

EU Declaration of Conformity with Article List



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EU certificate No. G10
037258 0012 Rev. 03 and Expiration Date 2031-03-09
issued by Notified Body TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

Product Family Description
Enter Feeding Pump

Product name
Amika+

Article number
Refer to attachment

Device classification according to Annex VIII, clause 6, rule 12

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.

Nanchang/ 30.03.2026

Xin Luo, Senior Manager Regulatory Affairs

签署人：
Xin Luo
签名者名称：Xin Luo
签名原因：我批准此文档
签名时间：30-3月-2026 | 9:07 上午 CEST
68E35EE33A5

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 Feeding Pump

Article Number	Product Name	Basic UDI-DI	Intended Purpose
Z044210	Amika+ FR	4052682AEN04012aCF000AX5	Enteral feeding pump and accessories for administration through an enteral route (using a feeding tube) of nutrition and hydration fluids.
Z044220	Amika+ DE		
Z044230	Amika+ GB		
Z044233	Amika+ PH		
Z044234	Amika+ CDN		
Z044240	Amika+ BR		
Z044241	Amika+ CO		
Z044243	Amika+ PT		
Z044246	Amika+ CZ		
Z044254	Amika+ EE		
Z044255	Amika+ NO		
Z044257	Amika+ DK		
Z044259	Amika+ LT		
Z044260	Amika+ IT		
Z044261	Amika+ LV		

EU Declaration of Conformity with Article List

Z044270	Amika+ NL		
Z044280	Amika+ ES		
Z044290	Amika+ INT		
Z044292	Amika+ AU		
Z044294	Amika+ TW		
Z044250	Amika+ SE		
Z044293	Amika+ PL		
Z044262	Amika+ GR		
Z044248	Amika+ RO		
Z044251	Amika+ FI		
Z044242	Amika+ AR		
Z044253	Amika+ HR		
Z044291	Amika+ ZA		

Certificate Of Completion

Envelope Id: D8D71739-C344-4DE1-B56B-C8E707F63191
 Subject: Complete with Docusign: Amika+ MDR DoC_30.03.2026.docx
 Source Envelope:
 Document Pages: 3
 Certificate Pages: 1
 AutoNav: Enabled
 Envelopeld Stamping: Disabled
 Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna

Status: Completed
 Envelope Originator:
 Xiaomin Wang
 Else-Kröner-Straße 1
 Bad Homburg v.d.H, Hessen 61352
 Xiaomin.Wang@fresenius-kabi.com
 IP Address: 58.214.255.246

Record Tracking

Status: Original
 3/30/2026 9:03:39 AM
 Holder: Xiaomin Wang
 Xiaomin.Wang@fresenius-kabi.com
 Location: DocuSign

Signer Events

Xin Luo
 Xin.Luo@fresenius-kabi.com
 Security Level: Email, Account Authentication
 (Required), Login with SSO

Signature

Signature Adoption: Pre-selected Style
 Signature ID:
 9F403ED6-1BF7-4CD3-B02B-388E35EE33A5
 Using IP Address: 58.214.255.246

With Signing Authentication via Docusign password
 With Signing Reasons (on each tab):
 我批准此文档

Timestamp

Sent: 3/30/2026 9:04:18 AM
 Viewed: 3/30/2026 9:07:36 AM
 Signed: 3/30/2026 9:08:12 AM

Electronic Record and Signature Disclosure:
 Not Offered via Docusign

In Person Signer Events

Signature

Timestamp

Editor Delivery Events

Status

Timestamp

Agent Delivery Events

Status

Timestamp

Intermediary Delivery Events

Status

Timestamp

Certified Delivery Events

Status

Timestamp

Carbon Copy Events

Status

Timestamp

Witness Events

Signature

Timestamp

Notary Events

Signature

Timestamp

Envelope Summary Events

Status

Timestamps

Event	Status	Timestamp
Envelope Sent	Hashed/Encrypted	3/30/2026 9:04:18 AM
Certified Delivered	Security Checked	3/30/2026 9:07:36 AM
Signing Complete	Security Checked	3/30/2026 9:08:12 AM
Completed	Security Checked	3/30/2026 9:08:12 AM

Payment Events

Status

Timestamps