

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
10.03.2026

Xin Luo
Senior Manager Regulatory Affairs

签署人：

Xin Luo

Place and date of issue/

Name (printed letters), position and signature of authorized person/

签名者名称：Xin Luo
签名原因：我批准此文档

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

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EU Declaration of Conformity with Article List



Attachment to EU DECLARATION OF CONFORMITY

Enteral Feeding Pump

Article Number	Product Name	Basic UDI-DI	Intended Purpose
Z044110	Amika FR	4052682AEN04012aCF000AX5	Enteral feeding pump and accessories for administration through an enteral route (using a feeding tube) of nutrition and hydration fluids.
Z044120	Amika DE		
Z044130	Amika GB		
Z044133	Amika PH		
Z044136	Amika TH		
Z044139	Amika VN		
Z044140	Amika BR		
Z044141	Amika CO		
Z044142	Amika AR		
Z044143	Amika PT		
Z044144	Amika SK		
Z044145	Amika HU		
Z044146	Amika CZ		
Z044148	Amika RO		
Z044149	Amika BG		
Z044150	Amika SE		
Z044151	Amika FI		
Z044153	Amika HR		
Z044155	Amika NO		
Z044156	Amika RU		
Z044157	Amika DK		
Z044160	Amika IT		
Z044162	Amika GR		
Z044170	Amika NL		
Z044180	Amika ES		
Z044181	Amika ES 2		

EU Declaration of Conformity with Article List

Z044190	Amika INT		
Z044191	Amika ZA		
Z044192	Amika AU		
Z044193	Amika PL		
Z044199	Amika JP		