

## List of Production Sites:

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

**and**





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

Production Sites Per EC Certificate G2S 024492 2491 Rev. 00

**Revision 0 / 2019-11-29**

Content:	Page:
1. Tubing Systems.....	2
2. Accessories.....	2
3. Solutions .....	3

### Explanation:

-  Product category / Risk classes according Annex IX MDD
-  Production Site and Quality Control belonging to FME AG & Co. KGaA
-  OEM with Annex according to MDD / EN ISO 13485
-  Outsourced manufacturing process



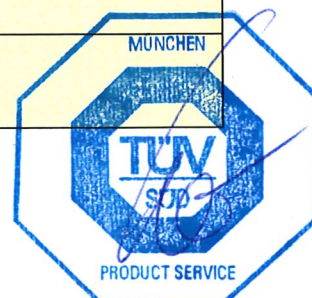
## 1. Tubing Systems

Product category		Risk Class
<b>1.1 HD-Tubing Systems</b>		<b>Is</b>
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	

## 2. Accessories

Product category		Risk Class
<b>2.1 HD-Accessories</b>		<b>Is</b>
Companies / Production Site(s)	Responsible FME 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>365 Healthcare</b> WR9 0LW Droitwich Spa/ Unit 1 West Bank, Berry Hill Industrial Estate, Droitwich, Worcestershire WR9 9AP UNITED KINGDOM	<b>Fresenius Medical Care Deutschland GmbH</b> Else-Kröner-Str. 1 61352 Bad Homburg / GERMANY	
<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	

Product category		Risk Class
<b>2.2 PD-Accessories</b>		<b>Is</b>
Companies / Production Site(s)	Responsible FME Quality Controls	
<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>Bioiks d.o.o.</b> Stegne 11 Ljubljana 1000 / SLOVENIA	<b>SIS-TER S.p.A.</b> Via Crema 8 26020 Palazzo Pignano / ITALY	
<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	





### 3. Solutions

Product category		Risk Class
3.1 HD Rinsing solutions		Is
3.2 AT Rinsing solutions		
Companies / Production Site(s)	Responsible FME 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	
Fresenius Medical Care Andina S.A. Km 1 Vía Sibería - Funza Intexzone Zona Franca lote 85 Bogotá, D.C. COLOMBIA	Fresenius Medical Care Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg / GERMANY	
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