



Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 077174 0016 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): **G2S 024492 2491 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_0016_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



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Product Category(ies):

- Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies
- Rinsing solutions

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**