- Confidential -



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

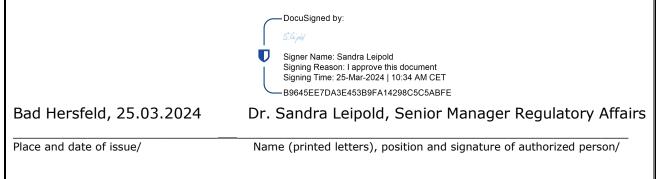
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We

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.



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

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