

DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU)2017/745

Product

Name: Surgical Face Mask

Model:

Adult, 3 layers with elastic ear loops.

WKI-SM50 17.5*9.5cm

WKI-SM50-1 17.5*9.5cm

Manufacturer

Name: WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.

Address: TangJiao XingWang Street, LiLin Town,ZhongKai Hi- Tech Zone,HuiZhou,GuangDong, China.

Authorized Representative

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Classification: Class I

Rule: according to Rule 1, Annex VIII of EU Medical Device Regulation(EU) 2017/745

Conformity assessment procedure:Annex II+III

SRN:

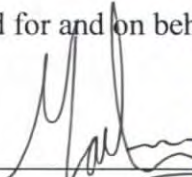
UDI-DI:

Product Model	UDI-DI	Position
WKI-SM50	26970739451702	On the label of the color box,50 pcs/color box.
WKI-SM50	36970739451709	On the label of the cases,40pcs color box/cases.
WKI-SM50-1	06970739451715	On the label of the pouch,1pc/pouch.
WKI-SM50-1	26970739451719	On the label of the color box,50 pcs/color box.
WKI-SM50-1	36970739451716	On the label of the cases,40pcs color box/cases.

The declaration of conformity is issued under the sole responsibility of WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd. according to ISO/IEC Guide 22 and EN45014. We confirm that the device that is covered by the declaration is in conformity with Medical Device Regulation(EU) 2017/745



Signed for and on behalf of Manufacturer



Mac Lai, General Manager



2020-3-23
Huizhou,, Date