

EU Declaration of Conformity with Article List



EU DECLARATION OF CONFORMITY

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

Product name
Infusion Pump

Article number
Refer to attachment

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
10.03.2026

Xin Luo
Senior Manager Regulatory Affairs

签署人：

Xin Luo

Place and date of issue/

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

签名者名称：Xin Luo

签名原因：我批准此文档

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

签名时间：10-3月-2026 | 8:40 上午 CET

9F403ED61BF74CD3B02B388E35EE33A5

EU Declaration of Conformity with Article List



Attachment to EU DECLARATION OF CONFORMITY

INfusia Infusion pump

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose
INFVP7S-ED3	Infusion pump	4052682AIV02012bCF000ADF	Z12030301	Infusion pump and accessories for administrate specific fluid through administration set.
ZINFVP7SE3	Infusion pump			
INFVP7S-IN-ED3	Infusion pump			
INFVP7S-MY-ED3	Infusion pump			
INFVP7S-TR-ED3	Infusion pump			
INFVP7E-FR-ED3	Infusion pump			
INFVP7S-PT-ED3	Infusion pump			
INFVP7S-ID-ED3	Infusion pump			
INFVP7S-VT-ED3	Infusion pump			
INFVP7S-RO-ED3	Infusion pump			