
EU Declaration of Conformity with article list



EU DECLARATION OF CONFORMITY

Annex IV of Medical Device Regulation (EU) 2017/745

Product Family Description
Accessory of Agilia Infusion System

Product name: Agilia Partner
Refer to attachment

Refer to attachment
Article number, serial number/batch number

Device classification according to Annex VIII, clause 6.5, rule 13

Class I

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, RoHS Directive 2011/65/UE 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/
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Brezins, on <i>Sept 14, 2021</i>	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

Accessory of Agilia infusion system

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)	4052682A ND22011x SF0000FZ	Z12030382	Agilia Partner is the software application dedicated to the maintenance of Agilia Connect infusion system devices and Link+ Agilia.	Lot number 320076076
ZK267049	Agilia Partner (Key 2 version)	4052682A ND22011x SD0000FB	Z12030382	Agilia Partner is the software application dedicated to the maintenance of Agilia Connect infusion system devices and Link+ Agilia.	Not applicable (Software has not a physical support)