


## **REGULATORY INFORMATION, REGARDING THE SALE ON THE UK MARKET.**

This product meets the requirements (innocuousness, comfort, robustness and protection against the risks claimed) of the PPE regulation (EU) 2016/425 on personal protective equipment, as amended to apply in GB and also meets the requirements of the UK MDR 2022 medical device regulation.

This product is  marked, by self-certification.  
The declaration of conformity is available on demand or at the following address :  
**[www.kolmi-hopen.com](http://www.kolmi-hopen.com)**

Groupe Kolmi Hopen UK responsible person is :  
**Medicom Healthpro Ltd**  
**Unit 1 Liliput Close, Brackmills Industrial Estate,**  
**Northampton, NN4 7EJ, United Kingdom**

The present document is not an IFU.  
Please refer to the attached IFU, available in each box of masks,  
for the official instruction for use.