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
Accessories of Amika/Amika+ Enteral Feeding System and Ambix Nova Infusion System

Product name
Amika and Ambix nova Partner

Article number
Refer to attachment

Device classification according to Annex VIII, clause 6.1, rule 9

Class 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.

Place and date of issue/	Name (printed letters), position and signature of authorized person/
Bad Hersfeld, 02.02.2023	Heinrich Martens, Vice President Regulatory Affairs

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

Attachment to EU DECLARATION OF CONFORMITY

ACCESSORIES OF AMIKA/AMIKA+ Enteral Feeding SYSTEM AND AMBIX NOVA INFUSION SYSTEM

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose
ZK267064	Amika and Ambix nova Partner	4052682AND2201llbSD0000G5	Z12030382 Infusion Instruments Software	a stand-alone maintenance software