebersburg, 27.03.2024

Sandra Leipold
Sr. Manager RA

S. Leipold
 Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signing Time: 27-Mar-2024 | 10:26 AM CET
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Place and date of issue/

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



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
M44310094	GraviSet Varioline with cover, ENFit

Certificate Of Completion

Envelope Id: B9CE1A06D5E140DAB3D8688DC265217C	Status: Completed
Subject: Complete with DocuSign: 603_TF Enteral Giving Sets and Accessories_class Is_EU DoC_27.03.2024_D...	
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Document Pages: 2	Signatures: 1
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Certified Delivery Events	Status	Timestamp
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Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	3/27/2024 10:22:50 AM
Envelope Updated	Security Checked	3/27/2024 10:25:32 AM
Envelope Updated	Security Checked	3/27/2024 10:25:32 AM
Certified Delivered	Security Checked	3/27/2024 10:23:11 AM
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Completed	Security Checked	3/27/2024 10:26:16 AM

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Status

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