

## 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  
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  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

签名时间：10-3月-2026 | 8:39 上午 CET

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### 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	Intended Purpose
ZK267064	Amika and Ambix nova Partner	4052682AND22011IbSD0000G5	a stand-alone maintenance software