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
Ambix Sets

Product name
Refer to attachment

Article Name
Refer to attachment

Device classification according to Annex VIII, clause 4.2 rule 2

Class IIa

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
14.02.2023

Heinrich Martens
Vice President Regulatory Affairs

Place and date of issue/ Name (printed letters), position and signature of authorized person/

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

Attachment to EU DECLARATION OF CONFORMITY

Infusion Sets

Ambix Sets

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose
M46421820	Ambix nova ambulatory Set	42502737NIV51412a000000ZF	A03010105	IV administration set for infusion pumps.
M46421910	Ambix nova stationary Set			
2892100	Ambix activ Set ambulatory			
2892098	Ambix activ Set stationary			