



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EC-certificate No. G10
037258 0012 Rev. 01 and Expiration Date 2026-03-09
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.

Bad Hersfeld / 03.02.2023

Place and date of issue/
Germany, on

Name (printed letters), position and signature of authorized person/
Heinrich Martens, Vice President Regulatory Affairs

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



Attachment to EU DECLARATION OF CONFORMITY

Enteral Feeding Pump

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose
Z044110	Amika FR	4052682AEN04 012aCF000AX5	Z12030303	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			
Z044190	Amika INT			

Z044191	Amika ZA			
Z044192	Amika AU			
Z044193	Amika PL			
Z044198	Amika JP			