ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 05 24492 02028

Manufacturer:

Fresenius Medical Care AG & Co. KGaA
61346 Bad Homburg
GERMANY

Product Category(ies):

- **Dialysers and Filters for haemodialysis**
- **Adsorber for therapeutic apheresis**
- **Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies**
- **Catheters and Accessories for haemodialysis and peritoneal dialysis**
- **Fistula needles**
- **Syringes**
- **Cleaning and disinfectant agents**
- **Concentrates and solutions for haemodialysis**
- **Dialysis fluid supply equipment**
- **Active medical devices for extracorporeal blood treatment and peritoneal dialysis**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713083654

Valid from: 2016-06-17
Valid until: 2021-06-16

Date, 2016-06-09

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

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Facility(ies):

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Fresenius Medical Care Deutschland GmbH
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97424 Schweinfurt, GERMANY

Fresenius Medical Care Deutschland GmbH
Ober-Erlenbach Plant
Steinmühlstraße 24
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