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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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 081775 0008 Rev. 02

Manufacturer:

BMC Medical Co., Ltd.
Room 110 Tower A Fengyu Building, No. 115 Fucheng Road
Haidian
100036 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

BMC Medical Co., Ltd.
Room 110 Tower A Fengyu Building, No. 115 Fucheng Road,
Haidian, 100036 Beijing, PEOPLE'S REPUBLIC OF CHINA

BMC (Tianjin) Medical Co., Ltd.
3/F, Building No.4, No.1 Xinxing Road, Wuqing District, 301700
Tianjin, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Masks; Tubes; Sleep Apnea Therapy Devices, Respiratory Insufficiency Ventilators and Accessories: CPAP, Auto CPAP, BPAP, Humidifier; Heated Humidifier and Accessories: Humidifier, Water Chamber, Nasal Cannula and Tubes; Sleep Apnea Diagnosis Devices and Accessories: Sleep Screener, Polysomnograph, Portable Sleep Diagnostic System.

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.

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Digitally signed by Ionaşcu Andrei
Date: 2021.02.01 09:49:20 EET
Reason: MoldSign Signature
Location: Moldova

Date, 2020-01-20

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