



DECLARATION OF CONFORMITY

Manufacturer:

Name:Guangdong Winsun Personal Care Products Co.,Ltd

Address:No.1 Guangxing Road, Xiqiao Sci-Tec Industrial Zone, Xiqiao Town, Nanhai District, Foshan City, Guangdong Province, P.R. China.

E-mail:Jessica@gdwinsun.cn

Whose Authorized Representative:

Name:SUNGO Europe B.V.

Address:Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Test report:SL52025258960201TX

Item No.:YS0011/YS0010/YS0023

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

Product Name	Disposable Medical Face Mask	Model	Non-sterile
BASIC UDI-DI	/	UMDNS CODE	49704
Intended Use	Disposable medical face mask is used for users to reduce the risk of the spread of infections, and it is not used for use by healthcare professionals in operating room or in other medical settings with similar requirement. The product is latex free, disposable and non-sterile.		
Classification	I, (MDR, Annex VIII, Rule 1)		

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

Conformity Assessment Route:Annex II and Annex III According to REGULATION (EU) 2017/745

Applicable Standard:

ISO13485:2016 EN ISO 14971:2012 ISO 10993-1:2018

EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN14683:2019

EN 1041:2008 EN ISO 15223-1:2016

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meets the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post production monitoring process.

Signature: 颜希仁

Position: Sales Director

Place: Foshan, China

Date: 2020-12-8

Seal/Stamp:

Guangdong Winsun Personal Care Products Co., Ltd

