



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 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

Page 1 of 9





Management Service

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| at the sites                                                                                                                         | scope                                                                                                                                                                                                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Fresenius Kabi AG</b><br>Else-Kröner-Str. 1<br>61352 Bad Homburg<br>Germany                                                       | Administrative Management and provision of central services on corporate and global level                                                                                                                                                                                    |
| <b>Fresenius Kabi Austria GmbH</b><br>Hafnerstr. 36<br>8055 Graz<br>Austria                                                          | Production and Logistics of Liquid Pharmaceuticals and Active Pharmaceutical Ingredients                                                                                                                                                                                     |
| <b>Fresenius Kabi Austria GmbH</b><br>Estermannstr. 17<br>4020 Linz<br>Austria                                                       | Production and Logistics of Liquid Pharmaceuticals and Active Pharmaceutical Ingredients                                                                                                                                                                                     |
| <b>Fresenius Kabi España, S.A.U.</b><br>Dr. Ferran 12<br>08339 Vilassar de Dalt<br>Spain                                             | Production of Liquid Pharmaceuticals and Irrigation Solutions                                                                                                                                                                                                                |
| <b>Labesfal - Laboratorios Almiro S.A.</b><br>Zona Industrial de Lagedo<br>3465-157 Santiago de Besteiros<br>Portugal                | Production and Logistics Operations of Pharmaceuticals, Medical Device Solutions and Patient Specific Compounding Products for Parenteral Nutrition                                                                                                                          |
| <b>Fresenius Kabi SSPC</b><br>No. 16, Beizha Road, Mashan, Binhu District<br>Wuxi, Jiangsu Province, P.R. China<br>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 |

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Page 2 of 9





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

Fred Wenke  
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Munich, 2025-05-08

Page 3 of 9





Management Service

CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT

## ENCLOSURE OF CERTIFICATE

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

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

Page 4 of 9





Management Service

CERTIFICAT

CERTIFICADO

CERTИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT

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

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Munich, 2025-05-08

Page 5 of 9





Management Service

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

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

Page 6 of 9





Management Service

CERTIFICAT

CERTIFICADO

CERTИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT

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

Fred Wenke  
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Munich, 2025-05-08

Page 7 of 9





Management Service

CERTIFICAT

CERTIFICADO

CERTИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT

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| <b>Fresenius Kabi Pharma Portugal Lda.</b><br>Taguspark - Edifício Inovação I, 223/224<br>Av. Jacques Delors 3<br>2740-122 Porto Salvo<br>Portugal                             | Logistics, Sales and Marketing of<br>Pharmaceutical Products, Medicinal Products,<br>Medical Devices and Enteral Nutrition,<br>Services including Technical Service                                                                                                                  |
| <b>Fresenius Kabi (Nanchang) Co. Ltd.</b><br>Qin Lan Road Nanchang Economic & Technological<br>Development Zone<br>Nanchang, Jiangxi Province, P.R. China<br>Post Code: 330013 | Design and manufacture of Disposable infusion<br>consumables; Design and Assembly of Active Medical<br>Devices such as Injection pump, Infusion pump,<br>Enteral feeding pump and Blood component separator                                                                          |
| <b>Fresenius Kabi Mexico S.A. de C.V.</b><br>Paseo del Norte 5300-A<br>45010 Guadalajara Technology Park,<br>Zapopan, Jalisco<br>Mexico                                        | Production of<br>Colloids, IV Drugs, Standard Solutions,<br>Enteral Nutrition                                                                                                                                                                                                        |
| <b>Fresenius Kabi Horátev CZ s.r.o.</b><br>Horátev 104<br>289 13 Horátev<br>Czech Republic                                                                                     | Production of Nonactive Medical Devices<br>and liquid Medicinal Products                                                                                                                                                                                                             |
| <b>Fresenius Kabi Warrendale</b><br>770 Commonwealth Drive<br>Warrendale, PA 15086<br>USA                                                                                      | Manufacturing of active and nonactive medical<br>devices and laboratory devices                                                                                                                                                                                                      |
| <b>Fresenius HemoCare GmbH</b><br>Gruener Weg 10<br>61169 Friedberg<br>Germany                                                                                                 | Production and Distribution of Active Medical Devices<br>for Autotransfusion System, Apheresis and Blood<br>Processing Systems including Devices and Software;<br>In Vitro Diagnostic Medical Devices (IVD) for<br>Analyzing of Blood Components,<br>including Near Patients Devices |

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Munich, 2025-05-08

Page 8 of 9







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| <b>Fresenius Kabi (Guangzhou) Co., Ltd.</b><br>No.43 Baoying Street<br>Guangzhou Free Trade Zone, P.R. China<br>Post Code: 510730 | Production and Storage of medical products    |
| <b>Fresenius HemoCare Netherlands B.V.</b><br>Runde ZZ 41<br>7881 HM Emmer-Compasuum<br>Netherlands                               | Production and Logistics of Enteral Nutrition |

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Page 9 of 9

