
EU Declaration of Conformity with article list



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EU-certificate No. [G10_037258_0012 Rev. 01](#) and Expiration Date [March 09, 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 order
Infusion pump management unit, mobile**

Product name
**Exelia Link
Exelia ComAdaptor**

article number, serial number
Refer to attachment

Device classification according to Annex VIII, rule 9
Class IIa - 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/

Brezins, on *July 20, 2023*

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

Product Family Description
Intravenous pole multi-outlet order

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose	From Serial Number
Z086010	Exelia Link	4052682AND31012bCF0000WH	Z12030399 - Infusion Instruments - Others	Infusion Pumps and Accessories for Administration of Fluids	25173874

Product Family Description
Infusion pump management unit, mobile

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose	From Serial Number
Z086904	Exelia ComAdaptor	4052682AND11012bHF0000W8	Z12030399 - Infusion Instruments - Others	Infusion Pumps and Accessories for Administration of Fluids	25172155