



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 17 07 81775 008

Manufacturer:**BMC Medical Co., Ltd.**

Room 110 Tower A Fengyu Building, No. 115 Fucheng Road
Haidian

100036 Beijing

PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:****Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80

20537 Hamburg

GERMANY

Product Category(ies):

Sleep Apnea Therapy Devices, Respiratory Insufficiency Ventilators and Accessories: CPAP, Auto CPAP, BPAP, Humidifier and Masks. 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.:

BJ1896307

Valid from:

2018-04-01

Valid until:

2023-03-31

**Date,** 2018-03-05

Stefan Preiß

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

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Facility(ies):

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3/F, Building No.4, No.1 Xinxing Road, Wuqing District, 301700
Tianjin, PEOPLE'S REPUBLIC OF CHINA