FRESENIUS KABI

EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to
EU certificate No. G10 037258 0012 Rev. 02 and Expiration Date 2026-03-09
issued by Notified Body TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

IV Syringes

Refer to attachment
(Product name)

Refer to attachment
(Article number)

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

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.

DocuSigned by:
S. Leipold
Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signing Time: 24-Jun-2024 | 11:03 AM CEST
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Asbach, 24.06.2024

Dr. Sandra Leipold, Senior Manager Regulatory Affairs

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

Attachment to EU DECLARATION OF CONFORMITY

IV Syringes

Basic UDI-DI: 42502737NIV50412a000000YG

Article Number	Product Name
M93000000	Injectomat® Syringe 50 ml with cannula 1.8 mm x 38 mm
M93000010	Injectomat® Syringe 50 ml
M93000020	Injectomat® Syringe 50 ml, light protected with cannula 1.8 mm x 38 mm
M93000030	Injectomat® Syringe 50 ml, light protected

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Certificate Of Completion

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Subject: Complete with Docusign: 504_TF IV Syringes_EU DoC_24.06.2024_Draft.docx
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Document Pages: 2
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Envelope Sent	Hashed/Encrypted	24 June 2024 | 09:57
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