ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 047402 0075 Rev. 01

Holder of Certificate: **Fresenius Kabi AG**
61346 Bad Homburg
GERMANY

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Sales, Distribution and Service of Active and Non-Active Medical Devices (including Solutions) for Enteral Nutrition, Infusion and Blood Processing**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713139720

Valid from: 2019-04-08
Valid until: 2022-03-31

Date, 2019-04-08

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Fresenius Kabi AG
61346 Bad Homburg, GERMANY

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

Fresenius Kabi France S.A.S.
5, Place du Marivel, 92316 Sèvres Cedex, FRANCE

Fenwal France SAS
Etaille, 36-400 La Chatre, FRANCE

Fresenius Kabi Deutschland GmbH Werk Mihla
Gartenstrasse 9, 99826 Mihla, GERMANY

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

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

MC Medizintechnik GmbH
Am Neuen Berg 8, 63755 Alzenau-Hörstein, GERMANY

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

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 Netherlands B.V.
Runde ZZ 41, 7881 HM Emmer Compascuum, THE NETHERLANDS

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Facility(ies):

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

Fenwal International, Inc.
Camino Real Industrial Park Road #122,
00683 San German, PUERTO RICO USA

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

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

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

Fresenius Kabi France S.A.S.
Zone industrielle Ecoparc 2, 350 Allée de la Butte à Colas,
27400 Heudebouville, FRANCE

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

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

Fresenius HemoCare Italia S.r.l.
Via San Pietro 1, 41037 Mirandola, ITALY

Fresenius HemoCare GmbH
Gruener Weg 10, 61169 Friedberg, GERMANY

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

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Facility(ies):

Fenwal International, Inc.
Road 357, Km 0.8, 00606 Maricao, PUERTO RICO USA

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

Fenwal, Inc.
Three Corporate Drive, Lake Zurich IL 60047, USA

Fresenius Kabi Deutschland GmbH
Production Unit Third Party Manufacturing
Pfingstweide 53, 61169 Friedberg, GERMANY

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