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
INfusia Helper

Product name
INfusia Helper

article number
Refer to attachment

Device classification according to Annex VIII, clause 6.5, 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 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.

Bad Hersfeld / 10.08.2021
Place and date of issue/

Heinrich Martens / Sen. Director RA
Name (printed letters), position and signature of authorized person/

Valid starting with the original date of the document until product change

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Attachment to EU DECLARATION OF CONFORMITY

INfusia Helper

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose
INFHELPER	INfusia Helper	405268AND22011xSD0000FB	Z12030382	A stand-alone maintenance software application running on a computer to maintain and configure the pump.