

### **EU Declaration of Conformity with article list**



#### EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EC-certificate No. G10 037258 0012 Rev. 02 and Expiration Date March 09th, 2026 issued by Notified Body TÜV Süd Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

> **Product Family Description** Intravenous pole multi-outlet holder

> > Product name Refer to attachment

> > Article number Refer to attachment

From serial number / Batch number Refer to attachment

Device classification according to Annex VIII LINK+ AGILIA range: Rule 12, Class IIb

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/

Source of Form:

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

Global-FORM-RA-000003201 Version: 5.0 Doc ref: FKBZ-DT0133\_DEC\_MDR-3

Page: 1 of 2



# **EU Declaration of Conformity with article list**



# Attachment to EU DECLARATION OF CONFORMITY

## LINK+ AGILIA range

#### LINK+ AGILIA

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z074601	LINK 4+ AGILIA	25773606	
Z076601	LINK 6+ AGILIA	25773636	4052682AND31012bCF0000WH
Z078601	LINK 8+ AGILIA	25773637	

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z074630	LINK 4+ AGILIA EU3	26047050	
Z076630	LINK 6+ AGILIA EU3	Not manufactured yet	4052682AND31012bCF0000WH
Z078630	LINK 8+ AGILIA EU3	Not manufactured yet	

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z074679	LINK 4+ AGILIA ID	Not manufactured yet	
Z076679	LINK 6+ AGILIA ID	Not manufactured yet	4052682AND31012bCF0000WH
Z078679	LINK 8+ AGILIA ID	Not manufactured yet	

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z074691	LINK 4+ AGILIA ASI	Not manufactured yet	
Z076691	LINK 6+ AGILIA ASI	Not manufactured yet	4052682AND31012bCF0000WH
Z078691	LINK 8+ AGILIA ASI	Not manufactured yet	

Article number	Product name	Serial number / Batch number	Basic UDI-DI
Z074642	LINK 4+ AGILIA LAM	Not manufactured yet	
Z076642	LINK 6+ AGILIA LAM	Not manufactured yet	4052682AND31012bCF0000WH
Z078642	LINK 8+ AGILIA LAM	Not manufactured yet	

Global-FORM-RA-000003201 Source of Form: Doc ref: FKBZ-DT0133\_DEC\_MDR-3

Version: 5.0

Page: 2 of 2