

**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)

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.

Bad Hersfeld / 03.02.2023



Place and date of issue/  
Germany, on

Name (printed letters), position and signature of authorized person/  
Heinrich Martens, Senior Director Regulatory Affairs

Germany, on

Heinrich Martens, Senior Director Regulatory Affairs

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

**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			