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

Management Service

CERTIFICATE

Certificate Registration No.: **12 104 24126 TMS** / Order No.: **70083720**

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that the organization

FRESENIUS KABI

Fresenius Kabi AG

Else-Kröner-Str. 1
61352 Bad Homburg
Germany

for the scope

Production, Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices, Active Pharmaceutical Ingredients and other Health Care Products and Services

including the sites see enclosure

has established and applies an Environmental Management System.

An audit was performed and has furnished proof
that the requirements according to

DIN EN ISO 14001:2015

are fulfilled.

The certificate is valid from **2025-05-06** until **2026-01-26**.

Fred Wenke
Head of Certification Body
Munich, 2025-05-08

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

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certificate holder:

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

at the sites	scope
Fresenius Kabi AG Else-Kröner-Str. 1 61352 Bad Homburg Germany	Administrative Management and provision of central services on corporate and global level
Fresenius Kabi Austria GmbH Hafnerstr. 36 8055 Graz Austria	Production and Logistics of Liquid Pharmaceuticals and Active Pharmaceutical Ingredients
Fresenius Kabi Austria GmbH Estermannstr. 17 4020 Linz Austria	Production and Logistics of Liquid Pharmaceuticals and Active Pharmaceutical Ingredients
Fresenius Kabi España, S.A.U. Dr. Ferran 12 08339 Vilassar de Dalt Spain	Production of Liquid Pharmaceuticals and Irrigation Solutions
Labesfal - Laboratorios Almiro S.A. Zona Industrial de Lagedo 3465-157 Santiago de Besteiros Portugal	Production and Logistics Operations of Pharmaceuticals, Medical Device Solutions and Patient Specific Compounding Products for Parenteral Nutrition
Fresenius Kabi SSPC No. 16, Beizha Road, Mashan, Binhu District Wuxi, Jiangsu Province, P.R. China Post Code: 214092	Design, Development and Manufacturing of Parenteral Nutrition and Enteral Nutrition Liquid, Manufacturing of Freeze-Dried Products (Vitamins), Tablets (Anti-allergen) and Purified Soybean Oil used for medicine, Research, Development of Food for Special Medical Purpose

Fred Wenke
Head of Certification Body
Munich, 2025-05-08

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at the sites	scope
Beijing Fresenius Kabi Pharmaceutical Co., Ltd. No. 57 Huatuo Road Bio-Medicine Industry Base Daxing District Beijing, P.R. China Post Code: 102609	Manufacturing and Logistics of Medicinal Products
Fresenius Kabi Oncology Ltd. Village - Kishanpura, Tehsil - Baddi Dist: Solan (H.P.) - 173205 India	Production of liquid & solid Pharmaceuticals
Fresenius Kabi India Private Ltd. A-3, MIDC. Ranjangaon Ganpati, Tal.-Shirur Dist. Pune - 412220 India	Production and Logistics of Liquid Pharmaceuticals
Fresenius Kabi Oncology Limited D-35, Industrial Area Kalyani, Dist. Nadia, West Bengal - 741235 India	Production of Active Pharmaceutical Ingredients and pharmaceutical excipients
Fresenius Kabi France S.A.S. 6, Rue du Rempart, 27400 Louviers France	Production of Liquid Pharmaceuticals, Irrigation Solutions and Nonactive Devices
Fresenius Kabi Ltd. Cestrian Court 1+2 Eastgate Way Manor Park Runcorn Cheshire, WA7 1NT United Kingdom	Production of patient specific solutions of pharmaceuticals, Logistics, Sales, Marketing and technical services from Enteral nutrition and medical devices
Fresenius Kabi France S.A.S. 5, place du Marivel 92316 Sèvres Cedex France	Sales and Marketing of Medicinal Products, Medical Devices and Enteral Nutrition

Fred Wenke
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Munich, 2025-05-08

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at the sites	scope
Fresenius Kabi France S.A.S. Zone industrielle Ecoparc 2, 350, Allée de la Butte à Colas 27400 Heudebouville France	Distribution of Medicinal Products, Medical Devices, Enteral and Oral Nutrition
Fresenius Kabi AB Rapsgatan 7 751 74 Uppsala Sweden	Production of Parenteral Solutions as Lipid Emulsions, Clinical Nutrition, Anaesthetics, Vitamins
Fresenius Kabi AB Kraftvägen 1 196 37 Kungsängen Sweden	Production of Active Pharmaceutical Ingredients and Logistics of Pharmaceuticals
Fenwal International, Inc. Carretera Sánchez Km, 18,5 Parque Industrial Itabo, Zone Franca Ind. de S.C. 91000 Haina Dominican Republic	Manufacturing of Blood Collection and Separation products, Sterilization, Storage and Support Systems
Fenwal Inc. **- A Fresenius Kabi Company Planta San German** Road 122 km. 05 00683 San German Puerto Rico	Manufacturing processes of medical devices with its support activities
Fresenius Kabi Tunisia MC 44 Route de Korba 8014 Bir Drassen, Beni Khalled Tunisia	Manufacturing of non-active medical devices for enteral nutrition, infusion and transfusion sets, and for sterilization, release and distribution of sterile sets to European Union Market Units
Fenwal Inc. **- A Fresenius Kabi Company Planta Maricao** Road 357 km. 08 00606 Maricao Puerto Rico	Production and distribution of (non-active) medical devices for collection, processing and storage of blood and blood components

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at the sites	scope
Fenwal, Inc. **- A Fresenius Kabi Company, Lake Zurich, Illinois** Three Corporate Drive Lake Zurich, IL 60047 USA	Research and Development activities of systems used for collection and processing and storage of blood and other cellular therapy
Fresenius Kabi Deutschland GmbH Freseniusstr. 1 61169 Friedberg Germany	Production of Infusion and Irrigation solutions for clinical purpose, Production of Fishoil
Fresenius Vial S.A.S. Le Grand Chemin 38590 Brézins France	Production of Medical Devices, Research and Development, Marketing, Sales and Logistic of Medical Devices and disposables
Fresenius Kabi Italia S.r.l. Via Camagre, 41 37063 Isola della Scala-Verona Italy	Production of Liquid Pharmaceuticals, Logistics, Sales and Marketing of Medicinal Products, Medical Devices and technical service
Fresenius HemoCare Italia S.r.l. Via San Pietro 1 41037 Mirandola (MO) Italy	Production of Medical Devices for blood treatment and related services in support of the production (Maintenance, Offices, Laboratories, Warehouse), Research and Development of products, materials and processes
Fresenius Kabi Polska Sp. z o.o. Sienkiewicza 25 99-300 Kutno Poland	Production and Logistics of Infusion solution with PE and PP bottles
Fresenius Kabi - PU Anápolis Av. Brasil Norte 1255, Bairro Cidade Jardim Cep 75080-240 Anapolis - GO Brazil	Production of sterile medicines in the following forms: Powders with aseptic preparation, small volume parenteral solutions with terminal sterilization and small volume parenteral solutions with aseptic preparation

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at the sites	scope
Fresenius Kabi PU USA, LLC 5200 Corporate Parkway West Wilson, NC 27893 USA	Production of sterile pharmaceuticals packaged in pre-filled (ready-to-use) syringes under the Simplist® brand and standard solution bags under the FreeFlex Brand
Fresenius Kabi USA, LLC 3159 Staley Road Grand Island, NY 14072 USA	Manufacturing of Generic Injectable Pharmaceutical Products
Fresenius Kabi USA, LLC 2020 North Ruby Street Melrose Park, IL 60160 USA	Manufacturing of Generic Injectable Pharmaceutical Products (in flip-top vial form)
Fresenius Kabi Manufacturing SA (Pty) Ltd. 6 Gibaud Road, Korsten 6020 Port Elizabeth Republic of South Africa	Production of parentals
Fresenius Kabi iPSUM S.r.l. Via San Leonardo 23 / Via Dello Sviluppo 15 45010 Villadose (RO) Italy	Production, logistics, innovation and development of active ingredients (APIs) and bulk pharmaceutical mixtures
Fresenius Kabi Vietnam Joint Stock Company Area 8, Nhon Phu ward Quy Nhon city, Binh Dinh Province Vietnam	Production of sterile liquid pharmaceuticals
FRESENIUS KABI BRASIL LTDA. Rodovia CE 040, Km 10, S/N 61700-000 Jacundá - Aquiraz-Ceará Brazil	Production of Liquid Medicinal Products and Storage of Medicinal Products, Enteral Nutrition and Medical Devices

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at the sites	scope
Clinico Medical Sp. z o.o. ul. Roberta Kocha 1, Blonie 55-330 Miękinia Poland	Manufacturing, including sterilization and logistics of non-active medical devices for enteral nutrition, infusion, transfusion and port systems
Fresenius Kabi iPSUM S.r.l. Località Masserie Almieri SNC (Zone Ind.) 86077 Pozzilli (IS) Italy	Production of active ingredients (APIs) and bulk pharmaceutical mixtures
Fresenius Kabi IPSUM S.r.l. Via A. Boito 13 20835 Taccano die Muggió (MB) Italy	Production of active ingredients (APIs) and bulk pharmaceutical mixtures
Fresenius Kabi iPSUM S.r.l. Via E. Mattei, 26 50039 Vicchio, (FI), Vicchio, (PD) Italy	Production of Active Pharmaceutical Ingredients and Ingredients for food and feed Additives and treatment of non-hazardous liquid waste
PT. Fresenius Kabi Combiphar Jl. Raya Simpang No. 383 40553 Padalarang Bandung Indonesia	Manufacture of Pharmaceutical Product. Production and Packaging of Ketoanalogues and Essential Amino Acids Tablets
Fresenius Kabi AB Bredgränd 14 753 20 Uppsala, Domkyrkoförs Sweden	Sales and Marketing of Medical Products and Enteral Nutrition
Fresenius Kabi Deutschland GmbH **Werk Mihla** Gartenstr. 9 99831 Amt Creuzburg/ OT Mihla 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

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at the sites	scope
Fresenius Kabi Pharma Portugal Lda. Taguspark - Edifício Inovação I, 223/224 Av. Jacques Delors 3 2740-122 Porto Salvo Portugal	Logistics, Sales and Marketing of Pharmaceutical Products, Medicinal Products, Medical Devices and Enteral Nutrition, Services including Technical Service
Fresenius Kabi (Nanchang) Co. Ltd. Qin Lan Road Nanchang Economic & Technological Development Zone Nanchang, Jiangxi Province, P.R. China Post Code: 330013	Design and manufacture of Disposable infusion consumables; Design and Assembly of Active Medical Devices such as Injection pump, Infusion pump, Enteral feeding pump and Blood component separator
Fresenius Kabi Mexico S.A. de C.V. Paseo del Norte 5300-A 45010 Guadalajara Technology Park, Zapopan, Jalisco Mexico	Production of Colloids, IV Drugs, Standard Solutions, Enteral Nutrition
Fresenius Kabi Horatev CZ s.r.o. Horátev 104 289 13 Horátev Czech Republic	Production of Nonactive Medical Devices and liquid Medicinal Products
Fresenius Kabi Warrendale 770 Commonwealth Drive Warrendale, PA 15086 USA	Manufacturing of active and nonactive medical devices and laboratory 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

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at the sites	scope
Fresenius Kabi (Guangzhou) Co., Ltd. No.43 Baoying Street Guangzhou Free Trade Zone, P.R. China Post Code: 510730	Production and Storage of medical products
Fresenius HemoCare Netherlands B.V. Runde ZZ 41 7881 HM Emmer-Compascuum Netherlands	Production and Logistics of Enteral Nutrition

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Munich, 2025-05-08

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