FRESENIUS KABI

EU Declaration of Conformity with article list

FRESENIUS KABI

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
Refer to attachment

From serial number / Batch number
AGILIA DUO: (Batch number) 24870102
AGILIA HOLDER AMBULANCE: (Serial number) 24870107

Device classification according to Annex VIII
AGILIA DUO: Rule 13, Class I
AGILIA HOLDER AMBULANCE: 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, 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
Brezins, on Feu. 27, 2023	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
Z073600	AGILIA DUO	4052682AND31011xHF0000BQ
Z073290	AGILIA HOLDER AMBULANCE INT	4052682NND32011xHF0000XS
Z073291	AGILIA HOLDER AMBULANCE INT 2	