

# List of Production Sites:

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

**and**





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

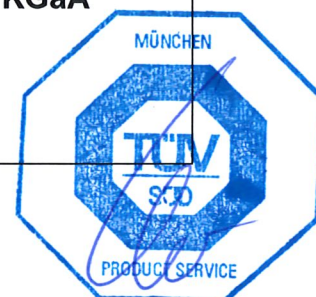
Production Sites per EC Certificate G1 024492 2490 Rev. 00

**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

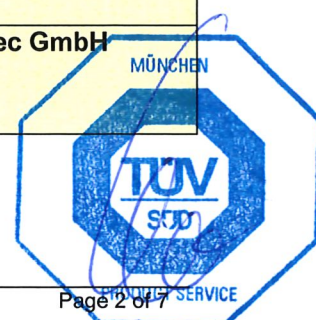
| Product category   |  | Risk Class |
|--|--|------------|
| 01 / 01 Hemodialyser / Hemofilter  |  | IIb        |
| Companies / Production Site(s)   | Responsible Quality Controls   |            |
| <b>Fresenius Medical Care Deutschland GmbH</b><br>St. Wendel Plant<br>Frankfurter Straße 6 - 8<br>66606 St. Wendel / GERMANY     | <b>Fresenius Medical Care Deutschland GmbH</b><br>St. Wendel Plant<br>Frankfurter Straße 6 - 8<br>66606 St. Wendel / GERMANY     |            |
| <b>Fresenius Medical Care SMAD</b><br>ZI de la Pontchonnière<br>Route de la Chanade / Savigny<br>69591 L'Arbresle Cedex / FRANCE | <b>Fresenius Medical Care SMAD</b><br>ZI de la Pontchonnière<br>Route de la Chanade / Savigny<br>69591 L'Arbresle Cedex / FRANCE |            |
| <b>Fresenius Medical Care Srbija d.o.o.</b><br>Beogradski put bb<br>26300 Vršac / SERBIA   | <b>Fresenius Medical Care Srbija d.o.o.</b><br>Beogradski put bb<br>26300 Vršac / SERBIA   |            |
| <b>Fresenius Medical Care Japan K.K.</b><br>Buzen Plant<br>92-7 Ohaza Kaimo<br>Buzen City, Fukuoka Pref.<br>828-0045 / JAPAN     | <b>Fresenius Medical Care Deutschland GmbH</b><br>St. Wendel Plant<br>Frankfurter Straße 6 - 8<br>66606 St. Wendel / GERMANY     |            |
| <b>Fresenius Medical Care (Jiangsu) Co. Ltd.</b><br>Guli Industry Park, Guli Zhen<br>Changshu City<br>Jiangsu Province / CHINA   |  |            |

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

| Product category   |  | Risk Class |
|--|--|------------|
| 01 / 03 Fluidfilter  |  | IIa        |
| Companies / Production Site(s)   | Responsible Quality Controls   |            |
| <b>Fresenius Medical Care Deutschland GmbH</b><br>St. Wendel Plant<br>Frankfurter Straße 6 - 8<br>66606 St. Wendel / GERMANY     | <b>Fresenius Medical Care Deutschland GmbH</b><br>St. Wendel Plant<br>Frankfurter Straße 6 - 8<br>66606 St. Wendel / GERMANY     |            |
| <b>Fresenius Medical Care SMAD</b><br>ZI de la Pontchonnière<br>Route de la Chanade / Savigny<br>69591 L'Arbresle Cedex / FRANCE | <b>Fresenius Medical Care SMAD</b><br>ZI de la Pontchonnière<br>Route de la Chanade / Savigny<br>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  |            |
| <b>Fresenius Medical Care Adsorber Tec GmbH</b><br>Magnesitstraße 9<br>3500 Krems / AUSTRIA | <b>Fresenius Medical Care Adsorber Tec GmbH</b><br>Magnesitstraße 9<br>3500 Krems / AUSTRIA |            |





### 3. Tubing Systems

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

### 4. Accessories

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





## 4. Accessories

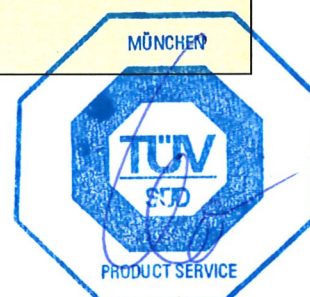
| <u>Product category</u>  |   | <u>Risk Class</u> |
|--|---|-------------------|
| <b>04 / 01 HD-Accessories</b>                                  |   | <b>Ila</b>        |
| <u>Companies / Production Site(s)</u>                          | <u>Responsible FME Quality Controls</u>                               |                   |
| <b>Bioiks d.o.o.</b><br>Stegne 11<br>Ljubljana 1000 / SLOVENIA | <b>SIS-TER S.p.A.</b><br>Via Crema 8<br>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><br>Via Crema 8<br>26020 Palazzo Pignano / ITALY  | <b>SIS-TER S.p.A.</b><br>Via Crema 8<br>26020 Palazzo Pignano / ITALY  |                   |
| <b>Fresenius Medical Care Deutschland GmbH</b><br>St. Wendel Plant<br>Frankfurter Str. 6-8<br>66606 St. Wendel / GERMANY | <b>Fresenius Medical Care Deutschland GmbH</b><br>St. Wendel Plant<br>Frankfurter Str. 6-8<br>66606 St. Wendel / GERMANY |                   |
| <b>Fresenius Medical Care Srbija d.o.o.</b><br>Beogradski put bb<br>26300 Vršac / SERBIA                                 | <b>Fresenius Medical Care Srbija d.o.o.</b><br>Beogradski put bb<br>26300 Vršac / SERBIA                                 |                   |
| <b>Kabomed for Medical Industries Company</b><br>10th of Ramadan city<br>B4 No 174 / EGYPT                               | <b>SIS-TER S.p.A.</b><br>Via Crema 8<br>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><br>Max-Planck-Strasse 21<br>61381 Friedrichsdorf / GERMANY  | <b>Fresenius Medical Care Deutschland GmbH</b><br>Else-Kröner-Str. 1<br>61352 Bad Homburg / GERMANY |                   |
| <b>Gambro Kathetertechnik Hechingen</b><br>Linsenaecker 1<br>72379 Hechingen / GERMANY  |   |                   |
| <b>HOLOPACK Verpackungstechnik GmbH</b><br>Bahnhofstrasse<br>74429 Sulzbach-Laufen / GERMANY<br><br>Bahnhofstrasse<br>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><br>St. Wendel Plant<br>Frankfurter Str. 6-8<br>66606 St. Wendel / GERMANY | <b>Fresenius Medical Care Deutschland GmbH</b><br>St. Wendel Plant<br>Frankfurter Str. 6-8<br>66606 St. Wendel / GERMANY |                   |





## 6. Needles

| <u>Product category</u>  |   | <u>Risk Class</u> |
|--|---|-------------------|
| <b>06 / 01 Fistula needles</b>   |   | <b>Ila</b>        |
| <u>Companies / Production Site(s)</u>  | <u>Responsible FME Quality Controls</u>   |                   |
| <b>Bionic Medizintechnik GmbH</b><br>Max-Planck-Strasse 21<br>61381 Friedrichsdorf / GERMANY | <b>Fresenius Medical Care Deutschland GmbH</b><br>Else-Kröner-Str. 1<br>61352 Bad Homburg / GERMANY |                   |
| <b>Nipro Corporation</b><br>3-9-3, Honjo-Nishi, Kita-ku<br>Osaka 531-8510 / JAPAN            |   |                   |

## 7. Syringes

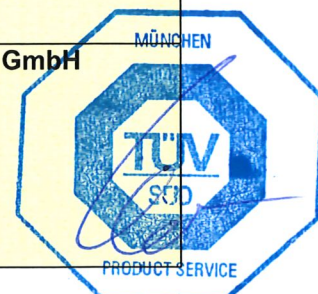
| <u>Product category</u>   |   | <u>Risk Class</u> |
|---|---|-------------------|
| <b>07 / 01 Heparin Syringes</b>   |   | <b>Ila</b>        |
| <u>Companies / Production Site(s)</u>   | <u>Responsible FME Quality Controls</u>   |                   |
| <b>Transcoject GmbH &amp; Co. KG</b><br>Rügenstraße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

## 8. Solutions

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

## 9. Cleaning and disinfectant agents

| <u>Product category</u>   |   | <u>Risk Class</u> |
|---|---|-------------------|
| <b>09 / 01 Disinfectants</b>  |   | <b>Ila</b>        |
| <u>Companies / Production Site(s)</u>   | <u>Responsible Quality Controls</u>   |                   |
| <b>Fresenius Medical Care UK Ltd.</b><br>Nunn Brook Road, Huthwaite<br>Sutton-in-Ashfield<br>Nottinghamshire NG 17 2HU<br>UNITED KINGDOM    | <b>Fresenius Medical Care (UK) Ltd.</b><br>Nunn Brook Road, Huthwaite<br>Sutton-in-Ashfield<br>Nottinghamshire NG 17 2H<br>UNITED KINGDOM   |                   |
| <b>Fresenius Medical Care Deutschland GmbH</b><br>Ober-Erlenbach Plant<br>Steinmühlstr. 24<br>61352 Bad Homburg / Ober-Erlenbach<br>GERMANY | <b>Fresenius Medical Care Deutschland GmbH</b><br>Ober-Erlenbach Plant<br>Steinmühlstr. 24<br>61352 Bad Homburg / Ober-Erlenbach<br>GERMANY |                   |
| <b>Ecolab Deutschland GmbH</b><br>Ecolab-Allee 1<br>40789 Monheim am Rhein / GERMANY  | <b>Fresenius Medical Care Deutschland GmbH</b><br>Else-Kröner-Str. 1<br>61352 Bad Homburg<br>GERMANY  |                   |
| <b>Dr. Schumacher GmbH</b><br>Am Roggenfeld 3<br>34323 Malsfeld / GERMANY   |   |                   |





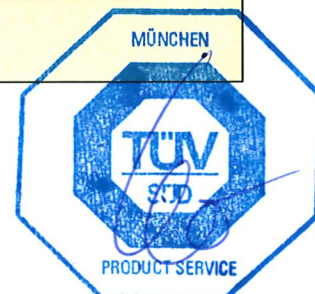
## 9. Cleaning and disinfectant agents

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

## 10. Dialysis fluids

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

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





## 11. Dialysis fluid supply equipment

| <u>Product category</u>  | <u>Risk Class</u>   |
|--|---|
| <b>11 / 01 Water treatment equipment</b><br><b>11 / 02 Central delivery systems</b><br><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><br>Kurfürst-Eppstein-Ring 4<br>63877 Sailauf / GERMANY   | <b>Fresenius Medical Care Deutschland GmbH</b><br>Schweinfurt Plant<br>Hafenstraße 9<br>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><br><b>12 / 02 HD machines and accessories</b><br><b>12 / 03 Acute dialysis machines and accessories</b><br><b>12 / 04 Machines for adsorption treatment and accessories</b><br><b>12 / 05 Monitoring devices</b><br><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><br>Schweinfurt Plant<br>Hafenstraße 9<br>97424 Schweinfurt / GERMANY  | <b>Fresenius Medical Care Deutschland GmbH</b><br>Schweinfurt Plant<br>Hafenstraße 9<br>97424 Schweinfurt / GERMANY |
| <b>Wild GmbH</b><br>Wildstraße 4<br>9100 Völkernmarkt / AUSTRIA  | <b>Fresenius Medical Care Deutschland GmbH</b><br>Schweinfurt Plant<br>Hafenstraße 9<br>97424 Schweinfurt / GERMANY |

