

# List of Production Sites:

**Fresenius Medical Care AG & Co. KGaA**

**and**





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

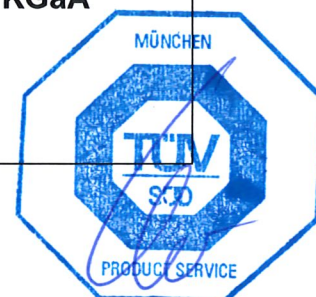
Production Sites per EC Certificate G1 024492 2490 Rev. 00

**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

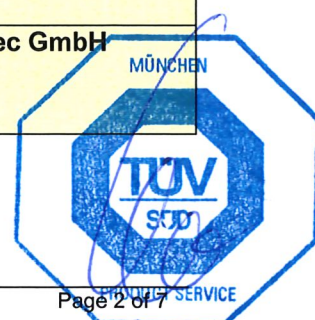
Product category		Risk Class
01 / 01 Hemodialyser / Hemofilter		IIb
Companies / Production Site(s)	Responsible Quality Controls	
Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter Straße 6 - 8 66606 St. Wendel / GERMANY	Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter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

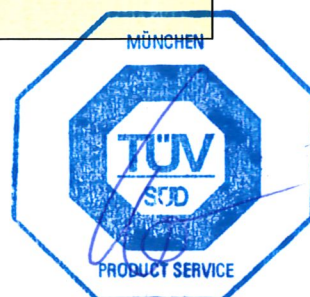


### 3. Tubing Systems

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

### 4. Accessories

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



## 4. Accessories

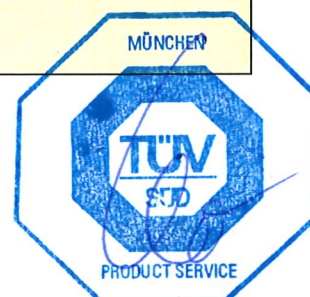
<u>Product category</u>		<u>Risk Class</u>
<b>04 / 01 HD-Accessories</b>		<b>Ila</b>
<u>Companies / Production Site(s)</u>	<u>Responsible FME Quality Controls</u>	
<b>Bioiks d.o.o.</b> Stegne 11 Ljubljana 1000 / SLOVENIA	<b>SIS-TER S.p.A.</b> Via Crema 8 26020 Palazzo Pignano / ITALY	

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

## 5. Catheters

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

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

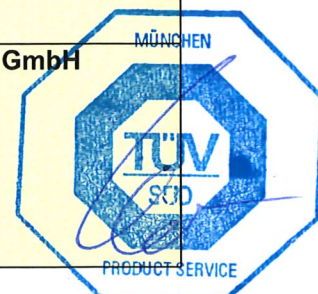
Product category		Risk Class
07 / 01 Heparin Syringes		Ila
Companies / Production Site(s)	Responsible FME Quality Controls	
Transcoject GmbH & Co. KG Rügenstraße 8 24539 Neumünster / GERMANY	Fresenius Medical Care Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg / GERMANY	

## 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		



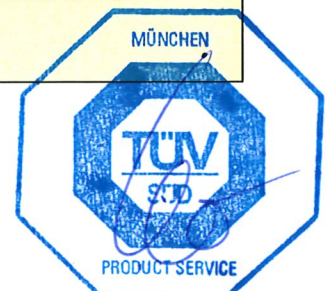
## 9. Cleaning and disinfectant agents

Product category		Risk Class
<b>09 / 01 Disinfectants</b>		<b>Ila</b>
<b>BIOXAL SA</b> Route des Varennes 71100 Chalon sur Saône / FRANCE	<b>Fresenius Medical Care Deutschland GmbH</b> Else-Kröner-Str. 1 61352 Bad Homburg GERMANY	
<b>Rühl AG &amp; Co. chemische Fabrik KG</b> Hugenottenstr. 105 61381 Friedrichsdorf / GERMANY		
<b>Fresenius KABI Espana, S.A.</b> Dr. Ferran 12 08339 Vilassar de Dalt Barcelona / SPAIN		
<b>Fresenius Medical Care</b> Production Sdn Bhd Lot 34618, PT 29466 Techpark@enstek 71760 Bandar Enstek, Negeri Sembilan MALAYSIA	<b>Fresenius Medical Care Deutschland GmbH</b> Ober-Erlenbach Plant Steinmühlstr. 24 61352 Bad Homburg /Ober-Erlenbach GERMANY	

## 10. Dialysis fluids

Product category		Risk Class
<b>10 / 01 HD-Concentrates</b>		<b>IIb</b>
<b>Companies / Production Site(s)</b>	<b>Responsible Quality Controls</b>	
<b>Fresenius Medical Care SMAD</b> ZI de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex / FRANCE	<b>Fresenius Medical Care SMAD</b> ZI de la Pontchonnière Route de la Chanade / Savigny 69591 L'Arbresle Cedex / FRANCE	
<b>Fresenius Medical Care Deutschland GmbH</b> Ober-Erlenbach Plant Steinmühlstr. 24 61352 Bad Homburg /Ober-Erlenbach GERMANY	<b>Fresenius Medical Care Deutschland GmbH</b> Ober-Erlenbach Plant Steinmühlstr. 24 61352 Bad Homburg /Ober-Erlenbach / GERMANY	
<b>Fresenius Medical Care UK Ltd.</b> Nunn Brook Road, Huthwaite Sutton-in-Ashfield Nottinghamshire NG 17 2HU UNITED KINGDOM	<b>Fresenius Medical Care UK Ltd.</b> Nunn Brook Road, Huthwaite Sutton-in-Ashfield Nottinghamshire NG 17 2HU UNITED KINGDOM	
<b>Fresenius Medical Care España S.A.</b> Ctra. Valderiolf KM 0,4 08430 La Roca del Valles, Barcelona / SPAIN	<b>Fresenius Medical Care España S.A.</b> Ctra. Valderiolf KM 0,4 8430 oca del Valles, Barcelona / SPAIN	
<b>VARIOPACK</b> Kolberger Str. 13-15 63667 Nidda-Harb / GERMANY	<b>Fresenius Medical Care Deutschland GmbH</b> Else-Kröner-Str. 1 61352 Bad Homburg / GERMANY	

Product category		Risk Class
<b>10 / 02 HD-Solutions</b>		<b>IIb</b>
<b>Fresenius Medical Care Deutschland GmbH</b> Frankfurter Straße 6 - 8 66606 St. Wendel / GERMANY	<b>Fresenius Medical Care Deutschland GmbH</b> Frankfurter Straße 6 - 8 66606 St. Wendel / GERMANY	



## 11. Dialysis fluid supply equipment

<u>Product category</u>	<u>Risk Class</u>
<b>11 / 01 Water treatment equipment</b> <b>11 / 02 Central delivery systems</b> <b>11 / 05 Fittings and tubes for water treatment systems</b>	<b>IIb / IIa</b>
<u>Companies / Production Site(s)</u>	<u>Responsible Quality Controls</u>
<b>Vivonic GmbH</b> Kurfürst-Eppstein-Ring 4 63877 Sailauf / GERMANY	<b>Fresenius Medical Care Deutschland GmbH</b> 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>
<b>12 / 01 PD machines and accessories</b> <b>12 / 02 HD machines and accessories</b> <b>12 / 03 Acute dialysis machines and accessories</b> <b>12 / 04 Machines for adsorption treatment and accessories</b> <b>12 / 05 Monitoring devices</b> <b>12 / 06 Multipurpose machines for apheresis therapies and acute dialysis</b>	<b>IIb / IIa</b>
<u>Companies / Production Site(s)</u>	<u>Responsible Quality Controls</u>
<b>Fresenius Medical Care Deutschland GmbH</b> Schweinfurt Plant Hafenstraße 9 97424 Schweinfurt / GERMANY	<b>Fresenius Medical Care Deutschland GmbH</b> Schweinfurt Plant Hafenstraße 9 97424 Schweinfurt / GERMANY
<b>Wild GmbH</b> Wildstraße 4 9100 Völkernmarkt / AUSTRIA	<b>Fresenius Medical Care Deutschland GmbH</b> Schweinfurt Plant Hafenstraße 9 97424 Schweinfurt / GERMANY

