

EU Quality Management System Certificate

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

MDR 724794 R000

Manufacturer: Fresenius Kabi AG

Address:

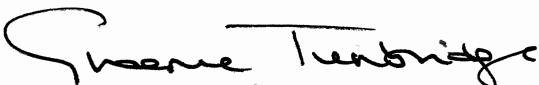
Else-Kröner-Str. 1
Bad Homburg
61352
Germany

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: **2024-11-20**

Starting Validity Date: **2024-11-20**

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

...making excellence a habit.™

EU Quality Management System Certificate

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

MDR 724794 R000

Device Schedule: Class III and Class IIb devices

Class IIb

Sterile irrigation solutions

Intended purpose

Intended to be used as irrigation solutions for internal (invasive) and external (non-invasive) application, including indications for:

- Moistening of gauze and dressings
- Rinsing/ Cleansing of instruments and equipment pre-, intra- and postoperations
- Rinsing/ Irrigation of operational fields pre-, intra- and postoperations
- Irrigation/ Cleansing of wounds, fistula and burns
- Irrigation/ Cleansing of mucosal surfaces of body orifices
- Irrigation/distension during diagnostic procedures
- Filling respiratory air humidifiers

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

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

Starting Validity Date: **2024-11-20**

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

...making excellence a habit.™

EU Quality Management System Certificate

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

MDR 724794 R000

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
Current	30294781	Issued



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

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

Starting Validity Date: **2024-11-20**

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

...making excellence a habit.™

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.