ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 17 04 47402 052

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 and Cell Separation;
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;
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.: 713104685_1

Valid from: 2017-06-08
Valid until: 2022-06-07

Date, 2017-06-06

Stefan Preiß

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

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Facility(ies):

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

Fresenius Kabi Deutschland GmbH
Gruener Weg 10, 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 HemoCare GmbH
Gruener Weg 10, 61169 Friedberg, GERMANY

Fresenius HemoCare Brasil Ltda.
Rua Roque Gonzáles, 128
Itapecerica da Serra / SP, BRAZIL

Fresenius Kabi Horatev CZ s.r.o.
Hořátev 104, 289 13, CZECH REPUBLIC

Fresenius Kabi (Guangzhou) Co., Ltd.
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PEOPLE'S REPUBLIC OF CHINA

Fresenius Kabi (Nanchang) CO., Ltd.
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330013 Nanchang, Jiangxi Province
PEOPLE'S REPUBLIC OF CHINA

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

Fresenius HemoCare Austria GmbH
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