LHM
▪ Past ▪ Present ▪ Future ▪

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DECLARATION OF CONFORMITY

Manufacturer:	LHM Medical Technology (Hong Kong) Limited
Address:	Unit No. 2, 3/F, Block A, Ko Fai Industrial Building, 7 Ko Fai Road, Yau Tong, Kowloon, Hong Kong 999077
EU Representative:	MedPath GmbH
	Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
Product name:	Fluid Resistant **Procedure Mask**
Model number:	LHM-E1601, LHM-E1602, LHM-E1603, LHM-E1604, LHM-E1605, LHM-E1606
Classification:	Class I per Rule 1 in Annex IX of MDD 93/42/EEC
Conformity assessment Route :	Annex VII of MDD 93/42/EEC

We herewith in our sole responsibility declare that the products mentioned above meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

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: 20th July, 2020

Ronald Chow
Managing Director

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