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
Accessory of Agilia Infusion System

Product name:
Agilia Partner

Article number, serial number/batch number
Refer to attachment

Device classification according to Annex VIII,
Agilia 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.

Place and date of issue/	Name (printed letters), position and signature of authorized person/
Brezins, on April 25, 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

Accessory of Agilia infusion system

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose	From Serial Number/Batch Number
ZK267049	Agilia Partner (Key 2 version)	4052682AND220 12bSD000048	Z12030382 - Infusion Instruments – Software	Software for use with Fresenius Kabi infusion devices	Not applicable (Software has not a physical support)

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Accessory of Agilia infusion system

DISCONTINUED

Article Number	Product Name	Basic UDI-DI	CND designation (include full text for applicable CND code)	Intended Purpose (include full text for intended purpose of the device)	Serial Number/Batch Number (add for batch specific DoCs)
Z067049	Agilia Partner (CD-ROM version) (Class I)	4052682AND22011xSF0000FZ	Z12030382	Agilia Partner is the software application dedicated to the maintenance of Agilia Connect infusion system devices and Link+ Agilia.	Last batch number 320086634