LHM
▪ Past ▪ Present ▪ Future ▪

CE

Declaration of Conformity

Manufacturer:	LHM Medical Technology (Hong Kong) Limited
Address:	Unit No. 2, 3/Floor, Block A, Ko Fai Industrial Building, No. 7 Ko Fai Road, Yau Tong, Kowloon, Hong Kong 999077
EU Representative:	MedPath GmbH
	Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
SRN of Authorized representative:	DE-AR-000000087
Product name:	Fluid Resistant Procedure mask
Model number:	LHM-E1301, LHM-E1302, LHM-E1303, LHM-E1304, LHM-E1305, LHM-E1306
Intended use:	The procedure 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.
Basic UDI-DI	48971121300174V
Classification of the device:	Class I
Applicable Regulation and Directives:	REGULATION (EU) 2017/745
Conformity assessment procedure:	Article 52 clause 7

We hereby declare that the above-mentioned device conforms to the mentioned regulation and directives as transposed into national legislation and standards, when used for the intended purpose and as per the instructions given in the operating manual, based on the voluntary assessment of the product sample and technical file.

All applicable harmonized Standards:

- EN ISO 13485: 2016 Medical devices -Quality management systems -Requirements for regulatory purposes
- EN ISO14971:2012 Medical devices—Application of risk management to medical devices
- EN ISO15223-1:2012 Symbols for use in the labelling of medical devices
- EN 14683: 2019 AC: 2019 Medical face masks-requirement and test methods
- EN 10993 series standards Biological evaluation of medical devices

Signature: 

Date of Issue: 2021.5.24

Martin Chui

Director

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