- Confidential -

FRESENIUS KABI

EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EU-certificate No. G11 037258 0015 Rev. 01 and Expiration Date 2027-07-31
issued by Notified Body (e.g. TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123)

Infusion Sets Gravity
Generic Devices: Secondary Lines

Refer to attachment
(Product name)

Refer to attachment
(article number)

Device classification according to Annex VIII, clause 4.2, rule 2

Class Is

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.

Dr. Sandra Leipold

Senior Manager Regulatory Affairs

DocuSigned by:
S. Leipold
B9645EE7DA35453...

19-Mar-2024

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

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

FRESENIUS KABI

Attachment to EU DECLARATION OF CONFORMITY

Infusion Sets Gravity
Generic Devices: Secondary Lines

Article Number	Product Name	Basic UDI-DI
M77460068Y	SL OP IP Light-protected, PUR material	42502737NIV50011s0000005W
M77460069Y	SL IP PUR material	42502737NIV50011s0000005W
M77460070Y	SL Filter IP PUR material	42502737NIV50011s0000005W