

## 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): DN-AR-000000001

**Product:**

Product Name	Model	EMDN Code and Name	Basic UDI-DI	Classification	Rule
iVolve N2 Nasal Mask	BMC-NM2	R03010102 - CPAP and NIV Masks	69485383 STA01Z3	IIa	Rule 2 According to annex VIII of the MDR
N4 Nasal Mask	NM4				
Nasal Mask	N5, N5A, N5B, N5H, N5AH, N5BH, N5+, N5A+, N5B+, N6				
P2 Nasal Pillows Interface	P2				
Nasal Pillows Interface	P2H, P6				
iVolve F1A Full Face Mask	BMC-FM1A				
F2 Full Face Mask	BMC-FM2				
F1B Full Face Mask	F1B				
F2 NV Full Face Mask	F2 NV1, F2 NV2				
Full Face Mask	F3, F4, F5, F5A, F5AS, F5+, F5A+, F6				

**Conformity Assessment Route: Annex IX exclude chapter II**

BMC Medical Co., Ltd.

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 62366-1:2015 +AMD1:2020, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 14971:2019, ISO/TR 24971:2020, EN ISO 5356-1:2015, EN ISO 17510:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, ISO 10993-10:2021, EN ISO 10993-23:2021, 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 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 0011 Rev. 00
Place, Date of Issue:	Beijing, 2023-02-27
Signature:	
Name:	Gao Chengwei
Position:	General Manager