

## 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. 02](#) and Expiration Date [March 09, 2026](#)  
issued by Notified Body (TÜV Süd Product Service GmbH,  
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123)

Product Family Description  
**Infusion pump, general purpose  
Test instrument, infusion device**

Product name  
**Exelia VP  
Exelia Drop Sensor**

article number, serial number  
Refer to attachment


**Exelia VP**  
Device classification according to Annex VIII, rule 12  
Class  IIa -  IIb

**Exelia Drop Sensor**  
Device classification according to Annex VIII, rule 9  
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.

| Place and date of issue/   | Name (printed letters), position and signature of authorized person/   |
|--|--|
| Brezins, on <i>May 23, 2024</i>  | Laurent KELLER<br>Regulatory Affairs Manager<br> |
| Valid starting with the original date of the document until product change |  |

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Attachment to EU DECLARATION OF CONFORMITY

Product Family Description  
Infusion Pump, general purpose

| Article Number | Product Name | Basic UDI-DI             | CND designation              | Intended Purpose  | From Serial Number |
|----------------|--------------|--------------------------|------------------------------|---|--------------------|
| Z085010        | Exelia VP    | 4052682AIV02012bCF000ADF | Z12030301 -<br>Infusion pump | Infusion Pumps and Accessories for Administration of Fluids | 25173893           |

Product Family Description  
Test instrument, infusion device

| Article Number | Product Name       | Basic UDI-DI             | CND designation                                 | Intended Purpose  | From Lot Number |
|----------------|--------------------|--------------------------|---|---|-----------------|
| Z073208        | Exelia Drop Sensor | 4052682AND37012bHF00006F | Z12030399 -<br>Infusion Instruments -<br>Others | Infusion Pumps and Accessories for Administration of Fluids | 1022            |