



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.

Bad Hersfeld, 22.01.2026

Place and date of issue/


 Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signing Time: 22-Jan-2026 | 11:41 AM CET
Sandra Leipold, Senior Manager Regulatory Affairs
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Valid starting with the original date of the document until product change



Attachment to EU DECLARATION OF CONFORMITY

Infusion Sets Gravity
Generic Devices: Secondary Lines
Intended Purpose: IV Secondary Infusion Line
Basic UDI-DI: 42502737NIV50011s0000005W

Article Number	Product Name
M77460068Y	SL OP IP Light-protected, PUR material
M77460069Y	SL IP PUR material
M77460070Y	SL Filter IP PUR material
M77460072	SL OP IP PE Light-protected, PE-lined fluid path (Polyethylene)
M77460073	SL Filter IP PE Light-protected, PE-lined fluid path (Polyethylene)
M77460065	SL 00 OP Light-protected