By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 724794 R002

Manufacturer: Fresenius Kabi AG

Address:
Else-Kröner-Str. 1
Bad Homburg
61352
Germany

Single Registration Number: DE-MF-000009273

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-11-20**

Current Issue Date: **2026-10-30**

Starting Validity Date: **2026-10-30**

Expiry Date: **2029-11-19**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Lavasorb	See MDR 766070
Freka-Clyss	See MDR 766071

Class IIb	Intended purpose
Sterile irrigation solutions	Intended to be used as irrigation solutions for internal (invasive) and external (non-invasive) applications
Solutions for Transfusion Technology	Intended for the anticoagulation of blood and blood components during apheresis.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Non-sterile irrigation solutions	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-11-20	30294781	Issued
2025-08-27	30499263	Supplemented – Addition of Lavasorb, addition of Sterile Water for Irrigation, and Sodium Chloride 0.9% devices to the Sterile Irrigation Solutions group. Amended – Administrative update to remove the indications from the intended purpose.
2026-01-27	30573028	Supplemented – Addition of device, Sodium bicarbonate 1.4% Fresenius (Non-sterile irrigation solutions).
2026-05-19	30634199	Amended – Change of subcontractor for Sodium Chloride 0.9% Fresenius.
2026-06-24	30169013	Supplemented – Addition of Solutions for Transfusion Technology; ACD-A and Sodium Citrate 4%
Current	30763860	Supplemented – Addition of Freka-Clyss

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