



EU DECLARATION OF CONFORMITY

Annex IV of Medical Device Regulation (EU) 2017/745

Product Family Description
Amika/Amika+ accessories

Product name
Refer to attachment

article number
Refer to attachment

Device classification according to Annex VIII
Amika USB Cable (LOT): Rule 1, Class I
Amika AC adapter/charger EUR (LOT): Rule 13, Class I
Amika AC adapter/charger INT (LOT): Rule 13, Class I
Smart Holder Power EU/JP Accessory (SN): Rule 13, Class I
Smart Holder COM EU Accessory (SN): Rule 13, Class I

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 / 08.12.2022

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

Amika / Amika+ accessories

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose
Z044905	Amika USB Cable	4052682NND11011xHF0000UH	Z12030399	The Amika USB cable is intended to connect the pump to a computer for configuration and maintenance of the Amika system.
Z044904	Amika AC adapter/charger EU	4052682AND12011xHF0000AD		The Amika AC adapter/charger is intended to use for power supply. It is intended to be connected to a Holder Power or Holder COM.
Z044907	Amika AC adapter/charger INT	4052682AND12011xHF0000AD		
CS1000428	Smart Holder Power EU Accessory	4052682AND31011xHF0000BQ		The Smart Holder Power/COM is intended to supply the operating power and to charge the battery for the pump installed on it when it is connected to the main power supply.
CS1000428JP	Smart Holder Power JP Accessory	4052682AND31011xHF0000BQ		
CS1000429	Smart Holder COM EU Accessory	4052682AND31011xHF0000BQ		