



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

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:

2024-05-26

Christoph 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**