

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

CAIR LGL
1 Allée des Chevreuils, Parc Tertiaire de Bois Dieu
69380 LISSIEU FRANCE

pour les activités
for the activities

Conception, fabrication et commercialisation de : Dispositifs médicaux non actifs et non implantables, pour la nutrition, l'aspiration, la thérapie respiratoire et oxygénation, la perfusion, la radiologie. Sets de soins stériles et accessoires. Désinfectants de dispositifs médicaux.

Design, manufacturing and sales of : Non active and non implantable medical devices, for nutrition, inhaling, respiratory therapy and oxygenation, perfusion, radiology. Sets of sterile care and accessories. Disinfectants of medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum
See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité / Effective date May 18th, 2021 (included)
Valable jusqu'au / Expiry date : September 17th, 2024 (included)
Etabli le / Issued on : May 18th, 2021

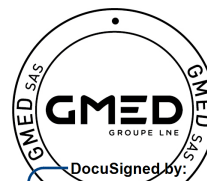


Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 9969-8

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 9969-7



Lionel DREUX
Certification Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites :

CAIR LGL
1 allée des Chevreuils – Parc Tertiaire de Bois Dieu
69380 LISSIEU
France

French version :

- **Siège social, conception, commercialisation, service client.**

English version :

- *Head office, design, sales, customer service.*

CAIR LGL
Zone d'Activités Croix Grand Borne
69930 SAINT LAURENT DE CHAMOUSSET
France

French version :

- **Fabrication, contrôle final**

English version :

- *Manufacturing, final control.*

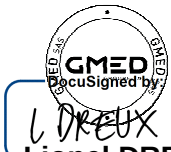
CAIR LGL
211 Rue Marius Berliet
69400 ARNAS
France

French version :

- **Logistique, stockage**

English version :

- *Logistic, storage.*


Lionel DREUX
Certification Director

CAIR TUNISIE
ZI Kalaa Kebira
4060 KALAA KEBIRA
Tunisie

French version :

- **Fabrication, contrôle final, commercialisation**

English version :

- *Manufacturing, final control, sales.*

4 sites / 4 sites


DocuSigned by:
Lionel DREUX
Certification Director



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that



Fresenius Kabi AG

Else-Kröner-Str. 1
61352 Bad Homburg
GERMANY

has established and applies
a Quality Management System for

**Design, Development, Production, Logistics and Sales and Marketing of
Medicinal Product, Medical Devices, Enteral Nutrition, Active Pharmaceutical
Ingredients, Patient-specific Solutions of Pharmaceuticals, and other
Healthcare Products, and Services including Technical Service**

including the sites see enclosure.

An audit was performed, Order No. **70083720**.

Proof has been furnished that the requirements
according to

DIN EN ISO 9001:2015

are fulfilled.

The certificate is valid from **2023-06-13** until **2025-04-22**.

Certificate Registration No.: **12 100 24126 TMS**.

Head of Certification Body
Munich, 2023-06-19





Management Service

Enclosure of Certificate Registration No.: 12 100 24126 TMS

Sites	Scope of application
<u>Region Europe</u>	
Fresenius Kabi AG Else-Kröner-Str. 1 61352 Bad Homburg GERMANY	Certificate Holder and Central Function
Fresenius Kabi Austria GmbH (Production Unit Linz and Market Unit Product Partnering Linz) Estermannstr. 17 4020 Linz AUSTRIA	Production, Logistics, Sales and Marketing of Liquid Pharmaceuticals and Active Pharmaceutical Ingredients
Fresenius Kabi Austria GmbH Hafnerstr. 36 8055 Graz AUSTRIA	Development and Production of Liquid and Lyophilized Pharmaceuticals including Biologicals, Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Other Health Care Products and Technical Service
Fresenius Kabi N.V. Brandekensweg 9 2627 Schelle BELGIUM	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Other Health Care Products and Services and Technical Service
Fresenius Kabi Bulgaria EOOD 1 Alexandar Jendov Str., 6th floor, ap 37 1113 Sofia BULGARIA	Marketing of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi SwissBioSim GmbH Terre Bonne Business Park Route de Crassier 23 Bâtiment A3 1262 Eysins SWITZERLAND	Research, Development, Marketing and Sales of Biosimilars
Fresenius Kabi (Schweiz) AG Am Mattenhof 4 6010 Kriens SWITZERLAND	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Service
Fresenius Kabi s.r.o. Na Strži, 1702/65, Nusle 140 00 Praha 4 CZECH REPUBLIC	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Service in the Czech Republic and Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices in the Slovak Republic
Fresenius Kabi Horátev CZ s.r.o. Horátev 104 289 13 Horátev CZECH REPUBLIC	Production of Nonactive Medical Devices
Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg GERMANY	Sales and Marketing of Pharmaceuticals, Products for Enteral Nutrition and Medical Devices, Sales of Patient Specific Solutions of Pharmaceuticals and for Enteral Nutrition. Management of Patient Transfer in the Nonclinical Area

Head of Certification Body
Munich, 2023-06-19





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Sites	Scope of application
<u>Region Europe</u>	
Fresenius Kabi Deutschland GmbH Daimlerstr. 22 61352 Bad Homburg GERMANY	Development, Production and Logistics of Enteral Nutrition
Fresenius Kabi Deutschland GmbH (Production Unit Third Party Manufacturing) Pfungstweide 53 61169 Friedberg (Hessen) GERMANY	Coordination of Third Party Manufacturing (External Production) and Release of Medicinal Products and Medical Devices
Fresenius HemoCare GmbH Gruener Weg 10 61169 Friedberg GERMANY	Development and Production of Active Medical Devices and Laboratory Devices
Fresenius Kabi Deutschland GmbH Gruener Weg 10 61169 Friedberg GERMANY	Design and Development of Active Medical Devices for Autotransfusion, Apheresis and Blood Processing, IVD Laboratory Devices
Fresenius Kabi Deutschland GmbH Werk Friedberg Freseniusstr. 1 61169 Friedberg GERMANY	Development and Production of Liquid Pharmaceuticals, Active Pharmaceutical Ingredients, Parenteral Nutrition and Irrigation Solutions and Services
Fresenius Kabi Logistik GmbH Freseniusstr. 1 61169 Friedberg GERMANY	Logistics of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi Deutschland GmbH Werk Bad Hersfeld Robert-Koch-Str. 5 36251 Bad Hersfeld GERMANY	Design and Development of Single-Use Medical Devices for Infusion, Transfusion, Enteral Feeding and Implantable Port Products
Fresenius Kabi Deutschland GmbH Werk Mihla Gartenstr. 9 99831 Amt Creuzburg/ OT Mihla GERMANY	Production of Components for Medical Devices and Primary Packaging
Fresenius Kabi Deutschland GmbH Zeppelinstr. 1c & Ludwig-Erhard-Str. 10 85375 Neufahrn GERMANY	Manufacturing and Logistic/Distribution of Patient specific Compounding Products for Parenteral Nutrition Therapy; Logistic/Distribution of Pharmaceuticals, Medical Devices and other Health Care Products; Manufacturing, Packaging, Labeling and Logistic/Distribution of Contract Manufacturing Products

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Sites	Scope of application
<u>Region Europe</u>	
Fresenius Kabi Deutschland GmbH Marienbader Platz 1 61348 Bad Homburg GERMANY	Design, Development, Production, Distribution and Servicing of Compounding Devices
MC Medizintechnik GmbH Am Neuen Berg 8 63755 Alzenau-Hörstein GERMANY	Service of Medical Devices and Service Training
Fresenius Kabi AB Islands Brygge 57 2300 København S. DENMARK	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Other Health Care Products and Services including Technical Service
Fresenius Kabi AB Ratamestarinkatu 7 a 00520 Helsinki FINLAND	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Other Health Care Products and Services including Technical Service
Fresenius Kabi Espana S.A.U. Marina, 16-18, 08005 Barcelona SPAIN	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Technical Service
Fresenius Kabi Espana S.A.U. Doctor Ferran 12 08339 Vilassar de Dalt, Barcelona SPAIN	Production and Logistics of Liquid Pharmaceuticals and Irrigation Solutions
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
Fresenius Kabi France S.A.S. 6, Rue du Rempart 27406 Louviers FRANCE	Production of Liquid Pharmaceuticals, Irrigation Solutions and Nonactive Medical Devices
Fresenius Kabi France S.A.S. Zone industrielle Ecoparc 2, 350, Allée de la Butte à Colas 27400 Heudebouville FRANCE	Logistics of Medical Devices, Pharmaceuticals and Enteral Nutrition
Fresenius Vial S.A.S. Le Grand Chemin 38590 Brézins FRANCE	Development and Production of Active Medical Devices, Logistics, Sales, Technical Service and Marketing of Medical Devices

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Sites	Scope of application
<u>Region Europe</u>	
Fenwal France S.A.S. Etaille 36400 La Chatre FRANCE	Production and Distribution of Nonactive Medical Devices and Transfusion Accessories
Calea UK Ltd Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT GREAT BRITAIN	Production of Patient-specific Solutions of Pharmaceuticals, Logistics, Sales and Marketing of Health Care Products and Services
Fresenius Kabi Ltd. Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT GREAT BRITAIN	Logistics, Sales, Marketing and Technical Service of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi Hellas A.E.E. 354 Mesoghion Avenue 15341 Agia Paraskevi Athens GREECE	Logistics, Sales and Marketing of Medicinal Products
Fresenius Kabi Hungary Kft. 1025 Budapest Szépvölgyi út 6 HUNGARY	Logistics, Sales, Marketing and Technical Service
Fresenius Kabi d.o.o. Radnička cesta 37A 10000 Zagreb CROATIA	Marketing of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi Ltd. Fresenius Kabi Ireland Unit 3B Fingal Bay Business Park Balbriggan K32YK12 CO. - Dublin IRELAND	Logistics, Sales, Marketing and Home Care relating to Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi Italia S.r.l. Via Camagre, 41 37063 Isola della Scala ITALY	Production of Liquid Pharmaceuticals and Nonactive Medical Devices, Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Other Health Care Products, Services including Technical Service
Fresenius Kabi iPSUM S.r.l. Via E. Mattei, 26 50039 Vicchio, (FI) ITALY	Production of Active Pharmaceutical Ingredients
Fresenius Kabi iPSUM S.r.l. Via San Leonardo 23 45010 Villadose (RO) ITALY	Production and Logistics of Active Pharmaceutical Ingredients and Bulk Medicinal Products

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Sites	Scope of application
<u>Region Europe</u>	
Fresenius Kabi iPSUM S.r.l. Via Roma 108 20051 Cassina de' Pecchi ITALY	Sales and Marketing of Active Pharmaceutical Ingredients and Bulk Medicinal Product
Fresenius Kabi iPSUM S.r.l. Località Masserie Almieri (Zone Ind.) 86077 Pozzilli (IS) ITALY	Production and Logistics of Active Pharmaceutical Ingredients and Bulk Medicinal Products
Fresenius HemoCare Italia S.r.l. Via San Pietro 1 41037 Mirandola ITALY	Development and Production of Nonactive Medical Devices
Fresenius Kabi Nederland B.V. Amersfoortseweg 10 E 3705 GJ Zeist (Huis ter Heide) NETHERLANDS	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices, Other Health Care Products and Services
Fresenius HemoCare Netherlands B.V. Enteral Nutrition Runde ZZ 41 7881 HM Emmer-Compascuum NETHERLANDS	Production and Logistics of Enteral Nutrition
Fresenius HemoCare Netherlands B.V. Runde ZZ 41 7881 HM - Emmer-Compascuum NETHERLANDS	Design and Development and Production including Sterilization of Non-active Medical Devices for Transfusion, Blood processing, Blood Donation and Filtration
Fresenius Kabi Norge AS Svinesundsveien 80 1788 Halden NORWAY	Production of Liquid Pharmaceuticals, Nonactive Medical Devices and Irrigation Solutions, Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi Norge AS Gjerdrums vei 10A 0484 Oslo NORWAY	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Service
Fresenius Kabi Polska Sp. z o.o. Sienkiewicza 25 99-300 Kutno POLAND	Production and Logistics of Liquid Pharmaceuticals
Clinico Medical Sp. z o.o. Blonie k / Wroclawia ul. Roberta Kocha 1 55-330 Miekinia POLAND	Production including Sterilization and Distribution of Non-Active Medical Devices for Enteral Nutrition, Infusion, Transfusion and Port Systems

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Sites	Scope of application
<u>Region Europe</u>	
Fresenius Kabi Polska Sp. z o.o. Al. Jerozolimskie 134 02-305 Warszawa POLAND	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Service
Labesfal - Laboratórios Almiro S.A. Zona Industrial de Lagedo 3465-157 Santiago de Besteiros PORTUGAL	Production, Logistics, Sales and Marketing of Medicinal Products including Patient-specific Compounding Products for Parenteral Nutrition and Pharmaceuticals, Medical Device (Irrigation Solutions) and other Health Care Products
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 Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi Romania S.R.L. Strada Henri Coandă, Nr. 2, Oraș Ghimbav 507075 - Județ Brașov ROMANIA	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Service
Fresenius Kabi AB Kraftvägen 1 196 37 Kungsängen SWEDEN	Production and Logistics of Liquid Pharmaceuticals and Active Pharmaceutical Ingredients
Fresenius Kabi AB Rapsgatan 7 751 74 Uppsala SWEDEN	Development & Production of Parenteral Solutions as Lipid Emulsions, Clinical Nutrition, Anaesthetics, Vitamins
Fresenius Kabi AB Bredgränd 14 751 74 Uppsala SWEDEN	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Other Health Care Products and Services including Technical Service
Fresenius Kabi Baltics UAB J. Basanavicius Str. 26 03224 Vilnius REPUBLIC OF LITHUANIA	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Service
Fresenius Kabi o.o.o. 125167 Moscow Leningradsky Avenue 37 build. 9, floor 3, room XXIV, office 15 Moscow RUSSIAN FEDERATION	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices

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Sites	Scope of application
<u>Region Africa</u>	
Fresenius Kabi Manufacturing SA (Pty) Ltd. 6 Gibaud Road, Korsten 6020 Port Elizabeth REPUBLIC OF SOUTH AFRICA	Production of Liquid Pharmaceuticals
Fresenius Kabi South Africa (Pty) Ltd. Stand 7, Growthpoint Business Park, 162 Tonetti Street 1685 Midrand, Gauteng REPUBLIC OF SOUTH AFRICA	Production of Patient-specific Solutions of Pharmaceuticals, Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices
<u>Region North Africa</u>	
Fresenius Kabi Tunisia SARL Route de Korba 8014 Bir Drassen-Beni Khalled-Nabeul TUNISIA	Manufacturing of non-active medical devices and device components
<u>Region Asia Pacific</u>	
Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way Mt Kuring-Gai, NSW 2080 AUSTRALIA	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Services in Australia and New Zealand
Fresenius Kabi Australia Pty Limited Unit 2, 18 Powers Road 2147 Seven Hills AUSTRALIA	Technical Service for Medical Devices
Fresenius Kabi (Nanchang) CO. Ltd. Qing Lan Road Nanchang Economic & Technological Development Zone Nanchang, Jiangxi Province, P.R. CHINA Post Code: 330013	Development, Production and Logistics of Nonactive and Active Medical Devices
Fresenius Kabi (Guangzhou) Co., Ltd. No.43 Baoying Street Guangzhou Free Trade Zone, P.R. CHINA Post Code: 510730	Production including Sterilization of Non-active Medical devices for Infusion, Transfusion, Blood processing, Blood Sampling, Blood Donation and Filtration
Fresenius Kabi (China) Co. Ltd. 16F, GrandyVIC Building, No. 16 Taiyanggong Mid Street Chaoyang District, Beijing, P.R. CHINA Post Code: 100028	Logistics, Sales and Marketing of Medical Devices

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Sites	Scope of application
<u>Region Asia Pacific</u>	
Beijing Fresenius Kabi Pharmaceutical Co., Ltd. 16F, GrandyVIC Building, No. 16 Taiyanggong Mid Street Chaoyang District, Beijing, P.R. CHINA Post Code: 100028	Sales and Marketing of Medicinal Products
Beijing Fresenius Kabi Pharmaceutical Co., Ltd. No. 57 Huatuo Road, Zhongguancun Science Park Daxing Bio-Medicine Park, Daxing District Post Code: 102600	Manufacturing and Logistics of Medicinal Products
Fresenius Kabi SSPC No. 16, Beizha Road, Mashan, Binhu District, Wuxi, Jiangsu, P.R. CHINA Post Code: 214092	Development, Manufacturing and Supply of Freeze-Dried Products, Large Volume Parenteral Products, Small Volume Parenteral Products, Enteral Products, Tablet Products (According to the Drug Approval Numbers), Medical Devices and Active Pharmaceutical Ingredients, Supply of Medical Devices and Dietary Nutrition
Fresenius Kabi Hong Kong Ltd. Room 5001-5027, 50/F Sun Hung Kai Centre, 30 Harbour Road, Wanchai, Hong Kong P.R. CHINA	Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Service
Fresenius Kabi Asia Pacific Ltd. (The Representative Office of Fresenius Kabi Asia Pacific Limited in Ho Chi Minh City) Floor 19, Harbour View Tower, 35 Nguyen Hue Street, District 1 Ho Chi Minh City VIETNAM	Marketing of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi Vietnam JSC Harbour View Tower, Floor 19, 35 Nguyen Hue St., Dist. 1 Ho Chi Minh City VIETNAM	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Service
Fresenius Kabi Vietnam JSC Area no. 8, Nhon Phu Ward Quy Nhon, Binh Dinh VIETNAM	Production of Liquid Pharmaceuticals
PT. Fresenius Kabi Indonesia Menara Bidakara 1, 18th floor, Jl. Jend. Gatot Subroto Kav.71-73, Menteng Dalam, Tebet South Jakarta - 12870 INDONESIA	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Service

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Management Service

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Sites	Scope of application
<u>Region Asia Pacific</u>	
Fresenius Kabi India Private Ltd. Ninth Floor, AP 81, S No 83, North Main Road, Mundhwa, Maharashtra Pune - 411036 INDIA	Logistics, Sales, Marketing and Technical Service
Fresenius Kabi India Private Ltd. A-3, MIDC. Ranjangaon Ganpati, Tal.-Shirur Dist. Pune - 412220 INDIA	Manufacture, Testing and Supply of Large Volume Parenterals (LVPs) Belonging to Pharmaceutical Formulations
Fresenius Kabi Oncology Limited D-35, Industrial Area, Kalyani, Dist. Nadia, West Bengal - 741235 INDIA	Production of Active Pharmaceutical Ingredients
Fresenius Kabi Oncology Limited Village - Kishanpura, P.O. Guru Majra Tehsil - Nalagarh, Dist. Solan, (H.P.) - 174101 INDIA	Technology Transfer and Manufacture of Liquid and Solid Pharmaceuticals
Fresenius Kabi Oncology Limited (Formulation) Echelon Institutional Area, Plot No. 11, Sector - 32 Gurgaon, Haryana - 122001 INDIA	Development and Technology Transfer of Liquid and Solid Pharmaceuticals
Fresenius Kabi Oncology Limited (Development of APIs) Echelon Institutional Area, Plot No. 11, Sector - 32 Gurgaon, Haryana - 122001 INDIA	Development of Active Pharmaceutical Ingredients
Fresenius Kabi Japan K.K. 3-32-42, Higashishinagawa Shinagawa-ku, Tokyo 140-0002 JAPAN	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices, Other Health Care Products and Services
Fresenius Kabi Korea Ltd. 8F-9F Apple Tower 69, Baekjegobun-ro Songpa-gu 05556 Seoul REPUBLIC OF KOREA	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Services
Fresenius Kabi Malaysia Sdn Bhd. # 3-1 & 3-2, Axis Technology Centre, Lot 13, Jalan 51A/225 46100 Petaling Jaya, Selangor MALAYSIA	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Service

Paul J. J. J.

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Management Service

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Sites	Scope of application
<u>Region Asia Pacific</u>	
Fresenius Kabi Philippines Inc. Units A&B, 18/F Aeon Center Alabang-Zapote Rd cor. North Bridgeway Avenue, 1781 Alabang, Muntinlupa City REPUBLIC OF THE PHILIPPINES	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Other Health Care Products and Services including Technical Services
Fresenius Kabi (Singapore) Pte Ltd. 238A Thomson Road #24-03/05 Novena Square Tower A 307684 Singapore REPUBLIC OF SINGAPORE	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Service
Fresenius Kabi (Thailand) Ltd. 93/1 GPF Witthayu Tower B, 10th Floor, Room no.1001-1003, Wireless Road Lumpini, Pathumwan, Bangkok 10330 THAILAND	Logistics, Sales and Marketing of Medicinal Products, Medical Devices and Enteral Nutrition and Services including Technical Service
Fresenius Kabi Taiwan Ltd. 5F, No. 32, Section 3, Ren-Ai. Rd. Taipei - 10653, R.O.C. TAIWAN	Sales and Marketing of Medicinal Products, Medical Devices, Enteral Nutrition, Parental Nutrition and Services including Technical Services
<u>Region Latin America</u>	
Fresenius Kabi S.A. 2677 Cabildo Av. 10° Floor C1428AAU Buenos Aires ARGENTINA	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Services
Nutri Home S.A. 2677 Cabildo Av. 10° Floor C1428AAU Buenos Aires ARGENTINA	Sales of Home Care Services
Fresenius Kabi S.A. Del Comercio Boulevard 757 Cordoba ARGENTINA	Production of Patient-specific Solutions of Pharmaceuticals and Nonactive Medical Devices
Fresenius Kabi S.A. Puente del Inca 2450 Calle 9, Lote 155 B1812IDX - Carlos Spegazzini - Ezeiza, Buenos Aires ARGENTINA	Production of Patient-specific Solutions of Pharmaceuticals
Fresenius HemoCare Brasil Ltda. Avenida Marginal Projetada 1652 G1 A G8 06463-200 - Fazenda Tamboré, Barueri - SP BRAZIL	Logistic, Sales, Marketing and Technical Service of Medical Devices and Other Health Care Products

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Sites	Scope of application
<u>Region Latin America</u>	
Fresenius Kabi Brasil Ltda. Rodoovia CE 040, S/No., Km 10 61700-000 Aquiraz-CE BRAZIL	Production of Liquid Medicinal Products and Logistics of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi Brasil Ltda. Av. Brasil Norte 1255, Bairro Cidade Jardim 75080-240 Anapolis - GO BRAZIL	Production of steril Pharmaceuticals
Fresenius HemoCare Brasil Ltda. Rua Roque Gonzales 128 06855-690 - Itapecerica da Serra – SP BRAZIL	Development and Production of Nonactive Medical Devices and Other Health Care Products and Technical Service
Fresenius Kabi S.A. Km 4 1/2 vá Durán tambo Av semillas 090701 Durán ECUADOR	Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Technical Service, Nutrition Center
Fresenius Kabi Chile Ltda. Pintor Cicarelli 235, San Joaquin 8940575 Santiago CHILE	Logistics, Sales and Marketing of Medicinal Products and Medical Devices and Services including Technical Service
Laboratorio Sanderson S.A. Carlos Fernández 244 San Joaquin 8940575 Santiago CHILE	Production of Sterile Liquid Pharmaceuticals, Logistics and Sales of Medicinal Products
Recetario Magistral Endovenoso S.A. Ignacio Valdivieso 2361 8940575 Santiago CHILE	Production, Logistics and Sales of Patient-specific Compounding Products for Parenteral Nutrition and Pharmaceuticals
Recetario Magistral Endovenoso S.A. Calle Dos 1942 Parque Industrial, Concepción CHILE	Production, Logistics and Sales of Patient-specific Compounding Products for Parenteral Nutrition and Pharmaceuticals
Fresenius Kabi Mexico S.A. de C.V. Paseo del Norte 5300A "Guadalajara Technology Park" Carretera Guadalajara-Nogales Km 12.5 45010 San Juan Ocotan, Zapopan, Jalisco MEXICO	Production of IV-Pharmaceuticals and Enteral Nutrition, Logistics, Sales and Marketing of Medicinal Products, Nutrition Products and Medical Devices
Fresenius Kabi Latin America Exports S.A. Ruta 8 km 17,500 – Edificio @2 Local 112 91600 Zonamerica, Montevideo URUGUAY	Sales of Medicinal Products, Enteral Nutrition and Medical Devices

Paul J. J. J.

Head of Certification Body
Munich, 2023-06-19





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Sites	Scope of application
<u>Region Latin America</u>	
Fresenius Kabi Colombia S.A.S. Av. Cra 7 #155C-20 North Point Torre E, Piso 40 Bogotá D.C. COLOMBIA	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Service
Fresenius Kabi Perú S.A. Av. Nicolas Arriola 345-349 Santa Catalina - La Victoria Lima 13 PERU	Logistics, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Services including Technical Service
<u>Region North America</u>	
Calea Ltd. 7111A-6th Street S.E., Calgary, Alberta T2H 2M8 CANADA	Production of Patient-specific Solutions of Pharmaceuticals and Logistics
Calea Ltd. 2785 Skymark Avenue, Unit 2, Mississauga, Ontario L4W 4Y3 CANADA	Production of Patient-specific Solutions of Pharmaceuticals, Logistics and Services
Calea Vancouver Inc. Unit 130-8061 Lougheed Hwy. Burnaby BC V5A 1W9 CANADA	Production of Patient-specific Solutions of Pharmaceuticals and Logistics
Fresenius Kabi Canada Ltd. 165 Galaxy Blvd, Suite 100 Toronto, Ontario M9W 0C8 CANADA	Logistics, Sales and Marketing of Medicinal Products and Medical Devices
Calea Pharmacy Ltd. 41 Brockley Drive, Unit 12, Stoney Creek, Ontario L8E 3P1 CANADA	Production of Patient-specific Solutions of Pharmaceuticals and Logistics
Fresenius Kabi Canada Ltd. 2400 Skymark Avenue, Unit 4 Mississauga L4W 5K5 CANADA	Production, Logistics and Sales of Compounded Products and Pharmaceuticals
Fresenius Kabi USA, LLC 2020 Ruby Street Melrose Park, IL 60160 USA	Production and Logistics of Liquid and Lyophilized Pharmaceuticals and Medical Devices
Fresenius Kabi USA, LLC 3159 Staley Road Grand Island, NY 14072 USA	Production and Logistics of Liquid and Lyophilized Pharmaceuticals and Medical Devices

Paul J. J. J.

Head of Certification Body
Munich, 2023-06-19





Management Service

Enclosure of Certificate Registration No.: 12 100 24126 TMS

Sites	Scope of application
<u>Region North America</u>	
Fresenius Kabi USA, LLC 2045 North Cornell Avenue Melrose Park, IL 60160 USA	Development and Testing of Liquid and Lyophilized Pharmaceuticals and Medical Devices
Fresenius Kabi USA, LLC 5200 Corporate Parkway Wilson, NC 27893 USA	Production and Logistics of Liquid Aseptically Filled and Terminally Sterilized Pharmaceutical Products and Combination Products
Fresenius Kabi USA, LLC 402 Apple Valley Road Duncan, SC 29334 USA	Logistics of Medicinal Products, Enteral Nutrition and Other Health Care Products
Fresenius Kabi USA, LLC 5245 North Sloan Lane, Suite 100 North Las Vegas, NV 89115 USA	Logistics of Medicinal Products, Enteral Nutrition, Medical Devices and Other Health Care Products
Fresenius Kabi USA, LLC 11900 122nd Street Pleasant Prairie, WI 53158 USA	Logistics of Medicinal Products, Enteral Nutrition, Medical Devices and Other Health Care Products
Fresenius Kabi Warrendale 770 Commonwealth Drive Warrendale, PA 15086 USA	Manufacturing of active and nonactive medical devices and laboratory devices
Fresenius Kabi USA, LLC Three Corporate Drive Lake Zurich, IL 60047 USA	Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Other Health Care Products
Fenwal, Inc. Three Corporate Drive Lake Zurich, IL 60047 USA	Design and Development, Distribution, Installation, Servicing and Repair of the System Medical Devices
Fenwal International, Inc. Carretera Sanchez Km 18.5, Parque Industrial Itabo, Zona Franca Ind. de S.C. 91000 Haina DOMINIKANISCHE REPUBLIK	Manufacture and Distribution of Disposable and Accessories for the Collection, Processing and Storage of Blood and Blood Components, and Electron-Beam Sterilization
Fenwal International Inc Camino Real Industrial Park Road #122 00683 San German PUERTO RICO	Production including Sterilization and Distribution of Non-active Medical devices for Transfusion, Blood sampling, Blood Donation and Filtration
Fenwal International Inc Road 357 Km 0.8 00606 Maricao PUERTO RICO	Production including Sterilization and Distribution of Non-active Medical devices for Blood sampling, Blood Donation and Filtration

Head of Certification Body
Munich, 2023-06-19



GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

OriGen Biomedical, Inc.
7000 Burleson Road, Bldg. D
AUSTIN, TX 78744 UNITED STATES

pour les activités
for the activities

Conception, Développement, Fabrication et Distribution de sacs pour culture cellulaire, sacs de congélation et dispositifs associés de transfert de fluides, solutions de cryoconservation et solutions de lavage pulmonaire. Fabrication sous contrat de dispositifs médicaux, (voir addendum)

*Design, development, manufacture and distribution of cell culture bags,
freezing bags and associated fluid transfer devices, cryopreservation solutions and lung lavage solutions.
Contract manufacturing of finished medical devices, (see addendum)*

réalisées sur le(s) site(s) de
performed on the location(s) of

OriGen Biomedical, Inc.
7000 Burleson Road, Bldg. D AUSTIN, TX 78744 USA
OriGen Biomedical, Inc.
2301 E St. Elmo Rd. Bldg. 1, Ste 110, AUSTIN, TX 78744 USA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485:2016

Début de validité / Effective date : August 4th, 2021 (included)
Valable jusqu'au / Expiry date : October 18th, 2024 (included)
Etabli le / Issued on : August 4th, 2021



GMED N° 34728-3

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 34728-2



On behalf of the President
Béatrice LYS
Technical Director

DocuSigned by:

Béatrice Lys
EF33BDA9BAA04A3...

Conception, Développement, Fabrication et Distribution de sacs pour culture cellulaire, sacs de congélation et dispositifs associés de transfert de fluides, solutions de cryoconservation et solutions de lavage pulmonaire. Fabrication sous contrat de dispositifs médicaux, sous ensembles et composants utilisés dans la congélation, le stockage et le traitement du sang, des cellules et des tissus.

Design, development, manufacture and distribution of cell culture bags, freezing bags and associated fluid transfer devices, cryopreservation solutions and lung lavage solutions. Contract manufacturing of finished medical devices, subassemblies and components used in the freezing, storage and processing of blood, cells and tissues.

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

OriGen Biomedical, Inc.

7000 Burleson Road, Bldg. D,
Austin, TX 78744 - USA

Conception, Développement, Fabrication et Distribution /
Design, Development, Manufacture, and Distribution

OriGen Biomedical, Inc.

2301 E St. Elmo Rd. Bldg. 1, Ste 110,
Austin, TX 78744 - USA

Fabrication, Assemblage, Conditionnement, Contrôle qualité /
Manufacture, Assembly, Packaging, quality control

2 sites / 2 sites



DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

	ASEGURAMIENTO SANITARIO		AUDITORIAS Y CERTIFICACIONES	
	CERTIFICADO CAPACIDAD DE ALMACENAMIENTO Y/O ACONDICIONAMIENTO (CCAA) DISPOSITIVOS MÉDICOS			
	Código: ASS-AYC-FM037	Versión: 04	Fecha de Emisión: 30/11/2020	Página 1 de 1

RADICACIÓN No 20211187976 FECHA 16/09/2021

EL (LA) SUSCRITO (A) DIRECTOR (A) TECNICO (A) DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS DEL INVIMA, CERTIFICA QUE EL ESTABLECIMIENTO RELACIONADO A CONTINUACIÓN, CUMPLE CON LAS CONDICIONES SANITARIAS, DE CONTROL DE CALIDAD, DE DOTACIÓN Y RECURSO HUMANO PARA EL ALMACENAMIENTO Y/O ACONDICIONAMIENTO DE DISPOSITIVOS MÉDICOS, DE ACUERDO CON LA LEGISLACIÓN VIGENTE (DECRETO 4725 DE 2005) Y EL MANUAL DE CONDICIONES DE ALMACENAMIENTO Y/O ACONDICIONAMIENTO DE DISPOSITIVOS MÉDICOS (RESOLUCIÓN 4002 DE 2007). FECHA DE VISITA DE CERTIFICACIÓN: 14/FEBRERO/2022.

1. ESTABLECIMIENTO IMPORTADOR

NOMBRE: KENKO MEDICARE S.A.S		
DIRECCIÓN: CARRERA 13 No 63-39 OFICINA 904		
TELÉFONO: 3168322825	E-MAIL: alonso.mora@kenkomed.com	
CIUDAD / MUNICIPIO: BOGOTÁ D.C.	DEPARTAMENTO: BOGOTÁ D.C.	PAÍS: COLOMBIA
NIT: 900.990.146-8		

2. REPRESENTANTE LEGAL O PROPIETARIO

NOMBRE: ALONSO MORA PLAZAS		
DIRECCIÓN: CARRERA 13 No 63-39 OFICINA 904		
TELÉFONO: 3168322825	E-MAIL: alonso.mora@kenkomed.com	
CIUDAD / MUNICIPIO: BOGOTÁ D.C.	DEPARTAMENTO: BOGOTÁ D.C.	PAÍS: COLOMBIA

3. DIRECCIÓN TÉCNICA

NOMBRE Y APELLIDOS: LUIS FERNEL GUILLÉN RUIZ
IDENTIFICACIÓN: C.C. No. 80.208.322 DE BOGOTÁ D.C.

4. ESTABLECIMIENTO DONDE SE ALMACENAN LOS PRODUCTOS

NOMBRE: BIKAR S.A.S- EN REORGANIZACION		
DIRECCIÓN: CARRERA 106 NO. 15A-25 MANZANA 12, LOTE 74 BODEGA 4 PISO 2		
CIUDAD / MUNICIPIO: BOGOTÁ D.C.	DEPARTAMENTO: BOGOTÁ D.C.	PAÍS: COLOMBIA

5. ACTIVIDAD AUTORIZADA

DISPOSITIVOS MÉDICOS, EQUIPOS BIOMÉDICOS DE TECNOLOGÍA NO CONTROLADA Y EQUIPOS BIOMÉDICOS DE TECNOLOGÍA CONTROLADA A CONDICIONES DE TEMPERATURA AMBIENTE *****
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CERTIFICADO NO. CADM3722	FECHA: BOGOTÁ D.C. 25 DE FEBRERO DE 2022
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Certificación vigente hasta el día 13 de FEBRERO de 2027.

Esta certificación de CCAA será válida siempre y cuando el establecimiento mantenga las condiciones higiénicas, técnicas, locativas y de control de calidad con las cuales se emitió el concepto técnico CUMPLE y estará sujeto a la vigilancia y control del Invima.



LUCIA AYALA RODRÍGUEZ
Director (a) Técnico (a) de Dispositivos Médicos
y Otras Tecnologías

Proyectó: 5200-07 ACMT / 5200-18 MGH C.C. Exp.: DC-3062	Revisó: 5200-04 MEOP	Aprobó: 5200-02 PAGG
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RADICACIÓN No 20181238651 FECHA 21/11/2019

El (LA) SUSCRITO (A) DIRECTOR (A) TÉCNICO (A) DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS DEL INVIMA CERTIFICA QUE EL ESTABLECIMIENTO RELACIONADO A CONTINUACIÓN REÚNE LAS CONDICIONES HIGIÉNICAS, TÉCNICAS, LOCATIVAS Y DE CONTROL DE CALIDAD, DE ACUERDO CON LA LEGISLACIÓN VIGENTE. VISITA INICIAL: 13 DE MAYO DE 2016 Y FECHA DE ÚLTIMA VISITA: 12 DE ABRIL 2019.

1. ESTABLECIMIENTO FABRICANTE

NOMBRE: ZUMO TECNOLOGÍA ZUMOTEC S.A		
DIRECCIÓN: CALLE 6 No. 13 - 65 BODEGA 1 y 2		
TELÉFONO: 6717887	E-MAIL: gerencia@zumotec.com	
CIUDAD / MUNICIPIO: BUCARAMANGA	DEPARTAMENTO: SANTANDER	PAÍS: COLOMBIA
NIT: 804.009.960-3		

2. REPRESENTANTE LEGAL O PROPIETARIO

NOMBRE: JOSÉ GABRIEL LÓPEZ ORTIZ		
DIRECCIÓN: CALLE 6 No. 13 - 65 BODEGA 1 y 2		
TELÉFONO: 6717887	E-MAIL: gerencia@zumotec.com	
CIUDAD / MUNICIPIO: BUCARAMANGA	DEPARTAMENTO: SANTANDER	PAÍS: COLOMBIA

3. DIRECCIÓN TÉCNICA

NOMBRE Y APELLIDOS: JULIAN MAURICIO GUERRERO RODRÍGUEZ		
IDENTIFICACIÓN: C.C.1.098.715.130 DE BUCARAMANGA		

4. LUGAR DONDE SE FABRICAN LOS PRODUCTOS

DIRECCIÓN: CALLE 6 No. 13 - 65 BODEGA 1 y 2		
CIUDAD / MUNICIPIO: BUCARAMANGA	DEPARTAMENTO: SANTANDER	PAÍS: COLOMBIA

5. PRODUCTOS AUTORIZADOS

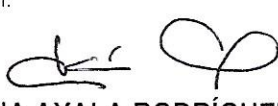
FABRICACIÓN, EMPAQUE, ALMACENAMIENTO Y ACONDICIONAMIENTO DE DISPOSITIVOS MÉDICOS: DESINFECTANTES PARA DISPOSITIVOS MÉDICOS Y EQUIPOS BIOMÉDICOS EN FORMA LÍQUIDA, GELES Y ESPUMAS, GEL LUBRICANTE ÍNTIMO Y GEL CONDUCTOR A CONDICIONES DE TEMPERATURA AMBIENTE. *****		
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CERTIFICADO No. 0212 – FECHA: BOGOTÁ D.C 12 DE ABRIL DE 2019

Este certificado de concepto técnico de condiciones sanitarias se otorga en cumplimiento a lo ordenado en el artículo 12 del Decreto 4725 de 2005, a los establecimientos fabricantes de dispositivos médicos, mientras cumplan con las Buenas Prácticas de Manufactura que expida el Ministerio Salud y Protección Social.

Esta certificación tendrá validez siempre y cuando el establecimiento mantenga las condiciones higiénicas, técnicas, locativas y de control de calidad con las que se emitió el concepto técnico REUNE para su expedición; de no mantenerse esas condiciones, se entenderá que esta certificación perderá sus efectos jurídicos y la persona natural y/o jurídica que en su favor se haya otorgado el certificado de concepto técnico de condiciones sanitarias, no podrá hacer uso del presente documento.

Con el fin de verificar lo anterior y en ejercicio de su función de inspección, vigilancia y control, el **Invima** visitará periódicamente a estos laboratorios y/o establecimientos, si comprueba que no cumple con las condiciones técnicas y sanitarias que sustentaron la expedición del certificado procederá a aplicar las medidas sanitarias de seguridad, sin perjuicio de las sanciones a que haya lugar (Artículo 68 del Decreto 4725 de 2005). Todos los folios de éste documento llevan sello del **Invima**. Documento válido únicamente en su original.


LUCIA AYALA RODRÍGUEZ

Director (a) Técnico (a) de Dispositivos Médicos
y Otras Tecnologías

Proyectó: 5200-08 CLRG C.C. Exp.: S-0045	Revisó: 5200-04 MEOR	Aprobó: 5200-01 SIPRC
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