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 005501 0002 Rev. 00

Manufacturer:

MedHemScience B.V.
Marco Polostraat 27
7825 VM Emmen
THE NETHERLANDS

Facility(ies):

MedHemScience B.V.
Marco Polostraat 27, 7825 VM Emmen, THE NETHERLANDS

Product Category(ies): **Non-invasive single use medical devices (class IIa) for long term storage of blood and tissue (components)**

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.

Report No.: 713139089

Valid from: 2018-11-08
Valid until: 2023-11-07

Date, 2018-11-08

Stefan Preiß

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

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