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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 047402 0087 Rev. 00

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

Product: **Irrigation Solutions**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713166262

Valid from: 2021-01-18
Valid until: 2024-05-26

Date, 2021-01-18

Christoph Dicks
Head of Certification/Notified Body



EC Certificate

EC Design-Examination Certificate
 Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
 (Devices in Class III)

No. G7 047402 0087 Rev. 00

Model(s): Lavasorb

Parameter:

Name	Number	Modell
Lavasorb Irrigation solution	89 15 62 (HSS 1562)	Lavasorb, 250 ml in Octavia container
Lavasorb Irrigation solution	89 15 64 (HSS 1564)	Lavasorb, 1000 ml in Octavia container
Lavasorb Irrigation solution	89 15 62 (HSS 1562S)	Lavasorb, 250 ml in Octavia container, singlepack
Lavasorb Irrigation solution	B231513	Lavasorb, 250 ml
Lavasorb Irrigation solution	B231513V	Lavasorb, 250 ml
Lavasorb Irrigation solution	B231515	Lavasorb, 1000 ml

Supplementary information to AR120 817245

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 Lavasorb Irrigation solution. Original NB Certificate Number: G7 047402 0087 Rev. 00 Legal manufacturer address updated from PO box to physical location

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
G7 047402 0087 Rev. 00	AR120 817245	93/42/EEC Annex II Section 4	30271874	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Lavasorb Irrigation solution. Original NB Certificate Number: G7 047402 0087 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