

# EC DECLARATION OF CONFORMITY

## REGULATION 745/2017 ON MEDICAL DEVICE

Name and address of the manufacturer: Guilin HBM Sanitary Protections, Inc  
/ No.1-2, Shuijing East Road, Economic and Technological Development Area, Guilin 541805, China

EC Authorized Representative:/ 4S HBM Limited  
Coliemore House, 3 Coliemore Road, Dalkey, Co. Dublin, A96A8, Republic of Ireland.

We, as the manufacturer, are exclusive responsible for the declaration of conformity. Herewith declare that the state medical device meets the provisions of Medical Device Regulation of EU 2017/745:2017 and its transportations in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Name of the medical device: / Medical Face masks  
Type I, Type II, Type IIR

Model/ Anti-Fog with Ties

UMDNS Code:/ 12458

Basic UDI -DI:/ N/A

Intended purpose / The Medical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

Classification/ Rule1, Class I  
CND code: T020601 Standard Surgical Face Masks  
according to annexVIII of directive EU 2017/745(MDR) /

CS reference:/ NA

Conformity assessment: / Declare the conformity of the abovementioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 / according to Article 52(7) of Regulation (EU) 2017/745 /

Guilin 2020.04.30

Place, date

General Manager

Name and function

HBYY-CE-01-0102

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