FRESENIUS KABI

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. 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
Accessories of Exelia Infusion System

Product name
Exelia Partner

Article number, serial number
Refer to attachment

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 June 14, 2024	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

ACCESSORIES OF EXELIA INFUSION SYSTEM

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose	From Serial Number
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)