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America

CERTIFICATE

No. QS6 037258 0030 Rev. 00

Certificate Holder: **Fresenius Kabi AG**
Else-Kröner-Str. 1
61352 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. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 037258 0030 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001232**
Report No.: **713226658**
Effective Date: **2023-04-03**
Expiry Date: **2026-04-02**

Date of Issue: 2023-03-30

(Renee Walker)
Director, US Certification Body, MHS

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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. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

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 and Development, Production, Distribution and Service of Blood Processing Systems including Devices, Software, Disposable Sets, Platelet Pooling Sets, Whole Blood Processing; Transfusion and Autotransfusion Systems, including Devices, Disposable Sets, Adapters, Reservoirs and Connection Lines; Apheresis Devices including Disposable Sets; Disposables for Blood Donation and Filtration (Blood Bags); Non-Active Single-Use Medical Devices for Infusion, Blood Sampling, Transfusion, Enteral Feeding and Implantable Port Products; Active Medical Devices for Enteral Feeding and Infusion Systems including Pumps, Software and Associated Devices used with Pumps and for Monitoring of Non-Vital Physiological Parameters; In-Vitro Diagnostic Devices used in the Analyzing of Blood Components, including Near Patients Devices

Date of Issue: 2023-03-30

(Renee Walker)
Director, US Certification Body, MHS

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Facility(ies):

Fresenius Kabi AG
Else-Kröner-Str. 1, 61352 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

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

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No. QS6 037258 0030 Rev. 00

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

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

Facility Scopes:

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
REPs Facility ID: F001232

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

Design, Development and Production including Sterilization of Disposables for Blood Donation and Filtration (Blood Bags); Non-Active Single-Use Medical Devices for Infusion, Blood Sampling, Transfusion and Enteral Feeding; Autotransfusion System Disposables, Connection Lines
REPs Facility ID: F002137

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

Design and Development of Disposable Sets for Blood Processing System, including Platelet Pooling, Whole Blood Processing, Blood Donation, Filtration (Blood Bags), Transfusion and Autotransfusion System, including Adapters, Reservoirs, Connection Lines; Design, Development and Production of Disposable Sets for Apheresis System
REPs Facility ID: F002143

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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 Single-Use Medical Devices for Enteral Feeding, Infusion, Transfusion and Implantable Port Products
REPs Facility ID: F001203

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

Design and Development of Disposables, Solutions, and Systems for the Collection, Processing and Storage of Blood and Blood Components, including the Sales, Distribution, Installation and Servicing of Apheresis and Infusion Systems
REPs Facility ID: F001228

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

Design and Development, Production, Distribution of Active Medical Devices for Enteral Feeding and Infusion Systems including Pumps, Software and Associated Devices used with Pumps, Monitoring of Non-Vital Physiological Parameters
REPs Facility ID: F002142

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

Design, Development and Sales of Non-Active Single-Use Medical Devices for Enteral Feeding, Infusion and Transfusion and Implantable Port Products
REPs Facility ID: F002140

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

Design and Development of Active and Non-Active Medical Devices for Blood Processing Systems including Devices and Software; Autotransfusion System including Device; Apheresis Device; In-Vitro Diagnostic Devices used in the Analyzing of Blood Components, including Near Patients Devices
REPs Facility ID: F002141

Fresenius HemoCare GmbH
Gruener Weg 10, 61169 Friedberg, GERMANY

Production and Distribution of Active Medical Devices for Blood Processing Systems including Devices and Software; Autotransfusion System including Device; Apheresis Device; In-Vitro Diagnostic Devices used in the Analyzing of Blood Components, including Near Patients Devices
REPs Facility ID: F002136

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 Disposables for Blood Processing System including Disposable Sets, Platelet Pooling Sets, Whole Blood Processing; Blood Donation and Filtration (Blood Bags); Non-Active Single-Use Medical Devices for Infusion, Blood Sampling and Transfusion
REPs Facility ID: F002144

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Facility Scopes:

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 Single-Use Medical Devices for Infusion, Transfusion, Blood Processing, Blood Sampling, Blood Donation and Filtration
REPs Facility ID: F002059

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

Production including Sterilization and Distribution of Disposables for Blood Donation and Filtration (Blood Bags); Non-Active Single-Use Medical Devices for Blood Sampling, Blood Components Sampling, and Transfusion
REPs Facility ID: F002134

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 the Collection, Processing and Storage of Blood and Blood Components
REPs Facility ID: F002134

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Facility Scopes:

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 and Infusion Systems including Pumps, Software and Associated Devices used with Pumps; and of Non-Active Single-Use Medical Devices for Enteral Feeding, Infusion and Transfusion
REPs Facility ID: F002138

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

Production including Sterilization and Distribution of Disposables for Blood Processing System including Disposable Sets, Platelet Pooling Sets, Whole Blood Processing; Blood Donation and Filtration (Blood Bags); Non-Active Single-Use Medical Devices for Infusion, Blood Sampling and Transfusion
REPs Facility ID: F002139

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