CE

EC Declaration of Conformity

Manufacturer:
Name: Medicov (Hangzhou) Medical Instrument Co., Ltd.
Address: Sanxin Village, Xinwan Street, Qiantang New Area, Hangzhou, Zhejiang,China.
Tel: +86-0571-56166171
Email: ymh@xdmade.com

Whose Authorized Representative:
Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the product(s)

Product Name	Surgical mask	**Model**	Flat Ear-Loop Type
BASIC UDI-DI	/	**UMDNS Code**	12447
Intended Use	It is intended to limit the transmission of infective agents between staff and patients during surgical procedures and other medical settings with similar requirements, reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.The product is disposable and non-sterile.		
Classification	I, (MDR, Annex VIII Rule 1)		

meet(s) the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

Applicable Standards:

ISO 13485:2016 *EN ISO 14971:2012* *ISO 10993-1:2018*

ISO 10993-5:2009 *ISO 10993-10:2010* *EN 14683:2019 Type IIR*

EN 1041:2008 *EN ISO 15223-1:2016*

The aforementioned device has been assigned to class I according to Appendix VIII of the Regulation (EU) 2017/745. It bears the CE mark.

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745.

The above mentioned declaration of conformity is exclusively under the responsibility of **Medicov (Hangzhou) Medical Instrument Co., Ltd.**

Name of General Manager	Maohang Ye
Signature	Maohang Ye
Date	20
Place	Zhejiang,China.
Seal (Manufacturer)	

扫描全能王 创建