

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

Uhealth Medical (Beijing) Protective Products Co., Ltd.
Room 128, Floor 1, Building 2, No.11 Courtyard,
Kechuang 14th Street, Economic and Technological
Development Zone, 101111 Beijing, P.R.China

Trademark:



SRN:

Not available yet

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

SRN:

Not available yet

Trade name:

Disposable Medical Face Mask

Product Name:

Disposable Medical Face Mask

Product code / Catalogue number:

LHKL-B-1 (LHKL-F-1) LHKL-L-1, LHKL-G-1 (earloop type)
LHKL-TB-1, LHKL-TL-1, LHKL-TG-1 (tie-on type)

Basic UDI

Not available yet

Classification acc. to MDR Ax. VIII:

Class I, rule 1

Applied Standard&Common Specification:

EN 14683:2019 +AC:2019

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

Name and ID of the Notified Body:

N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

For and on behalf of
Uhealth Medical (Beijing) Protective Products Co., Ltd.
北京联合康力防护用品有限公司

Legally binding signature, Function

Authorized Signature(s)

Beijing, China April 27th, 2020

Place, date



Uhealth Medical (Beijing) Products Co., Ltd.

Add. No.11, 14th Ke Chuang Rd. Economic Development Area
Rm 128, Building 2, Beijing, China 100176

Declaration

Dated: 22th of July, 2020

To whom may concern:

We Uhealth Medical (Beijing) Products Co., Ltd. Hereby declare that our facemask with the specification is as below:

Model Ref: LHKL-B-1 =LHKL-F-1

- Earloop
- 20+25+25gsm
- 9.5x17.5cm
- BFE≥99%
- EN14683:2019+AC:2019 Type IIR

which was sold to company of PROLIMAX HIGIENE INDUSTRIAL, S.L. with the face mask Model Ref: 64703 is same.

We kindly hope that you could understand with many thanks!

Uhealth Medical (Beijing) Products Co., Ltd.

General Manager: Cybil Zhai

Sign and stamp

For and on behalf of
Uhealth Medical (Beijing) products Co., Ltd.
北京联合康力医疗器械有限公司

.....
Authorized Signature(s)



Uhealth Medical (Beijing) Products Co., Ltd.

Add.: No.1 Military-Civil Integration Industrial Park, Daxing District, Beijing, China

3-Ply facemask (Ear loop)

Specification:

Size	Nose Clip	Ear loop	Color	Raw material	BFE
17.5x9.5cm±0.5cm	11cm	17.5cm	blue	25gsm+25gsm+20gsm	≥99%
Packing: 50pcs/box, 40box/carton					

Certificates:

CE Conformity of Declaration (CE DOC): See attachment

Test report: see attachment

- EN14683 TYPE IIR (see attachment)

Europe representative:

MedPath GmbH

Mies-van-der-Rohe-Strasse8 80807 Munich, Germany

CE Registration number: DE/CA61/1M50/139

Picture:

