

# Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **01 104 1600177**

Certificate Holder:



**Fresenius Kabi AG**

Else-Kröner-Str. 1  
61352 Bad Homburg  
Germany

including the locations according to annex

Scope:

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

Proof has been furnished by means of an audit that the requirements of ISO 14001:2015 are met.

Validity:

The certificate is valid from 2023-01-27 until 2026-01-26.  
First certification 2017

2023-02-03

A handwritten signature in blue ink, appearing to be 'P. Z.', written over a horizontal line.

TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Annex to certificate

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| <b>No.</b> | <b>Location</b>  | <b>Scope</b>  |
|------------|--|---|
| /01        | c/o Fresenius Kabi AG<br>Else-Kröner-Str. 1<br>61352 Bad Homburg<br>Germany  | Production, Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices, Active Pharmaceutical Ingredients and other Health Care Products and Services |
| /02        | c/o Fresenius Kabi Austria GmbH<br>Hafnerstr. 36<br>8055 Graz<br>Austria   | Production and Logistics of Liquid Pharmaceuticals and Active Pharmaceutical Ingredients  |
| /03        | c/o Fresenius Kabi Austria GmbH<br>Estermannstr. 17<br>4020 Linz<br>Austria  | Production and Logistics of Liquid Pharmaceuticals and Active Pharmaceutical Ingredients  |
| /04        | c/o Fresenius Kabi Deutschland GmbH<br>Production Unit Enteral Nutrition<br>Daimlerstr. 22<br>61352 Bad Homburg<br>Germany | Production, Innovation and Development of Enteral Nutrition   |
| /05        | c/o Fresenius Kabi España S.A.U.<br>Dr. Ferran 12<br>08339 Vilassar de Dalt<br>Spain                                       | Production and Logistics of Liquid Pharmaceuticals and Irrigation Solutions   |
| /06        | c/o Fresenius Kabi Norge AS<br>Svinesundsveien 80<br>1788 Halden<br>Norway   | Production of Liquid Pharmaceuticals, Nonactive Medical Devices, Irrigation Solutions, Desinfectant and Parenteral Nutrition  |

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| /07 | c/o Labesfal - Laboratorios Almiro S.A.<br>Zona Industrial do Lagedo<br>3465-157 Santiago de Besteiros<br>Portugal   | Production and Logistic Operation<br>of Pharmaceuticals and Medical<br>Device Solutions   |
| /08 | c/o Fresenius Kabi SSPC<br>No.16, Beizha Road<br>Mashan, Binhu District Wuxi<br>Jiansu Province<br>214092<br>Jiangsu<br>P.R. China                           | Design, Development and<br>Manufacturing of Parenteral Nutrition<br>and Enteral Nutrition Liquid,<br>Manufacturing of<br>Freeze Dried Products(Vitamins),<br>Tablets(Anti-allergen) and Purified<br>Soybean Oil used for medicine |
| /09 | c/o Beijing Fresenius Kabi<br>Pharmaceutical Co., Ltd<br>No. 57 Huatuo Road<br>Bio-medicine Industry Base<br>Daxing District<br>102609 Beijing<br>P.R. China | Production and Logistics of Liquid<br>and Solid Pharmaceuticals and<br>Enteral Nutrition  |
| /10 | c/o Fresenius Kabi Oncology Ltd.<br>Village:- Kishanpura, Tehsil:- Baddi<br>Dist.:- Solan, (H. P.)<br>India 173205<br>India                                  | Production of liquid & solid<br>Pharmaceuticals   |
| /11 | c/o Fresenius Kabi India Private Ltd.<br>A-3,MIDC. Ranjangaon Ganpati,<br>Tal.- Shirur 412220, Dist. Pune<br>India   | Production and Logistics of Liquid<br>Pharmaceuticals   |

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| /12 | c/o Fresenius Kabi Oncology Limited<br>D-35, Industrial Area<br>Kalyani, Dist. Nadia<br>741235 West Bengal<br>India                | Production of Active Pharmaceutical<br>Ingredients and pharmaceutical<br>excipients  |
| /13 | c/o Fresenius Kabi France S.A.S.<br>6, Rue du Rempart<br>27400 Louviers<br>France  | Production of Liquid Pharmaceuticals,<br>Irrigation Solutions and Nonactive<br>Devices   |
| /14 | c/o FHC (Holdings) Limited<br>Cestrian Court, Eastgate Way,<br>Manor Park<br>Runcorn<br>Cheshire<br>WA7 1NT<br>United Kingdom      | Production of patient specific<br>solutions<br>of pharmaceuticals, Logistics, Sales<br>and Marketing of Health care<br>products and technical services,<br>Enteral nutrition and medical devices |
| /15 | c/o Fresenius Kabi France S.A.S.<br>5, place du Marivel<br>92316 Sèvres Cedex<br>France  | Sales and Marketing of Medicinal<br>Products, Medical Devices and<br>Enteral Nutrition   |
| /18 | c/o Fresenius Kabi France S.A.S.<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 and Oral<br>Nutrition  |

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| /19 | c/o Fresenius Kabi AB<br>Rapgatan 7<br>SE-751 74 Uppsala<br>Sweden   | Production of Parenteral Solutions<br>as Lipid Emulsions, Clinical Nutrition,<br>Anaesthetics, Vitamins                                   |
| /20 | c/o Fresenius Kabi AB<br>Kraftvägen 1<br>SE-196 37 Kungsängen<br>Sweden  | Production of Active Pharmaceutical<br>Ingredients and Logistics of<br>Pharmaceuticals  |
| /21 | c/o Fenwal International, Inc.<br>Carretera Sánchez Km, 18,5<br>Parque Industrial Itabo<br>Zone Franca Ind. de S.C.<br>91000 Haina<br>Dominican Rep. | Manufacturing of Blood Collection<br>and Separation products,<br>Sterilization, Storage and Support<br>Systems                            |
| /23 | c/o Fresenius Kabi Company<br>Road 122 km 05<br>San German, P.R 00683<br>Puerto Rico   | Manufacturing processes of medical<br>devices with its support activities, and<br>Distribution Center or Finished Good                    |
| /24 | c/o Fresenius Kabi Tunisia<br>MC 44 Route de Korba<br>8014 Bir Drassen, Beni Khalled<br>Tunisia  | Manufacture and distribution of<br>enteral nutrition sets and infusion<br>and transfusion administration sets                             |
| /25 | c/o Fenwal Inc.-<br>A Fresenius Kabi Company<br>Planta Maricao<br>Road 357 Km. 08<br>Maricao<br>Puerto Rico 00606<br>Puerto Rico                     | Production and distribution of<br>(non-active) medical devices for<br>collection, processing and storage<br>of blood and blood components |

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| /26 | c/o Fenwal, Inc. –<br>A Fresenius Kabi Company<br>Lake Zurich,<br>West, Illinois<br>Three Corporate Drive<br>Lake Zurich IL 60047<br>USA | Research and Development activities<br>of systems used for collection and<br>processing and storage of blood<br>and other cellular therapy  |
| /27 | c/o Fresenius Kabi Deutschland GmbH<br>Freseniusstr. 1<br>61169 Friedberg<br>Germany   | Production of Infusion and Irrigation<br>solutions for clinical purpose,<br>Production of Fishoil   |
| /28 | c/o Fresenius Vial S.A.S.<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  |
| /29 | c/o Fresenius Kabi Italia S.r.l.<br>Via Camagre 41<br>37063 Isola della Scala-Verona<br>Italy  | Production of liquid pharmaceuticals<br>and nonactive medical device,<br>logistics, sales and marketing of<br>medicinal products, enteral nutrition,<br>medical devices and other health care<br>products services including technical<br>service |
| /30 | c/o Fresenius HemoCare Italia S.r.l.<br>Via San Pietro 1<br>41037 Mirandola (MO)<br>Italy  | Production of Medical Devices for<br>blood treatment and related services<br>in support of the production<br>(Maintenance, Offices, Laboratories,<br>Warehouse), Research and<br>Development of products, materials<br>and processes              |

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| /31 | c/o Fresenius Kabi Polska Sp. z o.o.<br>Sienkiewicza 25<br>99-300 Kutno<br>Poland  | Production of infusion liquids - simple fluids and antibiotics. Fluid packaging made of polyethylene                 |
| /33 | c/o Fresenius Kabi Brasil Ltda.<br>Av. Brasil Norte 1255<br>Bairro Cidade Jardim<br>Anápolis-Goiás - GO<br>75080-240<br>Brazil | Production of liquid and powders sterile   |
| /34 | c/o Laboratorio Sanderson SA<br>Carlos Fernández 244<br>8940575 San Joaquín<br>Chile   | Production of Sterile Liquid Pharmaceuticals, Logistics and Sales of Medicinal Products                              |
| /35 | c/o Recetario Magistral Endovenoso S.A.<br>Calle 2, N° 1946, Parque Ejercito<br>CONCEPCIÓN VIII Región<br>Chile                | Production, Logistics and Sales of Patientspecific Compounding Products for Parenteral Nutrition and Pharmaceuticals |
| /36 | c/o Recetario Magistral Endovenoso S.A.<br>Ignacio Valdivieso 2361, San Joaquín<br>8940577 Santiago<br>Chile                   | Production of patient specific compounding product for parenteral nutrition and pharmaceutical                       |
| /37 | c/o Fresenius Kabi Chile Ltda.<br>Pintor Cicarelli 235, San Joaquín<br>8950575 Santiago<br>Chile                               | Sales of medicinal products and medical devices (including technical service)  |



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| /38 | c/o Fresenius Kabi PU USA, LLC<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 |
| /39 | c/o Fresenius Kabi USA, LLC<br>3159 Staley Road<br>Grand Island, NY 14072<br>USA  | Manufacturing of Generic Injectable Pharmaceutical Products (in flip-top vial form)  |
| /40 | c/o Fresenius Kabi USA, LLC<br>2020 North Ruby Street<br>Melrose Park, IL 60160<br>USA  | Manufacturing of Generic Injectable Pharmaceutical products (in flip-top vial form)  |
| /41 | c/o Fresenius Kabi<br>Manufacturing SA (Pty) Ltd.<br>6 Gibaud Road, Korsten<br>Port Elizabeth, South Africa 6020<br>South Africa          | Manufacturing and packing of sterile Small Volume and Large Volume Pharmaceutical Parenterals  |
| /42 | c/o Fresenius Kabi iPSUM S.r.l.<br>Plant Villadose (RO)<br>Via S. Leonardo 23 /<br>Via Dello Sviluppo 15<br>45010 Villadose (RO)<br>Italy | Production, logistics, innovation and development of active ingredients (APIs) and bulk pharmaceutical mixtures  |
| /43 | c/o Fresenius Kabi Vietnam<br>Joint Stock Company<br>Area 8, Nhon Phu Ward,<br>Quy Nhon, Binh Dinh,<br>Vietnam                            | Production of sterile liquid pharmaceuticals   |



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| /44 | c/o FRESENIUS KABI BRASIL LTDA.<br>Rodovia CE 040, Km 10, S/N<br>JACUNDÁ – AQUIRAZ - CEARÁ - Brazil<br>AQUIRAZ - CE<br>61700-000<br>Brazil | Production of Liquid Medicinal<br>Products and Storage of Medicinal<br>Products, Enteral Nutrition and<br>Medical Devices                                   |
| /45 | c/o Clinico Medical Sp. z o.o.<br>Blonie k/Wroclawia<br>Roberta Kocha 1<br>55-330 Miękinia<br>Poland                                       | Production including Sterilization<br>and Distribution of non active<br>medical devices for enteral<br>Nutrition, Infusion, Transfusion<br>and Port Systems |
| /47 | c/o Fresenius Kabi iPSUM S.r.l.<br>Località Masserie Almiere<br>(Zone Ind.)<br>I-86077 POZZILLI (IS)<br>86077 POZZILLI<br>Italy            | Production of active ingredients<br>(APIs) and bulk pharmaceutical<br>mixtures  |
| /48 | c/o Fresenius Kabi iPSUM S.r.l.<br>Via A. Boito 13<br>I-20835 Taccona di Muggiò (MB)<br>Italy  | Production of active ingredients<br>(APIs) and bulk pharmaceutical<br>mixtures  |
| /49 | c/o Fresenius Kabi iPSUM S.r.l.<br>VIA ENRICO MATTEI 26<br>50039 VICCHIO (FI)<br>Italy   | Production of Active Pharmaceutical<br>Ingredients and Ingredients for food<br>and feed Additives and treatment of<br>non-hazardous liquid waste            |

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| /50 | c/o PT. Fresenius Kabi Combiphar<br>383 Jalan Raya Simpang<br>Padalarang Bandung, West Java 40553<br>Indonesia | Manufacture of Pharmaceutical Product in coordination with Joint Venture Company. Production and Packaging of Ketoanalogues and Essential Amino Acids Tablets  |
| /51 | c/o Fresenius Kabi AB<br>Bredgränd 14<br>SE-753 20 Sweden<br>Sweden  | Manufacturing, Innovation & Development, Logistics and Distribution, Sales and Marketing of Pharmaceutical Products, Medical Devices and Other Health Care Products and Services including Technical Service |
| /52 | c/o Fresenius Kabi Deutschland GmbH<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                                     |
| /53 | c/o Fresenius Kabi Hungary Ltd.<br>Szépvölgyi út 6<br>1025 Budapest-II. kerület<br>Hungary                     | Logistics, Sales, Marketing and Technical Service  |

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/54 c/o Fresenius Kabi Pharma Portugal  
Taguspark - Edifício Inovação I 223/224  
2740-122 Porto Salvo  
Portugal

Logistics, Sales and Marketing of  
Pharmaceutical Products, Medicinal  
Products, Medical Devices and  
Enteral Nutrition, Services including  
Technical Service

2023-02-03



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln