

Declaration of Conformity to Council Directive 93/42/EEC concerning Medical Devices

Manufacturer: BMC Medical Co., Ltd.
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European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product:

Product Category	Product Name	Model	UMDN Code	UMDN Name	Classification	Rule
Sleep Apnea Therapy Device and Accessories	Auto CPAP System	M1 Mini	11001	Continuous Positive Airway Pressure Units	Ila	Rule 9 According to annex IX of the MDD

Conformity Assessment Route: Annex II without chapter 4

We BMC Medical Co., Ltd. herewith declare that the above mentioned product(s) meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices. All supporting documentation is retained at the premises of the manufacturer. The Manufacturer is exclusively responsibility for the DOC.

Standards applied:

EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015, EN 60601-1-11:2015, ISO 80601-2-70:2015, EN 62366-1:2015, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012,

**ISO 5356-1:2015, ISO 5367:2014, EN 62304:2006+A1: 2015, ISO 18562-1:2017, ISO 18562-2:2017,
ISO 18562-3:2017, ISO 18562-4:2017**

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München, Germany
Identification Number:	0123
(EC) Certificate(s):	G1 081775 0008 Rev.02
Start of CE-marking:	2020-06-12
Place, Date of Issue:	Beijing, 2020-10-13
Signature:	
Name:	Jian Xu
Position:	General Manager

