FRESENIUS KABI

EU Declaration of Conformity with article list

FRESENIUS KABI

EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EU-certificate No. G10_037258_0012 Rev. 02 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
Infusion pump management unit, mobile

Product name
Exelia Combox
Exelia Therapy Manager

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/	Name (printed letters), position and signature of authorized person/
Brezins, on June 14, 2024	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
Infusion pump management unit, mobile

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose	From Serial Number
Z086710	Exelia Combox	4052682AND36012bCF00003F	Z12030399 – Infusion Instruments - Others	Infusion Pumps and Accessories for Administration of Fluids	25171237
Z086810	Exelia Therapy Manager	4052682AND35012bCF00002G			25172150