





Product Service

Certificate

No. Q8 077174 0006 Rev. 03

Holder of Certificate: Fresenius Medical Care AG

Else-Kröner-Str. 1 61352 Bad Homburg GERMANY

Certification Mark:



Scope of Certificate: The Provision of Distribution (Marketing

and Sales (incl. Wholesale)), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis

Therapies

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q8 077174 0006 Rev. 03

Report No.: 713315153

 Valid from:
 2023-12-01

 Valid until:
 2025-03-31

Date, 2023-12-01

Christoph Dicks

Head of Certification/Notified Body





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Applied Standard(s): ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): Fresenius Medical Care Austria GmbH

Lundenburgergasse 5, 1210 Wien, AUSTRIA

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for

Dialysis and Apheresis Therapies

Fresenius Medical Care Belgium N.V.

Brownfieldlaan 15, 2830 Willebroek, BELGIUM

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care Bulgaria EOOD

26 Lyuben Karavelov, Floor 4, 5308 Gabrovo, BULGARIA

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care - CR, s.r.o.

Evropská 423/178, 160 00 Praha 6, CZECH REPUBLIC

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care Danmark A/S

Oldenburg Allé 1, 2630 Taastrup, DENMARK

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care Suomi Oy

Valimotie 13 b B, 00380 Helsinki, FINLAND

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies



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Facility(ies):

Fresenius Medical Care France S.A.S.

Parc Medicis, 47 avenue des Pépinières, 94832 Fresnes Cedex, FRANCE

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care GmbH

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The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care Magyarország Egészségügyi Kft.

Árpád fejedelem útja 26-28, 1023 Budapest, HUNGARY

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care Italia S.p.A.

Via Crema 8, 26020 Palazzo Pignano (CR), ITALY

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care Polska S.A.

Krzywa 13, 60118 Poznan, POLAND

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care Portugal, S.A.

Rua Comandante Joaquim Moreira, 268 & 310, 4470-573 Moreira, Maia, PORTUGAL

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies







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Facility(ies):

Fresenius Medical Care Slovenija d.o.o.

Gaji 28, 3000 Celje, SLOVENIA

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care Romania S.R.L.

Sos. Bucuresti-Ploiesti Nr. 19-21, 013682 Bucuresti, ROMANIA

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care Srbija d.o.o. Vršac

Omladinskih brigada 90d, 11070 Novi Beograd, SERBIA

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care Slovensko spol. s r.o.

Teplická 99, 921 01 Piešťany, SLOVAKIA

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care España S.A.U.

Ronda de Poniente 8, Planta Baja, 28760 Tres Cantos - Madrid, SPAIN

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care (Schweiz) AG

Aawasserstrasse 2, 6370 Oberdorf NW, SWITZERLAND

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies



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Facility(ies):

Fresenius Medical Care Nederland B.V.

Reitscheweg 5, 5232 BX `s-Hertogenbosch, THE NETHERLANDS

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Ecza Deposu A.S.

Rüzgarlibahçe Mah. Cumhuriyet Cad., Hasoglu Plaza no: 39 Kat: 7, 34805 Kavacik Istanbul, TÜRKIYE

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medikal Hizmetler A.S.

Rüzgarlibahçe Mah. Cumhuriyet Cad., Hasoglu Plaza no: 39, Kat: 7, 34805 Kavacik Istanbul, TÜRKIYE

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care (UK) Ltd.

Nunn Brook Road, Huthwaite, Sutton-in-Ashfield, Nottinghamshire NG17 2HU, UNITED KINGDOM

The Provision of Distribution (Marketing and Sales), Warehousing, Installation and Maintenance Servicing for Medical Devices for Dialysis and Apheresis Therapies

Fresenius Medical Care Hrvatska d.o.o.

Savska Opatovina 36, 10000 Zagreb, CROATIA

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Parameters: -/-