

## EU Declaration of Conformity with Article List



### EU DECLARATION OF CONFORMITY

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

Refer to attachment  
(Product name)

Refer to attachment  
(article number)

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

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  
30.03.2026

Xin Luo  
Senior Manager Regulatory Affairs

签署人：

Xin Luo

签名者名称：Xin Luo

签名原因：我批准此文档

签名时间：30-3月-2026 | 9:08 上午 CEST

Place and date of issue/

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

## EU Declaration of Conformity with Article List

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	Intended Purpose
N044530	Ambix nova GB	4052682AIV02012bCF0 00ADF	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		
N044540	Ambix nova BR		

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	Bad Homburg v.d.H, Hessen 61352
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