FRESENIUS KABI

E U D E C L A R A T I O N O F C O N F O R M I T Y

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
Ambix nova Sets

Product name
Ambix nova Sets

Article number
Refer to attachment

Device classification according to Annex VIII, clause 4.2 rule 2

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

                              Sr. Manager RA

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：2026年03月10日 18:39:10 CST

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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 nova Sets

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