



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:**

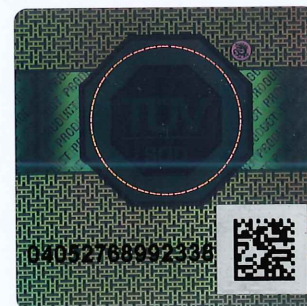
2017-06-08

**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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**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****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 Horátev CZ s.r.o.**

Hořátev 104, 289 13, CZECH REPUBLIC

**Fresenius Kabi (Guangzhou) Co., Ltd.**No. 43 Baoying Street, Free Trade Zone, 510730 Guangzhou  
PEOPLE'S REPUBLIC OF CHINA**Fresenius Kabi (Nanchang) CO., Ltd.**

Qin Lan Road

Nanchang Economic &amp; Technological Development Zone

330013 Nanchang, Jiangxi Province

PEOPLE'S REPUBLIC OF CHINA



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No. G1 17 04 47402 052

#### Facility(ies):

**Fresenius Kabi France S.A.S.**

6, Rue du Rempart, BP 611, 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 HemoCare Austria GmbH**

Pebering 19, 5301 Eugendorf, AUSTRIA

**Fresenius HemoCare Italia S.r.l.**

Via San Pietro 1, 41037 Mirandola, ITALY

**Fresenius HemoCare Netherlands B.V.**

Runde ZZ 41, 7881 HM Emmer Compascuum  
THE NETHERLANDS

**Fenwal, Inc.**

Three Corporate Drive, Lake Zurich IL 60047  
USA

**Fenwal International, Inc.**

Camino Real Industrial Park Road #122, 00683 San German  
PUERTO RICO USA

**Fenwal International, Inc.**

Carretera Sanchez Km 18.5  
Parque Industrial Itabo, Zona Franca Ind. de S.C., Haina  
DOMINICAN REPUBLIC

**Fenwal International, Inc.**

Road 357, Km 0.8, 00606 Maricao  
PUERTO RICO USA

**Fenwal France SAS**

Etaillé, 36400 La Châtre  
FRANCE