



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 024492 2493 Rev. 00

Manufacturer:

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

Facility(ies):

Fresenius Medical Care AG & Co. KGaA
Else-Kröner-Str. 1, 61352 Bad Homburg,
GERMANY

Product Category(ies):

Heparin Syringes

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

Report No.:

713163830_3

Valid from:

2019-12-12

Valid until:

2024-05-26

Date,

2019-12-12

Christoph Dicks
Head of Certification/Notified Body