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**EU Declaration of Conformity with article list**

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**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  
Accessories of Exelia Infusion System

Product name  
Exelia Partner

Article number, serial number  
Refer to attachment


Device classification according to Annex VIII,  
Exelia Partner, Rule 9, Class 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.

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Place and date of issue/ Brezins, on <i>July 20, 2023</i>	Name (printed letters), position and signature of authorized person/ Laurent KELLER Regulatory Affairs Manager 
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Valid starting with the original date of the document until product change



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**Attachment to EU DECLARATION OF CONFORMITY**

**ACCESSORIES OF EXELIA INFUSION SYSTEM**

<b>Article Number</b>	<b>Product Name</b>	<b>Basic UDI-DI</b>	<b>CND designation</b>	<b>Intended Purpose</b>	<b>From Serial Number</b>
ZK267067	Exelia Partner (in Key2)	4052682AND22012bSD000048	Z12030382 - Infusion Instruments - Software	Software for use with Fresenius Kabi infusion devices	Not applicable (Software has no physical support)