



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 0078 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; Devices for Autotransfusion,
Apheresis, Cell Separation, and Photopheresis;
Accessories for Blood Donation Systems
NON ACTIVE MEDICAL DEVICES (class IIa / IIb / III)
Enteral and Parenteral Feeding Products;
Infusion, Transfusion and Transfer Sets incl.
Accessories; Drainage Products,
Irrigation Solutions; Medical Containers; Filters;
Catheter (class IIa / IIb / III) and
Port Systems (class III); Blood Donation Systems and
Accessories; Disposables for Autotransfusion,
Apheresis and Cell Separation, and Photopheresis;
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.:

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Valid from:

2019-05-09

Valid until:

2022-06-07

Date,

2019-05-09

Stefan Preiß



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Facility(ies):

Fresenius Kabi España S.A.U.

Doctor Ferran 12, 08339 Vilassar de Dalt Barcelona, SPAIN

Clinico Medical Sp. z o.o. Blonie k / Wroclawia

ul. Roberta Kocha 1, 55-330 Blonie / Miekinia, POLAND

Fresenius Kabi Deutschland GmbH Werk Friedberg

Freseniusstrasse 1, 61169 Friedberg, GERMANY

Fresenius Kabi France S.A.S.

6, Rue du Rempart, 27400 Louviers, FRANCE

Fresenius Kabi Italia S.r.l.

Via Camagre, 41, 37063 Isola della Scala, ITALY

Fresenius Kabi Norge AS

Svinesundsveien 80, 1788 Halden, NORWAY

Fresenius HemoCare Italia S.r.l.

Via San Pietro 1, 41037 Mirandola, ITALY

Fresenius Kabi Deutschland GmbH

Gruener Weg 10, 61169 Friedberg, GERMANY

Fresenius HemoCare Netherlands B.V.

Runde ZZ 41, 7881 HM Emmer Compascuum,
THE NETHERLANDS

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Fresenius HemoCare GmbH

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Fresenius Vial S.A.S.

Le Grand Chemin, 38590 Brézins, FRANCE



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Facility(ies):

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Fenwal France SAS

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