



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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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.

**Report No.:** BJ19963043

**Valid from:** 2020-01-20

**Valid until:** 2023-03-31

**Date,** 2020-01-20

Christoph Dicks  
Head of Certification/Notified Body

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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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