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

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 081775 0008 Rev. 03

Manufacturer:

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

Product Category(ies): **Tube; Mask; Nasal Cannula; Sleep Apnea Therapy Device and Accessories; Respiratory Insufficiency Ventilator and Accessories; Respiratory High-Flow Therapy Device and Accessories; Sleep Apnea Diagnosis Device and Accessories.**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 081775 0008 Rev. 03

Report No.: BJ20096301

Valid from: 2021-04-08
Valid until: 2023-03-01

Date, 2021-04-08

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

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