



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EC-certificate No. G10
037258 0012 Rev. 01 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

Intended purpose: "IV Syringes for power driven syringe pumps for fluid administration"

Refer to attachment
(Product name)

Refer to attachment
(article number, serial number/batch number – if applicable)

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.

Bad Hersfeld, 19.02.2024 Dr. Sandra Leipold, Sr Manager RA

Place and date of issue/

Name (printed letters), position and signature of authorized person

DocuSigned by:
S. Leipold
Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signed on: 19 Feb 2024 | 1:44 PM CET
B9645EE7DA3E453B9FA14298C5C5ABFE

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



Attachment to EU DECLARATION OF CONFORMITY

IV Syringes

Article Number	Product Name	Basic UDI-DI	EMDN
M93000000	Injectomat® Syringe 50 ml with cannula 1.8 mm x 38 mm	42502737NIV50412a000000YG	A020102
M93000010	Injectomat® Syringe 50 ml	42502737NIV50412a000000YG	A020102
M93000020	Injectomat® Syringe 50 ml, light protected with cannula 1.8 mm x 38 mm	42502737NIV50412a000000YG	A020102
M93000030	Injectomat® Syringe 50 ml, light protected	42502737NIV50412a000000YG	A020102