



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EU certificate No. G11
037258 0015 Rev 00 and Expiration Date 2027-07-31
issued by Notified Body TÜV SÜD Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

Transfer Devices

Intended Purpose: "For withdrawal and admixture of IV solutions (e.g. drugs or lipids)"

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.

Asbach, 30.11.2023

Dr. Sandra Leipold
Sr. Manager RA

A handwritten signature in blue ink, appearing to read 'S. Leipold', written over a horizontal line.

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

Transfer Devices

Intended Purpose:

Reconstitute and/or admix drugs prior to administration to the patient. The device may be used for pediatric and adult populations.

Article Number	Product Name	Basic UDI-DI	EMDN designation (include full text for applicable EMDN code)
2867001	Freka Lipoflow	42502737NIV50611s000000BC	A0799 – ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS - OTHER
2870103	Freeflex+ Transfer Adapter	42502737NIV50611s000000BC	A0799 – ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS - OTHER