



Product Service

# Certificate

No. Q5 037258 0026 Rev. 04

**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, 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, 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. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_037258_0026_Rev.04)

**Report No.:** 713344090

**Valid from:** 2025-04-01

**Valid until:** 2028-03-31

**Date,** 2025-03-21

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



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## Facility(ies):

**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 Besteiros, PORTUGAL

Production including Sterilization and Distribution of Irrigation Solutions



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## Facility(ies):

### **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 Horátev 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 USA

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 USA

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