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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 024492 2490 Rev. 00

Facility(ies):

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


i.V. Oleksandr Zaika



Product Service

TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 Munich · Germany

To whom it may concern

Add value.
Inspire trust.

Munich, 2021-01-18
Order No.: 713200947

Confirmation concerning Certificate G1 024492 2490 Rev. 00 and associated manufacturers

We confirm the following certificate:

G1 024492 2490 Rev. 00 (valid until 2024-05-26)

issued to the legal medical device manufacturer:

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

and

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

Further we confirm the following Annex, List of Production Sites per EC Certificate G1 024492 2490 Rev. 00 Version 2 dated 2020-12-16, pages 2 to 9 of this letter.



i.A. Randolph Köhler
TÜV SÜD PRODUCT SERVICE GMBH
Medical Health Services
Foreign Affairs



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List of Production Sites:

Fresenius Medical Care AG & Co. KGaA

and

FME critical Suppliers [acc. MDD 93/42/EEC]

Production Sites per EC Certificate G1 024492 2490 Rev. 00

Version 2 / 2020-16-12

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Explanation:



Product category / Risk classes according Annex IX MDD



FME Production Site / Quality Control belonging to FMC AG & Co. KGaA



OEM with Annex according to MDD / EN ISO 13485



Outsourced manufacturing process

1. Dialysers and Filters

Product category		Risk Class
01 / 01 Hemodialyser / Hemofilter		IIb
Companies / Production Site(s)	Responsible Quality Controls	
Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Straße 6 - 8 66606 St. Wendel GERMANY	Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Straße 6 - 8 66606 St. Wendel GERMANY	
Fresenius Medical Care SMAD Z.I. de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex FRANCE	Fresenius Medical Care SMAD Z.I. de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex FRANCE	
Fresenius Medical Care Japan K.K. Buzen Plant 92-7 Ohaza Kaimo Buzen City, Fukuoka Pref. 828-0045 / JAPAN	Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Straße 6 - 8 66606 St. Wendel / GERMANY	
Fresenius Medical Care (Jiangsu) Co. Ltd. Guli Industry Park, Guli Zhen Changshu City Jiangsu Province CHINA		

Product category		Risk Class
01 / 02 Plasmapheresefilter		IIb
Companies / Production Site(s)	Responsible Quality Controls	
Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Straße 6 - 8 66606 St. Wendel GERMANY	Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Straße 6 - 8 66606 St. Wendel GERMANY	

Product category		Risk Class
01 / 03 Fluidfilter		IIa
Companies / Production Site(s)	Responsible Quality Controls	
Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Straße 6 - 8 66606 St. Wendel GERMANY	Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Straße 6 - 8 66606 St. Wendel GERMANY	
Fresenius Medical Care SMAD Z.I. de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex FRANCE	Fresenius Medical Care SMAD Z.I. de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex FRANCE	

2. Adsorber

Product category		Risk Class
02 / 01 Adsorber for therapeutic apheresis		IIb
Companies / Production Site(s)	Responsible Quality Controls	
Fresenius Medical Care Adsorber Tec GmbH Magnesitstraße 9 3500 Krems AUSTRIA	Fresenius Medical Care Adsorber Tec GmbH Magnesitstraße 9 3500 Krems AUSTRIA	

3. Tubing Systems

Product category		Risk Class
03 / 01 HD-Bloodlines 03 / 02 AT-Bloodlines 03 / 03 HD-Tubing systems 03 / 06 AT-Tubing systems		Ila
Companies / Production Site(s)	Responsible Quality Controls	
SIS-TER S.p.A. Via Crema 8 26020 Palazzo Pignano ITALY	SIS-TER S.p.A. Via Crema 8 26020 Palazzo Pignano ITALY	
Nova Med GmbH Antalya Serbest Bölgesi Merkez Şubesi No: 16, Liman Serbest Bölgesi Mahallesi 07070 Antalya TURKEY	Nova Med GmbH Antalya Serbest Bölgesi Merkez Şubesi No: 16, Liman Serbest Bölgesi Mahallesi 07070 Antalya TURKEY	
Fresenius Medical Care Srbija d.o.o. Vršac Beogradski put bb 26300 Vršac SERBIA	Fresenius Medical Care Srbija d.o.o. Vršac Beogradski put bb 26300 Vršac SERBIA	
Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Str. 6-8 66606 St. Wendel GERMANY	Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Str. 6-8 66606 St. Wendel GERMANY	
Rontis Dooel Veles Dolno Orizari BB 1400 Veles REPUBLIC OF NORTH MACEDONIA	SIS-TER S.p.A. Via Crema 8 26020 Palazzo Pignano (CR) ITALY	
F.M. S.p.A. Via Farini 65 bis 13043 Cigliano (VC) ITALY		
Bioiks d.o.o. Stegne 11 Ljubljana 1000 SLOVENIA		
Fresenius Medical Care (Jiangsu) Co. Ltd. Guli Industry Park, Guli Zhen Changshu City Jiangsu Province CHINA		

4. Accessories

<u>Product category</u>		<u>Risk Class</u>
04 / 01 HD-Accessories		Ila
<u>Companies / Production Site(s)</u>	<u>Responsible Quality Controls</u>	
SIS-TER S.p.A. Via Crema 8 26020 Palazzo Pignano ITALY	SIS-TER S.p.A. Via Crema 8 26020 Palazzo Pignano ITALY	
Nova Med GmbH Antalya Serbest Bölgesi Merkez Şubesi No: 16, Liman Serbest Bölgesi Mahallesi 07070 Antalya TURKEY	Nova Med GmbH Antalya Serbest Bölgesi Merkez Şubesi No: 16, Liman Serbest Bölgesi Mahallesi 07070 Antalya TURKEY	
Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Str. 6-8 66606 St. Wendel GERMANY	Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Str. 6-8 66606 St. Wendel GERMANY	
Bioiks d.o.o. Stegne 11 Ljubljana 1000 SLOVENIA	SIS-TER S.p.A. Via Crema 8 26020 Palazzo Pignano ITALY	

<u>Product category</u>		<u>Risk Class</u>
04 / 02 PD-Accessories		IIb / Ila
<u>Companies / Production Site(s)</u>	<u>Responsible Quality Controls</u>	
SIS-TER S.p.A. Via Crema 8 26020 Palazzo Pignano ITALY	SIS-TER S.p.A. Via Crema 8 26020 Palazzo Pignano ITALY	
Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Str. 6-8 66606 St. Wendel GERMANY	Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Str. 6-8 66606 St. Wendel GERMANY	
Fresenius Medical Care Srbija d.o.o. Vršac Beogradski put bb 26300 Vršac SERBIA	Fresenius Medical Care Srbija d.o.o. Vršac Beogradski put bb 26300 Vršac SERBIA	
Kabomed for Medical Industries Company 10th of Ramadan city B4 No 174 EGYPT	SIS-TER S.p.A. Via Crema 8 26020 Palazzo Pignano ITALY	

5. Catheters

Product category		Risk Class
05 / 01 HD-Catheters and Accessories		Ila
Companies / Production Site(s)	Responsible FME Quality Controls	
Bionic Medizintechnik GmbH Max-Planck-Straße 21 61381 Friedrichsdorf GERMANY	Fresenius Medical Care Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg GERMANY	
Gambro Kathetertechnik Hechingen Linsenaecker 1 72379 Hechingen GERMANY		
HOLOPACK Verpackungstechnik GmbH Bahnhofstrasse 74429 Sulzbach-Laufen GERMANY Bahnhofstrasse 73453 Abtsmünd-Untergröningen GERMANY		

Product category		Risk Class
05 / 02 PD- Catheters		IIb
Companies / Production Site(s)	Responsible Quality Controls	
Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Str. 6-8 66606 St. Wendel GERMANY	Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Str. 6-8 66606 St. Wendel GERMANY	

6. Needles

Product category		Risk Class
06 / 01 Fistula needles		Ila
Companies / Production Site(s)	Responsible FME Quality Controls	
Bionic Medizintechnik GmbH Max-Planck-Straße 21 61381 Friedrichsdorf GERMANY	Fresenius Medical Care Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg GERMANY	
Nipro Corporation 3-9-3, Honjo-Nishi, Kita-ku Osaka 531-8510 JAPAN		
Bain Medical Equipment (Guangzhou) Co., Ltd. No.10, Junchen Road Eastern Area, Economic and Technological Development District Guangzhou 510760 P.R. CHINA		

7. Syringes

<u>Product category</u>		<u>Risk Class</u>
07 / 01 Heparin Syringes		Ila
<u>Companies / Production Site(s)</u>	<u>Responsible FME Quality Controls</u>	
Transcoject GmbH & Co. KG Rügenstraße 8 24539 Neumünster GERMANY	Fresenius Medical Care Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg GERMANY	

8. Solutions

<u>Product category</u>		<u>Risk Class</u>
08 / 03 Solutions for regional anticoagulation		IIb
<u>Companies / Production Site(s)</u>	<u>Responsible Quality Controls</u>	
Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Str. 6-8 66606 St. Wendel GERMANY	Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Str. 6-8 66606 St. Wendel GERMANY	

9. Cleaning and disinfectant agents

<u>Product category</u>		<u>Risk Class</u>
09 / 01 Disinfectants		Ila
<u>Companies / Production Site(s)</u>	<u>Responsible Quality Controls</u>	
Fresenius Medical Care (UK) Ltd. Nunn Brook Road, Huthwaite Sutton-in-Ashfield Nottinghamshire NG 17 2HU UNITED KINGDOM	Fresenius Medical Care (UK) Ltd. Nunn Brook Road, Huthwaite Sutton-in-Ashfield Nottinghamshire NG 17 2HU UNITED KINGDOM	
Fresenius Medical Care Deutschland GmbH Ober-Erlenbach Plant Steinmühlstr. 24 61352 Bad Homburg / Ober-Erlenbach GERMANY	Fresenius Medical Care Deutschland GmbH Ober-Erlenbach Plant Steinmühlstr. 24 61352 Bad Homburg / Ober-Erlenbach GERMANY	
Ecolab Deutschland GmbH Ecolab-Allee 1 40789 Monheim am Rhein GERMANY	Fresenius Medical Care Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg GERMANY	
Dr. Schumacher GmbH Am Roggenfeld 3 34323 Malsfeld GERMANY		
BIOXAL SA Route des Varennes 71100 Chalon sur Saône FRANCE		
Rühl AG & Co. chemische Fabrik KG Hugenottenstr. 105 61381 Friedrichsdorf GERMANY Quellenweg 5 61381 Friedrichsdorf GERMANY		

9. Cleaning and disinfectant agents

Product category		Risk Class
09 / 01 Disinfectants		Ila
Companies / Production Site(s)	Responsible Quality Controls	
Fresenius Kabi España, S.A.U. Doctor Ferran 12 08339 Vilassar de Dalt Barcelona SPAIN	Fresenius Medical Care Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg GERMANY	
Fresenius Medical Care Production Sdn Bhd Lot 34618, PT 29466 Techpark@enstek 71760 Bandar Enstek, Negeri Sembilan MALAYSIA	Fresenius Medical Care Deutschland GmbH Ober-Erlenbach Plant Steinmühlstr. 24 61352 Bad Homburg /Ober-Erlenbach GERMANY	

10. Dialysis fluids

Product category		Risk Class
10 / 01 HD-Concentrates		Ilb
Companies / Production Site(s)	Responsible Quality Controls	
Fresenius Medical Care SMAD Z.I. de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex FRANCE	Fresenius Medical Care SMAD Z.I. de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex FRANCE	
Fresenius Medical Care Deutschland GmbH Ober-Erlenbach Plant Steinmühlstr. 24 61352 Bad Homburg /Ober-Erlenbach GERMANY	Fresenius Medical Care Deutschland GmbH Ober-Erlenbach Plant Steinmühlstr. 24 61352 Bad Homburg /Ober-Erlenbach GERMANY	
Fresenius Medical Care (UK) Ltd. Nunn Brook Road, Huthwaite Sutton-in-Ashfield Nottinghamshire NG 17 2HU UNITED KINGDOM	Fresenius Medical Care (UK) Ltd. Nunn Brook Road, Huthwaite Sutton-in-Ashfield Nottinghamshire NG 17 2HU UNITED KINGDOM	
Fresenius Medical Care España S.A. Ctra. Vallderiof, km 0,4 08430 La Roca del Vallés, Barcelona SPAIN	Fresenius Medical Care España S.A. Ctra. Vallderiof, km 0,4 08430 La Roca del Vallés, Barcelona SPAIN	
VARIOPACK Kolberger Str. 13-15 63667 Nidda-Harb GERMANY	Fresenius Medical Care Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg GERMANY	

Product category		Risk Class
10 / 02 HD-Solutions		Ilb
Companies / Production Site(s)	Responsible Quality Controls	
Fresenius Medical Care Deutschland GmbH Frankfurter Straße 6 - 8 66606 St. Wendel GERMANY	Fresenius Medical Care Deutschland GmbH Frankfurter Straße 6 - 8 66606 St. Wendel GERMANY	

11. Dialysis fluid supply equipment

<u>Product category</u>		<u>Risk Class</u>
11 / 01 Water treatment equipment		IIb / IIa
11 / 02 Central delivery systems		
11 / 05 Fittings and tubes for water treatment systems		
<u>Companies / Production Site(s)</u>	<u>Responsible Quality Controls</u>	
Vivonic GmbH Kurfürst-Eppstein-Ring 4 63877 Sailauf GERMANY	Fresenius Medical Care Deutschland GmbH Schweinfurt Plant Hafenstraße 9 97424 Schweinfurt GERMANY	

12. Active medical devices for extracorporeal blood treatment and peritoneal dialysis

<u>Product category</u>		<u>Risk Class</u>
12 / 01 PD machines and accessories 12 / 02 HD machines and accessories 12 / 03 Acute dialysis machines and accessories 12 / 04 Machines for adsorption treatment and accessories 12 / 05 Monitoring devices 12 / 06 Multipurpose machines for apheresis therapies and acute dialysis		IIb / IIa
<u>Companies / Production Site(s)</u>	<u>Responsible Quality Controls</u>	
Fresenius Medical Care Deutschland GmbH Schweinfurt Plant Hafenstraße 9 97424 Schweinfurt GERMANY	Fresenius Medical Care Deutschland GmbH Schweinfurt Plant Hafenstraße 9 97424 Schweinfurt GERMANY	
Wild GmbH Wildstraße 4 9100 Völkemarkt AUSTRIA	Fresenius Medical Care Deutschland GmbH Schweinfurt Plant Hafenstraße 9 97424 Schweinfurt GERMANY	