

CERTIFICATE

No. Q1N 16 03 24492 01958



Product Service

Holder of Certificate: **Fresenius Medical Care AG & Co. KGaA**
61346 Bad Homburg
GERMANY

Certification Mark:



Scope of Certificate: **Design, Development and Production
of Medical Devices and in-vitro-Diagnostics
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). See also notes overleaf.

Report No.: 713077579

Valid from: 2016-04-11

Valid until: 2019-04-10



Date, 2016-04-07

Stefan Preiß

Page 1 of 2





Product Service

CERTIFICATE**No. Q1N 16 03 24492 01958****Applied
Standard(s):**

EN ISO 13485:2012 + AC:2012
 Medical devices - Quality management systems –
 Requirements for regulatory purposes
 (ISO 13485:2003 + Cor. 1:2009)
 DIN EN ISO 13485:2012

Facility(ies):

Fresenius Medical Care Deutschland GmbH
 St. Wendel Plant
 Frankfurter Straße 6 - 8
66606 St. Wendel, GERMANY

Fresenius Medical Care Deutschland GmbH
 Schweinfurt Plant
 Hafenstraße 9
97424 Schweinfurt, GERMANY

Fresenius Medical Care Deutschland GmbH
 Ober-Erlenbach Plant
 Steinmühlstraße 24
61352 Bad Homburg / Ober-Erlenbach, GERMANY

Fresenius Medical Care - SMAD
 Z.I. de la Pontchonnière
 Route de la Chanade / Savigny
69591 L'Arbresle Cedex, FRANCE

Fresenius Medical Care UK Ltd.
 Nunn Brook Road, Huthwaite
 Sutton-in-Ashfield
Nottinghamshire NG17 2HU, UNITED KINGDOM

SIS-TER S.p.A.
 Via Crema 8
26020 Palazzo Pignano (CR), ITALY

Fresenius Medical Care Espana S.A.
 Ctra. Vallderiof km 0,4
08430 La Roca del Vallès / Barcelona, SPAIN

Novamed GmbH
 Free Trade Zone
 P.O. Box 35
07070 Antalya, TURKEY

Fresenius Medical Care Srbija d.o.o.
 Beogradski put bb
26300 Vršac, SERBIA

Fresenius Medical Care Adsorber Tec GmbH
 Magnesitstraße 9
3500 Krems, AUSTRIA

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CERTIFICATE

No. Q4N 16 03 24492 01957



Product Service

Holder of Certificate: **Fresenius Medical Care AG & Co. KGaA**
61346 Bad Homburg
GERMANY

Certification Mark:

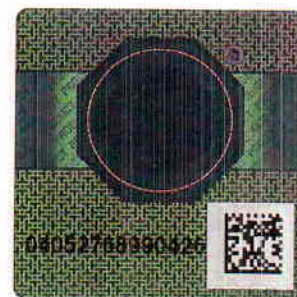


Scope of Certificate: **Marketing, Sales and Servicing of
Medical Devices and in-vitro Diagnostics
for Dialysis and Apheresis Therapies**

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). See also notes overleaf.

Report No.: 713077579

Valid from: 2016-04-11
Valid until: 2019-04-10



Date, 2016-04-07

Stefan Preiß

Page 1 of 3



CERTIFICATE**No. Q4N 16 03 24492 01957**

Product Service

**Applied
Standard(s):**

EN ISO 13485:2012 + AC:2012
 Medical devices - Quality management systems –
 Requirements for regulatory purposes
 (ISO 13485:2003 + Cor. 1:2009)
 DIN EN ISO 13485:2012

Facility(ies):

Fresenius Medical Care GmbH
 Else-Kröner-Straße 1
61352 Bad Homburg, GERMANY

Fresenius Medical Care UK Ltd.
 Nunn Brook Road, Huthwaite
 Sutton-in-Ashfield
Nottinghamshire NG17 2HU, UNITED KINGDOM

Fresenius Medical Care Nederland BV
 Mandenmaker 22
5253 RC Nieuwkuijk, THE NETHERLANDS

Fresenius Medical Care Belgium N.V.
 Brownfieldlaan 15
2830 Willebroek, BELGIUM

Fresenius Medical Care Portugal, SA
 Rua da Boaviagem, 35
 Lugar de Crestins – Moreira
4470-210 Maia, PORTUGAL

Fresenius Medical Care Magyarország Kft.
 Szépvölgyi út 35-37
1037 Budapest, HUNGARY

Fresenius Medical Care ČR, s.r.o.
 Evropská 423/178
160 00 Praha 6, CZECH REPUBLIC

Fresenius Medical Care Slovensko spol. s r.o.
 Teplická 99
92101 Piešťany, SLOVAK REPUBLIC

Fresenius Medical Care Slovenija d.o.o.
 Dobrovlje, Dobrava 14
3214 Zreče, REPUBLIC OF SLOVENIA

Fresenius Medical Care Bulgaria GmbH
 26 Ljuben Karavelov, Floor 4
5308 Gabrovo, BULGARIA

Fresenius Medical Care Polska S.A.
 Krzywa 13
60 118 Poznań, POLAND



Product Service

CERTIFICATE**No. Q4N 16 03 24492 01957****Facility(ies):**

Fresenius Medical Care Romania S.R.L.
 Sos. Bucuresti-Ploiesti Nr. 19-21
 Fabian Business Center, sector 1
013682 Bucuresti, ROMANIA

Fresenius Medical Care France S.A.S.
 Parc Medicis
 47, avenue des Pépinières
94832 Fresnes Cedex, FRANCE

Fresenius Medical Care España S.A.
 Ronda de Poniente 8, Planta Baja
 Parque empresarial Euronova Tres Cantos
Madrid 28760, SPAIN

Fresenius Medical Care Suomi Oy
 Valimotie 13 b B
00380 Helsinki, FINLAND

Fresenius Medical Care Italia S.p.A.
 Via Crema 8
26020 Palazzo Pignano (CR), ITALY

Fresenius Medical Care DK A/S
 Oldenburg Allé 1
2630 Taastrup, DENMARK

Fresenius Medical Care (Schweiz) AG
 Aawasserstrasse 2
6370 Oberdorf NW, SWITZERLAND

Fresenius Medical Care Austria GmbH
 Lundenburger Gasse 5
1210 Wien, AUSTRIA

Fresenius Medical Srbija d.o.o.
 Jurija Gagarina 11 - 11a
11000 Beograd, SERBIA

Fresenius Medikal Hizmetler A.Ş.
 Rüzgarlıbahçe Mah. Cumhuriyet Cad.
 Hasoğlu Plaza no: 39, Kat: 7
34805 Kavacık Istanbul, TURKEY

Fresenius Ecza Deposu A.Ş.
 Rüzgarlıbahçe Mah. Cumhuriyet Cad.
 Hasoğlu Plaza no: 39, Kat: 7
34805 Kavacık Istanbul, TURKEY

CERTIFICATE

No. Q4 16 04 24492 01960



Product Service

Holder of Certificate:

Fresenius Medical Care AG & Co. KGaA
61346 Bad Homburg, GERMANY

Organisational units:

Management Board, Research & Development,
Technical Department, Manufacturing Operations,
Supply Chain, Human Resources,
Marketing, Sales, QREM
(Quality, Regulatory Affairs & Management Systems)

Certification Mark:**Scope of Certificate:**

- Design, Development, Production,
Marketing, Sales and Servicing of Medical
Devices and in-vitro Diagnostics for
Dialysis and Apheresis Therapies
- Dialysis Services

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
EN ISO 9001:2008
EN ISO 14001:2004

The certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining an INTEGRATED MANAGEMENT SYSTEM which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

713077579

Valid from:

2016-04-11

Valid until:

2019-04-10

Date: 2016-04-07

S. Preiß
Stefan Preiß





Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH
certifies that

Fresenius Medical Care AG & Co. KGaA
Else-Kröner-Straße 1
61352 Bad Homburg
GERMANY

including the
sites and scope of application
see enclosure

has established and applies
a Quality Management System.

An audit was performed, Order No. **70095541**.
Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2019-01-18** until **2022-04-18**.

Certificate Registration No.: **12 100 24924 TMS**.

H. Wegner

Product Compliance Management
Munich, 2019-01-21





Management Service

Enclosure of Certificate No.:

12 100 24924 TMS

Sites	Scope of application
Fresenius Medical Care AG & Co. KGaA Else-Kröner-Straße 1 61352 Bad Homburg, GERMANY	Management Board including Management of Research & Development and Manufacturing Operations; Human Resources and QREM (Quality, Regulatory Affairs & Management Systems)
Fresenius Ecza Deposu A.Ş. Rüzgarlıbahçe Mah. Cumhuriyet Cad. Hasoğlu Plaza no:39, Kat:7 34805 Kavacık Istanbul, TURKEY Fresenius Medical Care Srbija d.o.o. Jurija Gagarina 11-11a 11000 Beograd, SERBIA Fresenius Medical Care GmbH Else-Kröner-Straße 1 61352 Bad Homburg, GERMANY Fresenius Medical Care Slovensko spol. s.r.o. Teplická 99 92101 Piešťany, SLOVAK REPUBLIC Fresenius Medical Care France S.A.S. Parc Medicis 47, avenue des Pépinières 94832 Fresnes Cedex, FRANCE Fresenius Medical Care (UK) Ltd. Nunn Brook Road, Huthwaite Sutton-in-Ashfield Nottinghamshire NG 17 2HU, UNITED KINGDOM Fresenius Medical Care Nederland B.V. Mandenmaker 22 5253 RC Nieuwkuijk, THE NETHERLANDS Fresenius Medical Care Belgium N.V. Brownfieldlaan 15 2830 Willebroek, BELGIUM Fresenius Medical Care Portugal, SA Rua da Boaviagem, 35 Lugar de Crestins - Moreira, 4470-210 Maia, PORTUGAL Fresenius Medical Care Magyarország Egészségügyi Kft. 1037 Budapest, Szépvölgyi út 35-37, HUNGARY	Marketing, Sales and Servicing of Medical Devices for Dialysis and Apheresis Therapies

M. Wegner

Product Compliance Management
 Munich, 2019-01-21



CERTIFICAT

CERTIFICADO

CERTИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Management Service

Enclosure of Certificate No.:

12 100 24924 TMS

Sites	Scope of application
Fresenius Medical Care - ČR, s.r.o. Evropská 423/178 160 00 Praha 6, CZECH REPUBLIC Fresenius Medical Care Slovenija d.o.o. Gaji 28 3000 Celje, REPUBLIC OF SLOVENIA Fresenius Medical Care Polska Sp. zo.o. Krzywa 13 60-118 Poznań, POLAND Fresenius Medical Care DK A/S Oldenburg Allé 1 2630 Taastrup, DENMARK Fresenius Medical Care Suomi Oy Valimotie 13 b B 00380 Helsinki, FINLAND Fresenius Medical Care (Schweiz) AG Aawasserstrasse 2 6370 Oberdorf NW, SWITZERLAND Fresenius Medical Care Austria GmbH Lundenburger Gasse 5 1210 Wien, AUSTRIA Fresenius Medical Care Italia S.p.A. Via Crema, 8 26020 Palazzo Pignano (CR), ITALY Fresenius Medical Care Romania S.R.L. Sos. București-Ploiesti Nr. 19-21, 013682 București, ROMANIA Fresenius Medikal Hizmetler A.Ş. Rüzgarlıbahçe Mah. Cumhuriyet Cad. Hasoğlu Plaza no:39, Kat:7 34805 Kavacık Istanbul, TURKEY FRESENIUS MEDICAL CARE ESPAÑA, S.A. RDA. PONIENTE, 8 PTA BAJA 28760 TRES CANTOS, SPAIN Fresenius Medical Care Bulgaria GmbH 26 Ljuben Karavelov, Floor 4 5308 Gabrovo, BULGARIA	Marketing, Sales and Servicing of Medical Devices for Dialysis and Apheresis Therapies

Product Compliance Management
Munich, 2019-01-21




Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 05 24492 02028

Manufacturer:

Fresenius Medical Care AG & Co. KGaA

61346 Bad Homburg

GERMANY



Product Category(ies):

- Dialysers and Filters for haemodialysis
- Adsorber for therapeutic apheresis
- Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies
- Catheters and Accessories for haemodialysis and peritoneal dialysis
- Fistula needles
- Syringes
- Cleaning and disinfectant agents
- Concentrates and solutions for haemodialysis
- Dialysis fluid supply equipment
- Active medical devices for extracorporeal blood treatment and peritoneal dialysis

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713083654

Valid from:

2016-06-17

Valid until:

2021-06-16



Date, 2016-06-09

S. Preiß

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 05 24492 02028

Facility(ies):

Fresenius Medical Care Deutschland GmbH
St. Wendel Plant
Frankfurter Straße 6 – 8
66606 St. Wendel, GERMANY

Fresenius Medical Care Deutschland GmbH
Schweinfurt Plant
Hafenstraße 9
97424 Schweinfurt, GERMANY

Fresenius Medical Care Deutschland GmbH
Ober-Erlenbach Plant
Steinmühlstraße 24
61352 Bad Homburg / Ober-Erlenbach, GERMANY

Fresenius Medical Care - SMAD
Z.I. de la Pontchonnière
Route de la Chanade / Savigny
69591 L'Arbresle Cedex, FRANCE

Fresenius Medical Care UK Ltd.
Nunn Brook Road, Huthwaite
Sutton-in-Ashfield
Nottinghamshire NG 17 2HU, UNITED KINGDOM

SIS-TER S.p.A.
Via Crema 8
26020 Palazzo Pignano (CR), ITALY

Fresenius Medical Care Espana S.A.
Ctra. Vallderiof km 0,4
08430 La Roca del Vallès / Barcelona, SPAIN

Novamed GmbH
Free Trade Zone
P.O. Box 35
07070 Antalya, TURKEY

Fresenius Medical Care Srbija d.o.o.
Beogradski put bb
26300 Vršac, SERBIA

Fresenius Medical Care Adsorber Tec GmbH
Magnesitstraße 9
3500 Krems, AUSTRIA



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 16 05 24492 02443

Manufacturer:

Fresenius Medical Care AG & Co. KGaA

61346 Bad Homburg

GERMANY



Product Category(ies):

- Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies
- Rinsing solutions

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

713083654

Valid from:

2016-06-17

Valid until:

2021-06-16



Date, 2016-06-09

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in Class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 16 05 24492 02443

Facility(ies):

Fresenius Medical Care Deutschland GmbH
St. Wendel Plant
Frankfurter Straße 6 – 8
66606 St. Wendel, GERMANY

SIS-TER S.p.A.
Via Crema 8
26020 Palazzo Pignano (CR), ITALY



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH
certifies that

Fresenius Medical Care AG & Co. KGaA
Else-Kröner-Straße 1
61352 Bad Homburg
GERMANY

has established and applies
a Quality Management System for

Top Management Responsibility
for Design and Production of Medical Devices
for Dialysis and Apheresis Therapies.

An audit was performed, Report No. **70088628**.
Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid in conjunction
with the main certificate from **2018-09-15** until **2022-04-10**.

Certificate Registration No.: **12 100 25789/01 TMS**.

M. Wegmann

Product Compliance Management
Munich, 2018-09-21





Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH
certifies that

Fresenius Medical Care AG & Co. KGaA
Else-Kröner-Straße 1
61352 Bad Homburg
GERMANY

including the
sites and scope of application
see enclosure

has established and applies
a Quality Management System.

An audit was performed, Report No. **70088628**.

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2018-09-15** until **2022-04-10**.

Certificate Registration No.: **12 100 25789 TMS**.

M. Wegner

Product Compliance Management
Munich, 2018-09-21





Management Service

**Enclosure of Certificate Registration No.:
12 100 25789 TMS**

Sites	Scope of application
Fresenius Medical Care AG & Co. KGaA Else-Kröner-Straße 1 61352 Bad Homburg GERMANY	Top Management Responsibility for Design and Production of Medical Devices for Dialysis and Apheresis Therapies
Fresenius Medical Care Deutschland GmbH Ober-Erlenbach Plant Steinmühlstraße 24 61352 Bad Homburg / Ober-Erlenbach GERMANY	Production of Concentrates and Disinfectants for Hemodialysis, Assembling of Procedure Packs for Dialysis and Apheresis Therapies
Fresenius Medical Care Deutschland GmbH Schweinfurt Plant Hafenstraße 9 97424 Schweinfurt GERMANY	Design and Production of Machines and related Treatment Modules for Hemodialysis, Peritoneal Dialysis and Apheresis, Monitoring Devices and related Disposables, Medical Software
Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Straße 6 - 8 66606 St. Wendel GERMANY	Design and Production of Hemodialyzers, Hemofilters, Dialysate Filters, Bloodlines, Tubing Systems and related Disposables for Hemodialysis and Peritoneal Dialysis, Sterile Solutions
Vivonic GmbH Kurfürst-Eppstein-Ring 4 63877 Sailauf GERMANY	Design and Production of Water Treatment and Central Delivery Systems
Fresenius Medical Care Adsorber Tec GmbH Magnesitstraße 9 3500 Krems AUSTRIA	Design and Production of Adsorber, related Solutions and Disposables for Apheresis Therapies

M. Wegmann

Product Compliance Management
Munich, 2018-09-21





Management Service

**Enclosure of Certificate Registration No.:
12 100 25789 TMS**

Sites	Scope of application
SIS-TER S.p.A. Via Crema 8 26020 Palazzo Pignano, Cremona ITALY	Design and Production of Bloodlines, Tubing Systems and related Disposables for Hemodialysis, Peritoneal Dialysis and Apheresis
Fresenius Medical Care - SMAD Z.I. de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex FRANCE	Design and Production of Concentrates for Hemodialysis, Production of Hemodialyzers and related Disposables
Fresenius Medical Care España, S.A. Ctra. Vallderiof km 0,4, La Roca del Vallès 08430 Barcelona SPAIN	Production of Concentrates for Hemodialysis
Fresenius Medical Care Srbija d.o.o. Beogradski put bb 26300 Vršac SERBIA	Production of Hemodialyzers, Dialysate Filters, Bloodlines, Tubing Systems and related Disposables for Hemodialysis and Peritoneal Dialysis, Concentrates for Hemodialysis
Fresenius Medical Care (UK) Ltd. Nunn Brook Road, Huthwaite Sutton-in-Ashfield NG 17 2HU Nottinghamshire UNITED KINGDOM	Production of Concentrates and Disinfectants for Hemodialysis
Nova Med GmbH Serbest Bölgesi Merkez Şubesi 07070 Antalya TURKEY	Production of Bloodlines, Tubing Systems and related Disposables for Hemodialysis

M. Wegner

Product Compliance Management
Munich, 2018-09-21



Deutsche
Akkreditierungsstelle
D-ZM-14143-01-00