
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. 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
Enteral Feeding Pump

Product name
Amika+

Article number
Refer to attachment

Device classification according to Annex VIII, clause 6.4 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 / 16.03.2023

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

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Attachment to EU DECLARATION OF CONFORMITY

Enteral Feeding Pump

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose
Z044210	Amika+ FR	4052682AEN04012aCF000AX5	Z12030303	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			
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			
Z044270	Amika+ NL			
Z044280	Amika+ ES			

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Z044290	Amika+ INT			
Z044292	Amika+ AU			
Z044294	Amika+ TW			