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 086486 0008 Rev. 00

Manufacturer:

Changzhou Biolight Medical Devices Co., Ltd.
Block C, Building 7, Israel Centre
No.123 Hexiang Road
Wujin District
213149 Changzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Changzhou Biolight Medical Devices Co., Ltd.
Block C, Building 7, Israel Centre, No.123 Hexiang Road, Wujin District, 213149 Changzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Phototherapeutic Medical Devices

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.: SH1980301

Valid from: 2019-07-23
Valid until: 2024-05-26

Date, 2019-07-23

Stefan Preiß
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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

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