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

TÜV SÜD 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 084106 0005 Rev. 01

Manufacturer:

MECOTEC GmbH
Sonnenallee 7 - 11
06766 Bitterfeld-Wolfen
GERMANY

Facility(ies):

MECOTEC GmbH
Sonnenallee 7 - 11, 06766 Bitterfeld-Wolfen, GERMANY

MECOTEC GmbH
Freiburger Str. 25, 75179 Pforzheim, GERMANY

Product Category(ies): Cold-air-devices and cryo-therapy-chambers

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.: 713156982

Valid from: 2019-05-13
Valid until: 2024-04-26

Date, 2019-05-13

Stefan Preiß

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

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

TÜV®