

CCIR ASIA PACIFIC LIMITED

Unit 20, 1/F, Office Block Two,
96 Siena Avenue, Discovery Bay North,
Hong Kong



DECLARATION OF CONFORMITY
MEDICAL DEVICES REGULATION MDR 2017/745
REGULATION (EU) 2016/425 FOR PERSONAL PROTECTIVE EQUIPMENT

MANUFACTURER

CCIR ASIA PACIFIC LIMITED, Unit 20, 1/F, Office Block Two, 96
Siena Avenue, Discovery Bay North, Hong Kong, CHINA
SRN:HK-MF-000003035

EU REPRESENTATIVE

LOTUS NL B.V., Koningin Julianaplein 10, 1e Verd, 2595AA, The
Hague, Netherlands
SRN:NL-AR-000000121

This certificate is valid for the following product:

**VINYL EXAMINATION GLOVES - NO STERILE - POWDERED AND POWDER
FREE**

Classification:

Class I according to rule 1 of the Annex VIII classification
rules of the Medical Devices Regulation Directive MDR (EU)
2017/745

Category III according to PPE Regulation (EU) 2016/425

We hereby confirm under our sole responsibility that the
products with CE marking above mentioned comply with:

- To the essential requirements (Annex I) of the Directive
2007/47/CE for medical devices and Medical Devices
regulation MDR 2017/745, and are subject to the test
certificate IN-03241/2014-B-4
Applied standards: UNE-EN 455-1:2001, UNE-EN 455-
2:2010+A1:2011 and UNE-EN 455-3:2007
- The applicable provisions of Regulation (UE) 2016/425 on
Personal Protective Equipment, and are subject to the
test certificate IN-01657-2013-OC-CE-E-1 and its update
IN-01657-2013-OC-CE-E-2, and EU Type Examination
Certificate (Module B) IN-00575/2019-OC-UE-E
Applied standards: EN 420:2003+A1:2009, EN ISO 374-1:2016
(Type C), EN 374-2/03, EN 374-3/03+AC/06 and EN 374-4:2013

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The certificates has been issued DM y EPI has been issued by:

- LEITAT - ACONDICIONAMIENTO TARRASENSE (MD and PPE)
C/ de la Innovació, 2, 08225 TERRASSA (BARCELONA) - ESPAÑA
- SATRA TECHNOLOGY CENTRE LTD (Only for PPE)
Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16
8SD, United Kingdom



Echo Zhang
Quality Manager

Hong Kong, April 16th, 2021
Valid until April 16th, 2026