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**EU Declaration of Conformity with article list**

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**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  
**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.

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

Brezins, on *July 20, 2023*

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**

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