



**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 TÜV Süd Product Service GmbH,  
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

**Admixture Bags and Accessories**

Refer to attachment  
(Product name)

Refer to attachment  
(article number)

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

Class  Is  Im  Ir

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 12.03.2026*

Place and date of issue/

*S. Leipold*  
Dr. Sandra Leipold, Director Regulatory Affairs

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**

**Admixture Bags and Accessories**

**Basic UDI-DI: 42502737NIV50711s000000C9**

Article Number	Product Name	Intended purpose
F2859001	Freka® Mix Bag 1000 mL + 3-filling leads	IV admixture bag with filling leads
F2859011	Freka® Mix Bag 1000 mL	IV admixture bag
F2859021	Freka® Mix Bag 2000 mL	IV admixture bag
F2859031	Freka® Mix Bag 3000 mL	IV admixture bag
F2859041	Freka® Mix Bag 150 mL	IV admixture bag
F2859051	Freka® Mix Bag 250 mL	IV admixture bag
F2859061	Freka® Mix Bag 500 mL	IV admixture bag
F2859271	Gravity 3-filling leads	IV filling leads set
F2859311	Freka® Mix Bag 3000 mL + 3-filling leads	IV admixture bag with filling leads
F2859321	Freka® Mix Bag 2000 mL + 3-filling leads	IV admixture bag with filling leads
F2860051	Freka® Mix Bag 250 mL (Twist Off)	IV admixture bag
F2860061	Freka® Mix Bag 500 mL (Twist Off)	IV admixture bag
F2860231	Freka® Mix Bag 3000 mL +6-filling leads	IV admixture bag with filling leads + filter
F2860241	Freka® Mix Bag 3000 mL +6-filling leads, Multilayer	IV admixture bag with filling leads + filter
F2860261	Freka® Mix Bag 4000 mL +6-filling leads, Multilayer	IV admixture bag with filling leads + filter
F2860291	Freka® Mix Bag 2000 mL +6-filling leads (Twist Off)	IV admixture bag with filling leads + filter
F2860501	Gravity 1-filling lead	IV filling leads set + filter