
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
AGILIA LINK range: 24907819
FUNCTIONAL EARTH CABLE AGILIA LINK: 24902144

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): *pending information*

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/

Brezins, on *May 11, 2021*

Name (printed letters), position and signature of authorized person/

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
Z074110	AGILIA LINK 4 EU1	4052682AND31011xHF0000BQ
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	
Z074142	AGILIA LINK 4 LAM	
Z076142	AGILIA LINK 6 LAM	
Z078142	AGILIA LINK 8 LAM	
Z073609	FUNCTIONAL EARTH CABLE AGILIA LINK	