

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

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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



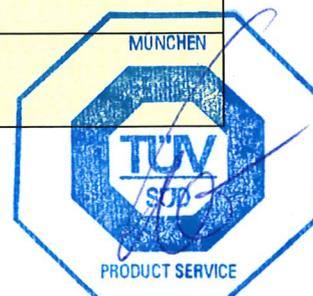
1. Tubing Systems

Product category		Risk Class
1.1 HD-Tubing Systems		Is
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	

2. Accessories

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

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



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	
Fresenius Kabi France S.A.S. 6, Rue du Rempart, BP 611 27406 Louviers / FRANCE	Fresenius Medical Care Adsorber Tec GmbH Magnesitstrasse 9 3500 Krems / AUSTRIA	

