

CE – DECLARATION OF CONFORMITY

DoC #	Version	Revision Date	Date of prev. issue	Date of first issue
00002020050	1.0	2020.05.10	-	2020.05.10

Issued by the manufacturer on the basis of European legislation and in accordance with the decision of the European Union Notified Body eligible to assess the conformity

The manufacturer

Jiangsu Eyoung Medical Devices Co., Ltd.
Dongtang Road 1, Zhenglu Town,
Tianning District,
Changzhou,
213115 China

hereby declares that the product as detailed below

(Object of the declaration)	
Product Type	H&S Protector
Description	Medical face masks, non-sterile Layered, blue medical device to be used in order to limit the transmission and/or inhalation of infectious agents such as viruses, bacteria, other micro-organisms and allergens.

is, under conditions of normal single use and solely on accordance of the instructions defined by the manufacturer, safe and effective and fully compliant to all legal conditions and requirements set out by EN 2017/745 of The European Parliament and of the Council.

The conformity was assessed by provisions:

Harmonised standard(s) and technical specification(s)	
EN 14683 Type I	Medical face masks - Requirements and test methods

Confirming that performance requirements are met evidenced by standard test methods and yielding

- Bacterial Filtration Efficiency (BFE): $\geq 95\%$
- Differential Pressure: $< 3.0 \text{ mm H}_2\text{O}/\text{cm}^2$
- Microbial cleanliness: $\leq 30 \text{ cfu/g}$

Signed on behalf of the manufacturer

Changzhou, China
May 10, 2020

Name, function, signature
Lin Shen, General Manager

