



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EC-certificate No. G10
037258 0012 Rev.02 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.

Ebersburg, 27.03.2024

Sandra Leipold
Sr. Manager RA

DocuSigned by:
S. Leipold
 Signer Name: Sandra Leipold
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Attachment to EU DECLARATION OF CONFORMITY

Enteral Giving Sets and Accessories

Basic UDI:
42502737NEN60312a000000H4

Article Number	Product Name
7751900	Amika EasyBag, ENFit
7751902	Amika Varioline, ENFit
7751903	Amika TwoLine EasyBag, ENFit
7751904	Amika Varioline Comfort, ENFit
7751905	Amika EasyBag mobile, ENFit
7751906	Amika Bag mobile, ENFit
7751907	Amika Pump Set Easybag, universal, ENFit
7751908	Amika Pump Set Bag, universal, ENFit
7751909	Amika Pump Set Varioline, universal, ENFit
7751910	Amika Pump Set TwoLine Easybag, universal, ENFit
7751913	Amika Pump Set Bag mobile, universal, ENFit
7751914	Amika Bag with cover, ENFit
7751915	Amika Bag mobile with cover, ENFit
7751916	Amika EasyBag mobile with cover, ENFit
7751917	Amika EasyBag with cover, ENFit
7751918	Amika EasyBag non med port with cover, ENFit
7751919	Amika Varioline with cover, ENFit
7751923	Applix Smart/Vision Bag, ENFit
7751924	Applix Smart/Vision Varioline, ENFit
7751925	Applix Smart/Vision TwoLine EasyBag, ENFit
7751926	Applix Smart/Vision Varioline Comfort, ENFit
7751927	Applix Smart/Vision EasyBag mobile, ENFit

Article Number	Product Name
7751928	Applix Smart/Vision Bag mobile, ENFit
7751929	Applix Smart/Vision EasyBag with cover, ENFit
7751930	Applix Smart/Vision EasyBag non med port with cover, ENFit
7751932	Applix Smart/Vision Varioline with cover, ENFit
7751933	Applix Smart/Vision Bag with cover, ENFit
7751934	Applix Smart/Vision Bag mobile with cover, ENFit
7751935	Applix Smart/Vision TwoLine EasyBag with cover, ENFit
7751943	Applix Smart/Vision Pump Set EasyBag, universal, ENFit
7751944	Applix Smart/Vision Pump Set EasyBag with cover, universal, ENFit
7751945	Applix Smart/Vision Pump Set Bag, 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
7751950	Applix Smart/Vision Pump Set Bag mobile, universal, ENFit
7751956	Amika, Bag, ENFit
7751994	Amika TwoLine EasyBag with cover, ENFit
7751995	Applix Smart/Vision EasyBag, ENFit
7751996	Applix Smart/Vision EasyBag mobile with cover, ENFit
7751998	Amika Pump Set Varioline Comfort, universal, ENFit
7751999	Amika Pump Set EasyBag mobile, universal, ENFit
7751715T	Amika Pump Set Bag, universal, ENFit
7752085T	Amika Pump Set EasyBag, universal, ENFit


Certificate Of Completion

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Document Pages: 3	Signatures: 1	Envelope Originator:	
Certificate Pages: 5	Initials: 0	Sandra Leipold	
AutoNav: Enabled		Else-Kröner-Straße 1	
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