



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EC-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)

Infusion pump

Refer to attachment
(Product name)

Refer to attachment
(article number)

Device classification according to Annex VIII, clause 6.4, rule 12


Class I Ib

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
20.03.2023

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 pump

Ambix nova pump

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose
N044530	Ambix nova GB	4052682AIV02012b CF000ADF	Infusion Pump Z12030301	Ambulatory infusion pump and accessories for IV administration of specific fluids.
N044510	Ambix nova FR			
N044590	Ambix nova INT			
N044520	Ambix nova DE			
N044546	Ambix nova CZ			
N044554	Ambix nova EE			
N044560	Ambix nova IT			
N044558	Ambix nova LT			
N044544	Ambix nova SK			
N044543	Ambix nova PT			
N044550	Ambix nova SE			
N044570	Ambix nova NL			
N044555	Ambix nova NO			
N044553	Ambix nova HR			
N044545	Ambix nova HU			
N044557	Ambix nova DK			
N044593	Ambix nova PL			
N044561	Ambix nova LV			
N044542	Ambix nova AR			
N044592	Ambix nova AU			
N044552	Ambix nova SL			
N044549	Ambix nova BG			
N044534	Ambix nova CDN			

