
EU Declaration of Conformity with article list



EU DECLARATION OF CONFORMITY

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

Product Family Description
Accessories of Exelia Infusion System

Product name
Exelia DuoLink
Exelia ComCable 10m
TM support
Exelia Maintenance Adaptor

article number, serial number/batch number
Refer to attachment

Exelia DuoLink
Exelia Maintenance Adaptor

Device classification according to Annex VIII, rule 13
Class I

Exelia ComCable 10m
TM support

Device classification according to Annex VIII, 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 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



EU Declaration of Conformity with article list



Attachment to EU DECLARATION OF CONFORMITY

Product Family Description
Accessories of Exelia Infusion System

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose	From Serial Number
Z086210	Exelia DuoLink	4052682AND31011xHF0000BQ	Z12030399 - Infusion instruments - others	Infusion Pumps and Accessories for Administration of Fluids	24633238
Z086902	Exelia Maintenance Adaptor	4052682AND11011xHF00009E	Z120030399 - Infusion instruments - others		24725934
Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose	From Batch Number
Z086906	Exelia ComCable 10m	4052682NND11011xHF0000UH	Z12030399 - Infusion instruments - others	Infusion Pumps and Accessories for Administration of Fluids	34774109
Z086900	TM support	4052682NND32011xHF0000XS	Z12030399 - Infusion instruments - others		2420