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

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

TÜV SÜD Product Service

Certificate

No. Q5 037258 0026 Rev. 03

Holder of Certificate: **Fresenius Kabi AG**
Else-Kröner-Str. 1
61352 Bad Homburg
GERMANY

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Sales, Distribution and Service of Active Medical Devices for Enteral Feeding, Infusion and their Accessories including Software, Monitoring of Non-vital Physiological Parameters, Autotransfusion System, Apheresis Devices, Blood Processing Systems and Devices including Device Disposables Sets, Software, and of Non-active Medical Devices for Enteral Feeding, Infusion, Transfusion, Irrigation Solutions, Implantable Port Products, Blood Sampling, Blood Donation and Filtration, In Vitro Diagnostic Medical Devices (IVD) for Analyzing of Blood Components, including Near Patients Devices.**
The Provision of Sterilization Services for Medical Devices.

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 037258 0026 Rev. 03

Report No.: 713296049 / 713301230 / 713296029

Valid from: 2024-03-05
Valid until: 2025-03-31

Date, 2024-03-06

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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No. Q5 037258 0026 Rev. 03

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Fresenius Kabi AG
Else-Kröner-Str. 1, 61352 Bad Homburg, GERMANY

Design and Development, Production, Sales, Distribution and Service of Active Medical Devices for Enteral Feeding, Infusion and their Accessories including Software, Monitoring of Non-vital Physiological Parameters, Autotransfusion System, Apheresis Devices, Blood Processing Systems and Devices including Device Disposables Sets, Software, and of Non-active Medical Devices for Enteral Feeding, Infusion, Transfusion, Irrigation Solutions, Implantable Port Products, Blood Sampling, Blood Donation and Filtration, In Vitro Diagnostic Medical Devices (IVD) for Analyzing of Blood Components, including Near Patients Devices.

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

Design and Development, Production including Sterilization, Service and Distribution of Active Medical Devices for Enteral Feeding, Infusion and their Accessories including Software; and of Non-active Medical Devices for Enteral Feeding, Infusion and Transfusion.

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

Design and Development, Production, Sales and Distribution of Active Medical Devices for Enteral Feeding, Infusion and their Accessories including Software, Monitoring of Non-vital Physiological Parameters.

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

Design and Development and Sales of Non-active Medical Devices for Enteral Feeding, Infusion, Transfusion and Implantable Port Products.

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Facility(ies):

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

Production including Sterilization and Distribution of Non-active Medical Devices for Enteral Feeding, Infusion, Transfusion and Implantable Port Products. The Provision of Sterilization Service for Medical Devices.

Fresenius Kabi Deutschland GmbH Werk Mihla
Gartenstrasse 9, 99831 Amt Creuzburg, GERMANY

Production of Components by Injection Molding Process and partly further Processing by Assembly into Pre-assemblies for Use in Primary and Secondary Packaging Materials.

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

Design and Development, Production including Sterilization and Distribution of Irrigation Solutions.

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

Production including Sterilization of Irrigation Solutions.

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

Sales of Medical Devices.

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

Distribution of Medical Devices.

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

Production, Distribution and Sales of Infusion Sets.

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Facility(ies):

Fresenius Kabi Norge AS
Svinesundsveien 80, 1788 Halden, NORWAY

Production including Sterilization and Distribution of Irrigation Solutions.

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

Production including Sterilization and Distribution of Irrigation Solutions.

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

Production including Sterilization and Distribution of Irrigation Solutions.

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

Design and Development, Production and Distribution of Disposables, Solutions, Systems and Accessories for the Collection, Processing and Storage of Blood and Blood Components to include the Installation, Service and Repair of the System Medical Devices.

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

Production including Sterilization of Non-active Medical Devices for Infusion, Transfusion, Blood processing, Blood Sampling, Blood Donation and Filtration.

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

Production including Sterilization and Distribution of Non-active Medical Devices for Infusion, Transfusion, Blood processing, Blood sampling, Blood Donation and Filtration.

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Facility(ies):

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

Design and Development and Production including Sterilization of Non-active Medical Devices for Transfusion, Blood processing, Blood Donation and Filtration.

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

Design and Development, Production including Sterilization of Non-active Medical Devices for Enteral Feeding, Infusion, Transfusion, Blood Sampling, Blood Donation, Filtration and Autotransfusion System Disposables.

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

Production including Sterilization and Distribution of Non-active Medical Devices for Infusion, Transfusion, Blood processing, Blood sampling, Blood Donation and Filtration. The Provision of Sterilization Service for Medical Devices.

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

Production including Sterilization and Distribution of Non-active Medical Devices for Blood sampling, Blood Donation and Filtration.

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

Production including Sterilization and Distribution of Non-active Medical Devices for Transfusion, Blood sampling, Blood Donation and Filtration.

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Facility(ies):

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

Design and Development of Active Medical Devices for Autotransfusion System, Apheresis and Blood Processing Systems including Devices and Software; Design and Development of non-active Medical Devices for Blood Processing including Apheresis and Autotransfusion; In Vitro Diagnostic Medical Devices (IVD) for Analyzing of Blood Components, including Near Patients Devices.

Fresenius HemoCare GmbH
Gruener Weg 10, 61169 Friedberg, GERMANY

Production and Distribution of Active Medical Devices for Autotransfusion System, Apheresis and Blood Processing Systems including Devices and Software; In Vitro Diagnostic Medical Devices (IVD) for Analyzing of Blood Components, including Near Patients Devices.

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

Production including Sterilization of
Non-active Medical Devices for Blood Donation.
The Provision of Sterilization Service for Medical Devices.

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

Design and Development, Production including Sterilization of Non-active Medical Devices for Blood Donation.

Fresenius Kabi Tunisia s.a.r.
Route de Korba MC 44, 8014 Bir Drassen, TUNISIA

Production and Distribution of sterile Enteral Nutrition Sets and sterile Infusion and Transfusion Administration Sets