FRESENIUS KABI

## EU Declaration of Conformity with article list

FRESENIUS KABI

# EU DECLARATION OF CONFORMITY

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

Product Family Description
Accessories of Exelia Infusion System

Product name
Exelia Partner
Exelia Maintenance Adaptor

Article number, serial number
Refer to attachment

Device classification according to Annex VIII,
Exelia Partner, Rule 13, Class I
Exelia Maintenance Adaptor, Rule 13, 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, RoHS Directive 2011/65/UE 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 March 07, 2022 | Laurent KELLER<br>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

### ACCESSORIES OF EXELIA INFUSION SYSTEM

| Article Number | Product Name | Basic UDI-DI | CND designation | Intended Purpose | From Serial Number |
|---|---|---|---|---|---|
| ZK267067 | Exelia Partner (in Key2) | 4052682AND22011xSD0000FB | Z12030382 - Infusion Instruments – Software | Software application dedicated to the maintenance of Exelia infusion system devices | Not applicable (Software has no physical support) |
| Z086902 | Exelia Maintenance Adaptor | 4052682AND11011xHF00009E | Z120030399 - Infusion instruments - others | Syringe Pumps and Accessories for IV Administration of Fluids.<br>Volumetric infusion Pump and Accessories for IV Administration of Fluids. | 24725934 |