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

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 047402 0082 Rev. 00

Manufacturer:

Fresenius Kabi AG
61346 Bad Homburg
GERMANY

Product Category(ies):

ACTIVE MEDICAL DEVICES (class IIa / IIb)
Devices for Autotransfusion, Apheresis, Cell Separation, and Photopheresis;
Accessories for Blood Donation Systems
NON ACTIVE MEDICAL DEVICES (class IIa / IIb)
Transfusion and Transfer Sets incl. Accessories; Medical Containers; Filters;
Blood Donation Systems and Accessories;
Disposables for Autotransfusion, Apheresis, Cell Separation, and Photopheresis

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Digitally signed by Talpis Andrei
Date: 2022.11.25 11:54:07 EET
Reason: MoldSign Signature
Location: Moldova

Report No.: 713168590

Valid from: 2020-05-19
Valid until: 2024-05-26

Date, 2020-05-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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A4 / 07.17