



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 037258 0026 Rev. 05

Holder of Certificate: Fresenius Kabi AG

Else-Kröner-Str. 1
61352 Bad Homburg
GERMANY

Certification Mark:



Scope of Certificate:

Design and Development, Production, Sales, Distribution and Service of Active Medical Devices for Enteral Feeding, Parenteral Nutrition, 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, Parenteral Nutrition, 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, Certification, Validation and Verification Regulations 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. 05

Report No.: 713375883_CN

Valid from: 2026-01-23
Valid until: 2028-03-31

Date, 2026-01-23

Christoph Dicks
Head of Certification/Notified Body



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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

Management for the Global Production Operation, the Global Design and Development Centers, the Global Marketing, Sales, Distribution and Servicing Sites, Global Quality Management and Global Regulatory Affairs

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, Apheresis and Blood processing systems including Devices and Software; Monitoring of Non-vital Physiological Parameters; 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 and Distribution of Active Medical Devices for Enteral Feeding, Infusion and their Accessories including Software; Apheresis Systems including Devices and 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, Product Release and Sales of Non-active Medical Devices for Enteral Feeding, Infusion, Transfusion and Implantable Port Products

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

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

Production including Sterilization and Distribution of Active Medical Devices for Autotransfusion System and Blood Processing Systems including Devices and Software; and of Non-active Medical Devices for Enteral Feeding, Infusion, Transfusion and



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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 Non-active Medical devices for Transfusion and
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 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 Besteiro,
PORTUGAL

Production including Sterilization and Distribution of Irrigation
Solutions



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Fenwal, Inc.

Three Corporate Drive, Lake Zurich IL 60047, USA

Design and Development and Distribution of Disposables, Solutions, Systems and Accessories for the Collection, Processing and Storage of Blood and Blood Components to include the Installation and Service of medical device systems

Fresenius Kabi (Guangzhou) Co., Ltd.

No. 43 Baoying Street, Free Trade Zone, 510730 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Production including Sterilization and Distribution 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

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

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



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Fenwal International, Inc.

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

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

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, Service 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 and Distribution of Non-active
Medical Devices for Blood Donation and Irrigation Solutions. 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 and Distribution 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



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Fresenius Kabi Deutschland GmbH

Marienbader Platz 1, 61348 Bad Homburg, GERMANY

Design, Development and Distribution of non-active Medical
Devices for Parenteral Nutrition; Design, Development, Production,
Service and Distribution for active Medical Device for Parenteral
Nutrition including Software