Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 047402 0083 Rev. 00

Manufacturer: **Fresenius Kabi AG**
61346 Bad Homburg
GERMANY

Product Category(ies): **ACTIVE MEDICAL DEVICES (class IIa / IIb)**
Infusion and Enteral Feeding Pumps
incl. Accessories; Drainage Containers;
NON ACTIVE MEDICAL DEVICES (class IIa / IIb / III)
Enteral and Parenteral Feeding Products; Infusion, Transfusion and Transfer Sets incl. Accessories; Drainage Products, Irrigation Solutions;
Port Systems, Catheter and Catheter Systems and Accessories

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713168590

Valid from: 2020-05-19
Valid until: 2024-05-26

Date, 2020-05-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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By Royal Charter

Supplementary information to AR120 817244

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to:

Fresenius Kabi AG
61346 Bad Homburg
Germany

Date: 11 October 2024

Changes Approved:

Date	Reference Number	Action
11 October 2024	30271874	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of irrigation solutions. Original NB Certificate Number: G1 047402 0083 Rev. 00 Legal manufacturer address updated from PO box to physical location.

Inspiring trust for a more resilient world.

11 October 2024

Fresenius Kabi AG
Else-Kröner-Str. 1
Bad Homburg v.d.H
61352
Germany

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	**BSI Reference Number**	**Directive and Annex**	**Reference Number**	**Changes approved**
G1 047402 0083 Rev. 00	AR120 817244	93/42/EEC Annex II excluding Section 4	30271874	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of irrigation solutions. Original NB Certificate Number: G1 047402 0083 Rev. 00 Legal manufacturer address updated from PO box to physical location.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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