
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
Refer to attachment

Article number, serial number
Refer to attachment

From serial number
Refer to attachment

Device classification according to Annex VIII, rule 1
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 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 *March 17, 2026* 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	Intended purpose	Serial number/Batch number
Z073496	AGILIA NURSE CALL CABLE	4052682NND11011xHF0000UH	Infusion Pumps and Accessories for Administration of Fluids	24870103
Z073491	AGILIA USB CABLE			24870101
Z073551	LINK+ AGILIA USB CABLE			24870106
Z073601	LINK+ AGILIA RS232 CABLE			24870105
Z073602	LINK+ AGILIA NURSE CALL CABLE			24870104