



Product Service

**Confirmation Statement on validity of EC Certificate (MDD)**

pursuant to Directive 93/42/EEC concerning medical devices

**No. GCQ 077174 0014 Rev. 00****Manufacturer:****Fresenius Medical Care AG**Else-Kröner-Str. 1  
61352 Bad Homburg  
GERMANY

**This Confirmation Statement**      **G1 024492 2490 Rev. 00**  
**is only valid in combination**  
**with the following**  
**EC Certificate (MDD):**

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD). It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later. The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: [www.tuvsud.com/ps-cert?q=cert:GCQ\\_077174\\_0014\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:GCQ_077174_0014_Rev.00)

**Report No.:** 713315153\_FME2023-04\_MDD**Valid until:** 2024-05-26Christoph Dicks  
Head of Certification/Notified Body**Issue Date:** 2023-12-01



**Confirmation Statement on validity of EC Certificate (MDD)**

pursuant to Directive 93/42/EEC concerning medical devices

**No. GCQ 077174 0014 Rev. 00**

**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
- Solutions
- Cleaning and disinfectant agents
- Concentrates and solutions for haemodialysis
- Dialysis fluid supply equipment
- Active medical devices for extracorporeal blood treatment and peritoneal dialysis

**Description of Change:**

Change of legal name from

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

to

**Fresenius Medical Care AG  
61346 Bad Homburg  
GERMANY**