

EC Declaration Of Conformity

Manufacturer:

Name: Wuyi Xiaozhen sanitary products Co., Ltd
Address: No.18 Huanglong 3rd. road, Huanglong Industrial Park, Hushan Street, Wuyi, Jinhua , Zhejiang, China
Tel: +86-579-87617191
Email: sales01@cnxiazhen.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	Disposable medical face mask(non-sterile)	Model	XZ002
BASIC UDI-DI	/	UMDNS Code	12447
Intend Use	Disposable medical face mask(non-sterile) is used for patients in order to reduce the risk of the spread of infections, and it is not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements. 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+AC:2019*
EN 1041:2008 *EN 15223-1:2016* *(TYPE II)*

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

Wuyi Xiaozhen sanitary products Co., Ltd

Name of authorized signatory: Wang Wenbin

Position held in the company: General Manager

Place: Zhejiang Province, China

Signature:

Date: 2020-06-10

Seal/Stamp:

