



America

CERTIFICATE

No. QS6 047402 0088 Rev. 02

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

Certification Mark:



Scope of Certificate: **See page 2 for Overall Scope Statement.**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **31-565-4579**

Effective Date: **2020-11-30**

Expiry Date: **2023-04-02**

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Date of Issue: 2020-12-15

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Manager, US Certification Body,
Medical and Health Services



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Regulatory Requirements:

Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820
- 21 CFR Part 821

Overall Scope Statement:

Design, Development and Manufacture of Blood Processing System including Device, PC, Software, Disposable Sets, Platelet Pooling Sets, Whole Blood Processing; Autotransfusion System including Device Disposable Sets, Adapters, Reservoirs and Connection Lines; Apheresis Device including Disposable Sets; Disposables for Blood Donation and Filtration (Blood Bags); Single-Use Medical Devices for Infusion, Blood Sampling, Transfusion, Enteral Feeding and Implantable Port Products; Active Medical Devices for Enteral Feeding and Infusion including Accessories; In-Vitro Diagnostic Devices used in the Analyzing of Blood Components, including Near Patient Devices

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Facility(ies):

Fresenius Kabi AG
 61346 Bad Homburg, GERMANY

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

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

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

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

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

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

Fresenius HemoCare GmbH
 Gruener Weg 10, 61169 Friedberg, GERMANY

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

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

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

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

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

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

Facility Scopes:

Fresenius Kabi AG
61346 Bad Homburg, GERMANY

Medical Device Division including all Management for the Global Manufacturing Operation, the Global Design and Development Centers, the Global Marketing, Sales, Distribution and Servicing Sites, Global Quality Management and Global Regulatory Affairs
DUNS No: 31-565-4579

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

Design, Development and Manufacture of Disposables for Blood Donation and Filtration (Blood Bags); Single-Use Medical Devices for Infusion, Blood Sampling, Transfusion and Enteral Feeding; Autotransfusion System, Disposable Set, Connection Lines
DUNS No: 43-991-8327

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

Design and Development of Disposable Sets for Blood Processing System, including Platelet Pooling, Whole Blood Processing, Blood Donation, Filtration (Blood Bags) and Transfusion; Design, Development and Manufacture of Disposable Sets for Apheresis System and Autotransfusion System, including Adapters, Reservoirs, Connection Lines
DUNS No: 40-259-1754

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

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

Manufacture of Single-Use Medical Devices for Infusion, Transfusion,
 Enteral Feeding and Implantable Port Products
 DUNS No: 36-608-6606

Fenwal, Inc.

Three Corporate Drive, Lake Zurich IL 60047, USA

Design and Development, Manufacturing and Distribution of
 Disposables, Solutions, Systems and Accessories for the Collection,
 Processing and Storage of Blood and Blood Components to include
 the Installation, Servicing and Repair of the System Medical Devices
 DUNS No: 79-451-9020

Fresenius Vial S.A.S

Le Grand, Chemin, 38590 Brézins, FRANCE

Design, Development and Manufacture of Active Medical Devices
 for Enteral Feeding and Infusion including Accessories
 DUNS No: 38-344-1953

Fresenius Kabi Deutschland GmbH Werk Bad Hersfeld

Robert-Koch-Strasse 5, 36251 Bad Hersfeld, GERMANY

Design, Development and Distribution of Single-Use Medical Devices
 for Infusion, Transfusion, Enteral Feeding and Implantable Port
 Products
 DUNS No: 34-104-8889

Fresenius Kabi Deutschland GmbH

Gruener Weg 10, 61169 Friedberg, GERMANY

Design and Development of Blood Processing System including
 Device, PC, Software; Whole Blood Processing; Autotransfusion
 System including Device; Apheresis Device; In-Vitro Diagnostic
 Devices used in the Analyzing of Blood Components, including
 Near Patients Devices
 DUNS No: 31-432-0752

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Fresenius HemoCare GmbH

Gruener Weg 10, 61169 Friedberg, GERMANY

Manufacture of Blood Processing System including Device, PC, Software, Whole Blood Processing; Autotransfusion System including Device; Apheresis Device; In-Vitro Diagnostic Devices used in the Analyzing of Blood Components, including Near Patients Devices

DUNS No: 31-318-8350

Fresenius Kabi (Guangzhou) Co., Ltd.

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

Manufacture of Disposables for Blood Processing System including Disposable Sets, Platelet Pooling Sets, Whole Blood Processing; Blood Donation and Filtration (Blood Bags); Single-Use Medical Devices for Infusion, Blood Sampling and Transfusion

DUNS No: 52-917-1056

Fenwal International, Inc.

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

Production and Distribution of Non-Active Medical Devices for Collection, Processing and Storage of Blood and Blood Components, and Sterilization by Electron-Beam

DUNS No: 87-148-6601

Fenwal International, Inc.

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

Manufacture including Sterilization and Distribution of Disposables for Blood Donation and Filtration (Blood Bags); Single-Use Medical Devices for Blood Sampling, Blood Components Sampling, and Transfusion

DUNS No: 93-831-4754

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No. QS6 047402 0088 Rev. 02

Fenwal International, Inc.

Road 357, Km 0.8, 00606 Maricao, PUERTO RICO USA

Production and Distribution of Non-Active Medical Devices (including Solutions) for the Collection, Processing and Storage of Blood and Blood Components

DUNS No: 09-116-4590

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, Distribution and Service of Active and Non-Active Single-Use Medical Devices for Enteral Nutrition, Infusion and Transfusion

DUNS No: 54-767-0864

Fresenius Kabi Horátev CZ s.r.o.

Horátev 104, 289 13 Horátev, CZECH REPUBLIC

Manufacture of Disposables for Blood Processing System including Disposable Sets, Platelet Pooling Sets, Whole Blood Processing; Disposables for Blood Donation and Filtration (Blood Bags); Single-Use Medical Devices for Infusion, Blood Sampling and Transfusion

DUNS No: 88-885-4531

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