FRESENIUS KABI

# EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to
EU certificate No. G10 0372580012 Rev. 02 and Expiration Date 2026-03-09
issued by Notified Body (e.g. TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123)

**Filters**
Intended Purpose: "Sterile, single use filters for filtration in IV therapy"

Refer to attachment
(Product name)

Refer to attachment
(Article Number)

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

Class x 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, 15.05.2024 Dr. Sandra Leipold, Sr. Manager, RA S. Leipold

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

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## Attachment to EU DECLARATION OF CONFORMITY

### TF Filter

| Article Number | Product Name | Basic UDI-DI | EMDN designation |
|---|---|---|---|
| M77401050 | Infufil Air 120h, 0.2 µm, positive, 10 $cm^2$ | 42502737NIV51012a000000VT | A040101 (ADMINISTRATION AND ASPIRATION FILTERS) |
| M77401060 | Lipifil Air 24h, 1.2 µm, 10 $cm^2$ | 42502737NIV51012a000000VT | A040101 (ADMINISTRATION AND ASPIRATION FILTERS) |