

CCIR ASIA PACIFIC LIMITED

Room 303, 3rd Floor, St. George's Building, 2 Ice
House Street, Central Hong Kong



**EC DECLARATION OF CONFORMITY
MEDICAL DEVICE REGULATION MDR (EU) 2017/745
REGULATION (EU) 2016/425 FOR PERSONAL
PROTECTION EQUIPMENT**



MANUFACTURER

CCIR ASIA PACIFIC LIMITED, Room 303, 3rd Floor, St. George's
Building, 2 Ice House Street, Central Hong Kong
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:

**GMDN AND PRODUCT CODE: 47176 VINYL EXAMINATION GLOVE - NON-
STERILE - POWDERED AND POWDER-FREE**

Basic UDI-DI:489712016CCIR-007025S

Classification:

Class I according to rule 1 of the classification according to
Annex VIII of the Regulation on medical devices MDR (EU)
2017/745

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

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

- The essential requirements of Directive 2007/47/CE and Regulation MDR (EU) 2017/745 on medical devices, and are subject to test certificate No. TTCN 113235 0005 Rev.00. Standards applied: UNE-EN 455-1:2020/A1 :2022, UNE-EN 455-2:2015 and UNE-EN 455-3:2015.
- Provisions from Regulation (EU) 2016/425 for personal protective equipment are subject to the EU type examination certificate (Module B) 2777/25511-01/E00-00 and test reports SPC0033637/2218, SPC0325101/2202/CC/C, SPC0325101/2202/3, CHM0301957/2036/JH/A, IN-00575/2019-B and (CE certificate) IN-00575-2019-OC-UE-E.

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Standards applied: EN ISO 21420:2020, EN ISO 374-1:2016+A1 :2018 (Type C), EN 374-2/2019, EN 16523-1:2015+A1 :2018, EN 374-4 :2019 et EN ISO 374-5:2016, ISO 16604:2004.

The MD and PPE certificates have been issued by:

- TÜV SÜD PSB Pte LTD (MD)
15 International Business Park - SINGAPORE
- SATRA TECHNOLOGY CENTRE LTD (PPE)
Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, United Kingdom
- LEITAT - ACONDICIONAMIENTO TARRASENSE (PPE)
C/ de la Innovació, 2, 08225 TERRASSA (BARCELONA) - SPAIN



Echo Zhang
Quality manager

Hong Kong, March 17, 2024
Valid until March 16, 2027