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

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 092486 0010 Rev. 00

Manufacturer:

Suzhou Yuyue Medical Technology Co., Ltd.
No. 9 Jinfeng Road
Suzhou Science & Technology Town
215163 Suzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Suzhou Yuyue Medical Technology Co., Ltd.
No. 9 Jinfeng Road, Suzhou Science & Technology Town, 215163 Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Sleep apnea breathing therapy mask

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.: SH1985201

Valid from: 2020-01-09
Valid until: 2024-05-26

Date, 2020-01-09

Christoph Dicks
Head of Certification/Notified Body

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

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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