

Declaration of Conformity to Council Regulation (EU) 2017/745 concerning Medical Devices

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

SRN(Single Registration Number): CN-MF-000010157

European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

SRN(Single Registration Number): DE-AR-000000001

Product:

Product Category	Product Name	Model	CND Code and Name	Basic UDI-DI	Classification	Rule
Oxygen Concentrator	Oxygen Concentrator	SO1 5A SO1 5B	Z12159004 OXYGEN CONCENTRATORS	69485383 OC001RG	IIB	Rule 12 According to annex VIII of the MDR

Conformity Assessment Route: Annex IX without chapter II

We BMC Medical Co., Ltd. herewith declare that the above mentioned product(s) meet the Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices. All supporting documentation is retained at the premises of the manufacturer. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Standards applied:

EN 60601-1:2006/A2:2021, EN 60601-1-2:2015/A1:2021, EN 60601-1-6:2010/A2:2021,

BMC Medical Co., Ltd.

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EN 60601-1-11:2015/A1:2021, EN 60601-1-8:2007/A2:2021, EN ISO 80601-2-69:2020,
EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 10993-17:2009,
EN ISO 10993-18:2020, EN ISO 18562-1:2020, EN ISO 18562-2:2020, EN ISO 18562-3:2020,
EN ISO 18562-4:2020, EN 62366-1:2015 +AMD1:2020, IEC 62366-2:2016, EN ISO 14971:2019,
ISO/TR 24971:2020, EN 62304:2006+A1: 2015, EN ISO 15223-1:2021, EN ISO 20417:2021,
EN ISO 17664-1:2021, ISO/TR 20416:2020

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Germany

Identification Number: 0123

(EC) Certificate(s): G10 081775 0014 Rev. 00

Place, Date of Issue: Beijing, 2024-01-18

Signature: 

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