

EC DECLARATION OF CONFORMITY

Manufacturers Name:	Premium Plus International Ltd.
Manufacturers Address:	1001, Yuen Long Trading Centre No. 33, Wang Yip Street West Yuen Long N.T. Hong Kong
Authorized Representative Name:	Premium Plus UK Ltd.
Authorized Representative Address:	Unit 2, Knighton Heath Industrial Estate Bournemouth, Dorset BH11 8NE United Kingdom
Device Group:	Face Masks
Models	See Appendix 1
Classification:	I According to Annex IX of MDD 93/42/EEC
Conformity Assessment Route:	Council Directive 93/42/EEC (MDD) Annex VII

We herewith declare that the products mentioned in this declaration meet the provisions of the Council Directive 93/42/EEC for Medical Devices, amended by Council Directive 2007/47/EC. All supporting documentation is retained under the premises of the Manufacturer. We are exclusively responsible for the DoC.

Standards Applied:

EN ISO 13485:2016 / EN ISO 14971: 2019 / EN1041:2008+A1:2013 / EN ISO 15223-1: 2016 / EN ISO 10993-1: 2018 / MEDDEV2.12/1: 2013 rev.8 / MEDDEV 2.7/1: 2016 rev.4 / EN 14683:2019 / ASTM F2100: 2019

Place and Date of issue: Hong Kong, 01/06/2020

Signature:



Name: Wei Jun, for and on behalf of Premium Plus International Ltd.
Position: General Manager

APPENDIX 1

Devices covered under this Declaration of Conformity for Generic Device Group:

Face Masks

Product Code(s)	Product Name
2288	Disposable Ear-Loop Face Masks Type IIR/ Level 3
2288T (Previously Model 2299)	Disposable Tie-On Face Masks Type IIR/ Level 3
FS2288	Disposable Ear-Loop Face Masks with Shield Type IIR/ Level 3