

List of Production Sites:

Fresenius Medical Care AG & Co. KGaA

and





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

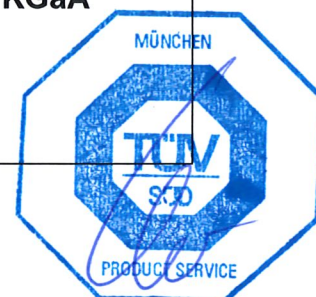
Production Sites per EC Certificate G1 024492 2490 Rev. 00

Revision 0 / 2020-01-22

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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

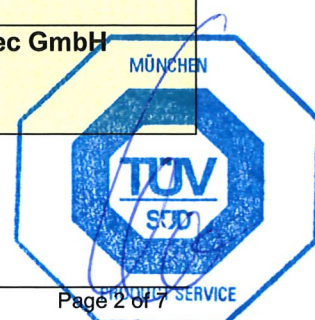
Product category		Risk Class
01 / 01 Hemodialyser / Hemofilter		IIb
Companies / Production Site(s)	Responsible Quality Controls	
Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Straße 6 - 8 66606 St. Wendel / GERMANY	Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Straße 6 - 8 66606 St. Wendel / GERMANY	
Fresenius Medical Care SMAD ZI de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex / FRANCE	Fresenius Medical Care SMAD ZI de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex / FRANCE	
Fresenius Medical Care Srbija d.o.o. Beogradski put bb 26300 Vršac / SERBIA	Fresenius Medical Care Srbija d.o.o. Beogradski put bb 26300 Vršac / SERBIA	
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 ZI de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex / FRANCE	Fresenius Medical Care SMAD ZI 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. Beogradski put bb 26300 Vršac / SERBIA	Fresenius Medical Care Srbija d.o.o. 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 Str. Dolno Orizari bb Veles / REPUBLIC OF 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

Product category		Risk Class
04 / 01 HD-Accessories		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 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	



4. Accessories

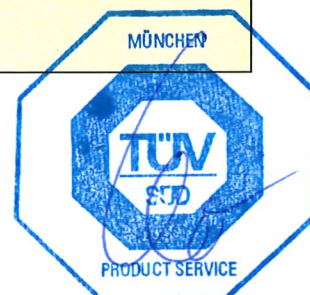
<u>Product category</u>		<u>Risk Class</u>
04 / 01 HD-Accessories		Ila
<u>Companies / Production Site(s)</u>	<u>Responsible FME Quality Controls</u>	
Bioiks d.o.o. Stegne 11 Ljubljana 1000 / SLOVENIA	SIS-TER S.p.A. Via Crema 8 26020 Palazzo Pignano / ITALY	

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

<u>Product category</u>		<u>Risk Class</u>
05 / 01 HD-Catheters and Accessories		Ila
<u>Companies / Production Site(s)</u>	<u>Responsible FME Quality Controls</u>	
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		

<u>Product category</u>		<u>Risk Class</u>
05 / 02 PD- Catheters		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	



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		

7. Syringes

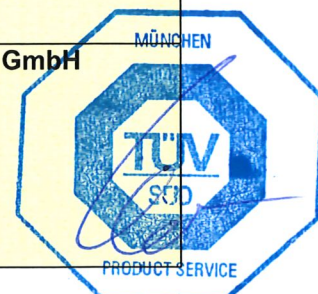
Product category		Risk Class
07 / 01 Heparin Syringes		Ila
Companies / Production Site(s)	Responsible FME Quality Controls	
Transcoject GmbH & Co. KG Rügenstraße 8 24539 Neumünster / GERMANY	Fresenius Medical Care Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg / GERMANY	

8. Solutions

Product category		Risk Class
08 / 03 Solutions for regional anticoagulation		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	

9. Cleaning and disinfectant agents

Product category		Risk Class
09 / 01 Disinfectants		Ila
Companies / Production Site(s)	Responsible Quality Controls	
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 2H 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		



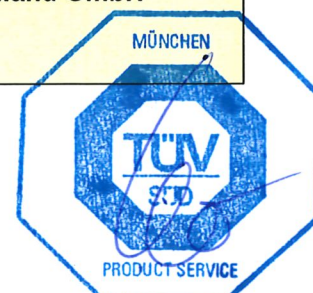
9. Cleaning and disinfectant agents

Product category		Risk Class
09 / 01 Disinfectants		Ila
BIOXAL SA Route des Varennes 71100 Chalon sur Saône / FRANCE	Fresenius Medical Care Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg GERMANY	
Rühl AG & Co. chemische Fabrik KG Hugenottenstr. 105 61381 Friedrichsdorf / GERMANY		
Fresenius KABI Espana, S.A. Dr. Ferran 12 08339 Vilassar de Dalt Barcelona / SPAIN		
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		IIb
Companies / Production Site(s)	Responsible Quality Controls	
Fresenius Medical Care SMAD ZI de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex / FRANCE	Fresenius Medical Care SMAD ZI 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. Valderiolf KM 0,4 08430 La Roca del Valles, Barcelona / SPAIN	Fresenius Medical Care España S.A. Ctra. Valderiolf KM 0,4 8430 oca del Valles, 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		IIb
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 11 / 02 Central delivery systems 11 / 05 Fittings and tubes for water treatment systems	IIb / IIa
<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

