

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. 01](#) 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>July 20, 2023</i>	Laurent KELLER Regulatory Affairs Manager 
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 - 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 - Infusion Instruments - Others	Infusion Pumps and Accessories for Administration of Fluids	1022