



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.

DocuSigned by:
S. Leipold
 Signer Name: Sandra Leipold
Signing Reason: I approve this document
Signing Time: 25-Mar-2024 | 10:34 AM CET
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Bad Hersfeld, 25.03.2024

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

Admixture Bags and Accessories

Basic UDI-DI: 42502737NIV50711s000000C9

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

Certificate Of Completion

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Subject: Complete with DocuSign: 507_TF Admixture Bags and Accessories_EU DoC_25.03.2024.docx	
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Envelopeld Stamping: Disabled	Cristina Munteanu
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	Bad Homburg v.d.H, Hessen 61352
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Signer Events	Signature	Timestamp
Sandra Leipold		Sent: 25 March 2024 07:04
Sandra.Leipold@fresenius-kabi.com		Viewed: 25 March 2024 10:34
Dr.		Signed: 25 March 2024 10:34
Security Level: Email, Account Authentication (Required)	Signature Adoption: Uploaded Signature Image	
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Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	25 March 2024 07:04
Certified Delivered	Security Checked	25 March 2024 10:34
Signing Complete	Security Checked	25 March 2024 10:34
Completed	Security Checked	25 March 2024 10:34
Payment Events	Status	Timestamps

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