
EU Declaration of Conformity with article list



EU DECLARATION OF CONFORMITY

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

Product Family Description
Rack for Infusion System
Accessory of Agilia Infusion System

Product name
Refer to attachment

Article number
Refer to attachment

From serial number
Refer to attachment

Device classification according to Annex VIII,
AGILIA LINK range: Rule 13, Class I
FUNCTIONAL EARTH CABLE AGILIA LINK: 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 <i>October 31, 2024</i>	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

RACK FOR INFUSION SYSTEM
ACCESSORY OF AGILIA INFUSION SYSTEM

Article number	Product name	Basic UDI-DI	Intended Purpose	Serial Number
Z074100	AGILIA LINK 4	4052682AND31011x HF0000BQ	Infusion Pumps and Accessories for Administration of Fluids	24907819
Z076100	AGILIA LINK 6			
Z078100	AGILIA LINK 8			
Z074110	AGILIA LINK 4 EU1			
Z076110	AGILIA LINK 6 EU1			
Z078110	AGILIA LINK 8 EU1			
Z074120	AGILIA LINK 4 EU2			
Z076120	AGILIA LINK 6 EU2			
Z078120	AGILIA LINK 8 EU2			
Z074130	AGILIA LINK 4 EU3			
Z076130	AGILIA LINK 6 EU3			
Z078130	AGILIA LINK 8 EU3			
Z074140	AGILIA LINK 4 EU4			
Z076140	AGILIA LINK 6 EU4			
Z078140	AGILIA LINK 8 EU4			
Z074141	AGILIA LINK 4 BR			

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Article number	Product name	Basic UDI-DI	Intended Purpose	Serial Number
Z076141	AGILIA LINK 6 BR			
Z078141	AGILIA LINK 8 BR			
Z074142	AGILIA LINK 4 LAM			
Z076142	AGILIA LINK 6 LAM			
Z078142	AGILIA LINK 8 LAM			
Z074156	AGILIA LINK 4 RU			
Z076156	AGILIA LINK 6 RU			
Z078156	AGILIA LINK 8 RU			
Z074191	AGILIA LINK 4 ASI			
Z076191	AGILIA LINK 6 ASI			
Z078191	AGILIA LINK 8 ASI			
Z073609	FUNCTIONAL EARTH CABLE AGILIA LINK	4052682NND13011x HF0000WF		24902144

