



**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  
Signing Reason: I approve this document  
Signing Time: 27-Mar-2024 | 10:29 AM CET  
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**Attachment to EU DECLARATION OF CONFORMITY**

**Enteral Giving Sets and Accessories**

Basic UDI:  
42502737NEN60312a000000H4

<b>Article Number</b>	<b>Product Name</b>
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**

Envelope Id: A3DAF20CE7F941B2B4A996F2E11766BC	Status: Completed
Subject: Complete with DocuSign: 603_TF Enteral Giving Sets and Accessories_class Ila_EU DoC_27.03.2024_...	
Source Envelope:	
Document Pages: 3	Signatures: 1
Certificate Pages: 5	Initials: 0
AutoNav: Enabled	Envelope Originator:
Envelopeld Stamping: Disabled	Sandra Leipold
Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna	Else-Kröner-Straße 1
	Bad Homburg v.d.H, Hessen 61352
	Sandra.Leipold@fresenius-kabi.com
	IP Address: 137.83.243.71

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Status: Original 3/27/2024 10:26:58 AM	Holder: Sandra Leipold Sandra.Leipold@fresenius-kabi.com	Location: DocuSign
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Sandra Leipold sandra.leipold@fresenius-kabi.com Dr. Security Level: Email, Account Authentication (Required), Login with SSO	 Signature Adoption: Uploaded Signature Image Signature ID: B9645EE7-DA3E-453B-9FA1-4298C5C5ABFE Using IP Address: 137.83.243.71  With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 3/27/2024 10:28:55 AM Viewed: 3/27/2024 10:29:46 AM Signed: 3/27/2024 10:30:55 AM

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ID: 01110a25-22b3-471c-8f97-db5299a15ab8

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**Intermediary Delivery Events**

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**Carbon Copy Events**

**Witness Events**

**Notary Events**

**Envelope Summary Events**

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	3/27/2024 10:28:55 AM
Certified Delivered	Security Checked	3/27/2024 10:29:46 AM
Signing Complete	Security Checked	3/27/2024 10:30:55 AM
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