



Management Service

# CERTIFICATE

Certificate Registration No.: **12 117 24126 TMS** / Order No.: **70083720**

**The Certification Body  
of TÜV SÜD Management Service GmbH**

certifies that the organization



**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  
Occupational Health and Safety Management System.

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

**DIN ISO 45001:2018**

are fulfilled.

The certificate is valid from **2024-06-20** until **2024-11-21**.

Fred Wenke  
Head of Certification Body  
Munich, 2024-06-25

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certificate holder:

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Else-Kröner-Str. 1, 61352 Bad Homburg, Germany

at the sites	scope
<b>Fresenius Kabi AG</b> Else-Kröner-Str. 1 61352 Bad Homburg Germany	Production, logistics, sales and marketing of medicinal products, enteral nutrition, medical devices, active pharmaceutical ingredients and other health care products and services.
<b>Labesfal - Laboratorios Almiro S.A.</b> 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.
<b>Fresenius Kabi SSPC</b> 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.
<b>Fresenius Kabi Oncology Ltd.</b> Village - Kishanpura, Tehsil – Baddi Dist: Solan (H.P.) - 173205 India	Production of liquid & solid pharmaceuticals.
<b>Fresenius Kabi India Private Ltd.</b> A-3, MIDC. Ranjangaon Ganpati, Tal.-Shirur Dist. Pune - 412220 India	Production and Logistics of liquid pharmaceuticals.
<b>Fresenius Kabi Oncology Limited</b> D-35, Industrial Area Kalyani, Dist. Nadia, West Bengal - 741235 India	Production of active pharmaceutical ingredients and pharmaceutical excipients.
<b>FHC (Holdings) Limited</b> Cestrian Court 1+2 Eastgate Way Manor Park Runcorn Cheshire, WA7 1NT United Kingdom	Production of patient specific solutions of pharmaceuticals, logistics, sales and marketing of health care products and technical services, enteral nutrition and medical devices.

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at the sites	scope
<b>Fenwal International, Inc.</b> 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.
<b>Fenwal Inc.</b> <b>- A Fresenius Kabi Company Planta Maricao</b> 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.
<b>Fenwal, Inc.</b> <b>- A Fresenius Kabi Company, Lake Zurich, Illinois</b> 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.
<b>Fresenius Kabi Italia S.r.l.</b> Via Camagre, 41 37063 Isola della Scala-Verona Italy	Production of liquid pharmaceuticals and nonactive medical device, logistics, sales and marketing of medicinal products, enteral nutrition, medical devices and other health care products services including technical service.
<b>Fenwal Inc.</b> <b>- A Fresenius Kabi Company Planta San German</b> Road 122 km. 05 00683 San German Puerto Rico	Manufacturing processes of medical devices with its support activities, and distribution center of finished good.
<b>Beijing Fresenius Kabi Pharmaceutical Co., Ltd.</b> No. 57 Huatuo Road Bio-Medicine Industry Base Daxing District Beijing, P.R. China Post Code: 102609	Production and logistics of liquid and solid pharmaceuticals and enteral nutrition.
<b>Fresenius Kabi Tunisia</b> MC 44 Route de Korba 8014 Bir Drassen, Beni Khaled Tunisia	Manufacture and distribution of enteral nutrition sets and infusion and transfusion administration sets.

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at the sites	scope
<b>Laboratorio Sanderson S.A.</b> Carlos Fernández 244 San Joaquín 8940575 Santiago Chile	Production of sterile liquid pharmaceuticals, logistics and sales of medicinal products.
<b>Recetario Magistral Endovenoso S.A.</b> Calle 2, N° 1946 Parque Ejercito IX Región Chile	Production, logistics and sales of patient specific compounding products for parenteral nutrition and pharmaceuticals.
<b>Recetario Magistral Endovenoso S.A.</b> Carlos Fernández Concha 244, San Joaquín 8940577 Santiago Chile	Production of patient specific compounding products for parenteral nutrition and pharmaceuticals.
<b>Fresenius Kabi Chile Ltda.</b> Carlos Fernández Concha 244, San Joaquín 8940577 Santiago Chile	Logistics, sales, and marketing of medicinal products and medical devices, services including technical service.
<b>Fresenius Kabi España, S.A.U.</b> Dr. Ferran 12 08339 Vilassar de Dalt Spain	Production and logistics of liquid pharmaceuticals and irrigation solutions.
<b>Fresenius Kabi Deutschland GmbH</b> Freseniusstr. 1 61169 Friedberg Germany	Production of infusion and irrigation solutions for clinical purpose, production of fish oil.
<b>Clinico Medical Sp. z o.o.</b> 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.

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CERTIFICADO



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CERTIFICATE



ZERTIFIKAT

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at the sites	scope
<b>Fresenius Kabi Austria GmbH</b> Hafnerstr. 36 8055 Graz Austria	Production and logistics of Liquid Pharmaceuticals and Active Pharmaceutical Ingredients
<b>Fresenius Kabi Polska Sp. z o.o.</b> Sienkiewicza 25 99-300 Kutno Poland	Production of infusion liquids - simple fluids and antibiotics. Fluid packaging made of polyethylene, logistics, stryków warehouse.
<b>Fresenius Kabi AB</b> Rapsgatan 7 751 74 Uppsala Sweden	Manufacturing, logistics and distribution, sales and marketing of pharmaceutical products, medical devices and other health care products and services including technical service.
<b>Fresenius Kabi AB</b> Kraftvägen 1 196 37 Kungsängen Sweden	Manufacturing, Logistics and Distribution, Sales and Marketing of Pharmaceutical Products, Medical Devices and other Health Care Products and Services including Technical Service
<b>Fresenius Vial S.A.S.</b> Le Grand Chemin 38590 Brézins France	Production of medical devices, research and development, marketing, sales and logistic of medical devices and disposables.
<b>Fresenius Kabi Austria GmbH</b> Estermannstr. 17 4020 Linz Austria	Production and logistics of liquid pharmaceuticals and active pharmaceutical ingredients.
<b>Fresenius Kabi Norge AS</b> Svinesundsveien 80 1788 Halden Norway	Production of liquid pharmaceuticals, nonactive medical devices, irrigation solutions, disinfectant and parenteral nutrition.

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at the sites	scope
<b>Fresenius Kabi Vietnam Joint Stock Company</b> Area 8, Nhon Phu ward Quy Nhon city, Binh Dinh Province Vietnam	Production of sterile liquid pharmaceuticals.
<b>PT. Fresenius Kabi Combiphar</b> Jl. Raya Simpang No. 383 40553 Padalarang Bandung Indonesia	Manufacture of pharmaceutical product in coordination with joint venture company. Production and packaging of ketoanalogues and essential amino acids tablets.
<b>Fresenius HemoCare Italia S.r.l.</b> 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.
<b>Fresenius Kabi iPSUM S.r.l.</b> 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.
<b>Fresenius Kabi IPSUM S.r.l.</b> Via A. Boito 13 20835 Taccano die Muggiό (MB) Italy	Production of active ingredients (APIs) and bulk pharmaceutical mixtures.
<b>Fresenius Kabi iPSUM S.r.l.</b> 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.
<b>Fresenius Kabi iPSUM S.r.l.</b> Località Masserie Almieri SNC (Zone Ind.) 86077 Pozzilli (IS) Italy	Production of active ingredients (APIs) and bulk pharmaceutical mixtures.

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at the sites	scope
<b>Fresenius Kabi (Nanchang) Co. Ltd.</b> Qin Lan Road Nanchang Economic & Technological Development Zone Nanchang, Jiangxi Province, P.R. China Post Code: 330013	Production, logistics, sales, innovation and development and marketing of medicinal products, enteral nutrition, medical devices, active pharmaceutical ingredients and other health care products and services.
<b>Fresenius Kabi AB</b> Bredgränd 14 753 20 Uppsala, Domkyrkoförs Sweden	Manufacturing, logistics and distribution, sales and marketing of pharmaceutical products, medical devices and other health care products and services including technical service.
<b>Fresenius Kabi Deutschland GmbH</b> <b>Werk Mihla</b> 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, which are supplied in bulk form to other Fresenius Kabi plants for further processing.
<b>Fresenius Kabi France S.A.S.</b> 6, Rue du Rempart, 27400 Louviers France	Production of liquid pharmaceuticals, irrigation solutions and nonactive devices.
<b>Fresenius Kabi Mexico S.A. de C.V.</b> Paseo del Norte 5300-A 45010 Guadalajara Technology Park, Zapopan, Jalisco Mexico	Production of IV-pharmaceuticals and enteral nutrition, logistics, sales and marketing of medicinal products, nutrition products and medical devices.
<b>Fresenius Kabi - PU Anápolis</b> Av. Brasil Norte 1255, Bairro Cidade Jardim Cep 75080-240 Anápolis – GO Brazil	Production of liquid and powders sterile.
<b>Fresenius Kabi USA, LLC</b> 3159 Staley Road Grand Island, NY 14072 USA	Manufacturing of generic injectable pharmaceutical products (in flip-top vial form).

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<b>Fresenius Kabi USA, LLC</b> 2020 North Ruby Street Melrose Park, IL 60160 USA	Manufacturing of generic injectable pharmaceutical products (in flip-top vial form).
<b>Fresenius Kabi Manufacturing SA (Pty) Ltd.</b> 6 Gibaud Road, Korsten 6020 Port Elizabeth Republic of South Africa	Manufacturing and packing of sterile small volume and large volume pharmaceutical parenterals.
<b>Fresenius Kabi Horátev CZ s.r.o.</b> Horátev 104 289 13 Horátev Czech Republic	Production of nonactive medical devices and liquid medicinal products.
<b>Fresenius Kabi PU USA, LLC</b> 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.
<b>Fenwal, Inc.</b> 770 & 765 Commonwealth Drive Warrendale, PA 15086 USA	Manufacturing of active and nonactive medical devices and laboratory devices.
<b>Fenwal France S.A.S.</b> Etaille 36400 La Chatre France	Production and distribution of nonactive medical devices and transfusion accessories.
<b>Fresenius HemoCare Netherlands B.V.</b> Runde ZZ 41 7881 HM Emmer-Compascuum Netherlands	Production and logistics of enteral nutrition.

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