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Zentralstelle der Länder  
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bei Arzneimitteln und  
Medizinprodukten  
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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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT  
 TÜV SÜD TÜV SÜD