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

Signature Not Verified
Dokument podpisany przez Agnieszka Maślak Fresenius Kabi Polska sp. z o.o.
Data: 2024.02.22 10:33:17 CET

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

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Product Service

Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

No. GDS 047402 0091 Rev. 00

Manufacturer:

Fresenius Kabi AG
61346 Bad Homburg
GERMANY

This List of Sites is only valid in combination with the following EC Certificate (MDD): **G1 047402 0083 Rev. 00**

The following pages list all sites under the manufacturer's quality system where product realisation processes are conducted for those devices covered by the aforementioned EC Certificate pursuant to the Directive 93/42/EEC (MDD) concerning medical devices.

Report No.: 713168590

Valid until: 2024-05-26

Issue Date: 2020-07-17

R. Köhler

(Randolf Köhler)
PS-MHS-FA-0 – Foreign Affairs

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Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

No. GDS 047402 0091 Rev. 00

Sites:

Fresenius Kabi Deutschland GmbH Werk Friedberg
Freseniusstrasse 1, 61169 Friedberg, GERMANY

Fresenius Kabi Deutschland GmbH Werk Bad Hersfeld
Robert-Koch-Strasse 5, 36251 Bad Hersfeld, GERMANY

Clinico Medical Sp. z o.o. Blonie k / Wroclawia
ul. Roberta Kocha 1, 55-330 Blonie / Miekinia, POLAND

Fresenius Vial S.A.S.
Le Grand Chemin, 38590 Brézins, FRANCE

Fresenius Kabi Norge AS
Svinesundsveien 80, 1788 Halden, NORWAY

Fresenius Kabi (Nanchang) CO., Ltd.
Qin Lan Road, Nanchang Economic & Technological,
Development Zone, 330013 Nanchang, Jiangxi Province,
PEOPLE'S REPUBLIC OF CHINA

Fresenius Kabi France S.A.S.
6, Rue du Rempart, 27400 Louviers, FRANCE

Labesfal Laboratórios Almiro, S.A.
Zona Industrial de Lagedo, 3465-157 Santiago de Besteiros,
PORTUGAL

Fresenius Kabi Italia S.r.l.
Via Camagre, 41, 37063 Isola della Scala, ITALY

Fresenius Kabi España S.A.U.
Doctor Ferran 12, 08339 Vilassar de Dalt Barcelona, SPAIN

Fresenius Kabi AG
61346 Bad Homburg, GERMANY

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