

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: 56286 - NITRILE EXAMINATION GLOVE - NON
STERILE - POWDER FREE**

Basic UDI-DI:489712016CCIR-007005N

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/EC and
Regulation MDR (EU) 2017/745 on medical devices, and are
subject to test certificate N° TTCN 113235 0004 REV.00
Applied standards: UNE-EN 455-1:2020/A1:2022, UNE-EN 455-
2:2015 et UNE-EN 455-3:2015
- The relevant provisions of Regulation (EU) 2016/425 for
personal protective equipment subject to the EU type
examination certificates (Module B) Ref.2777/24929-
01/E00-00 and test reports Ref.SPC0325101/2202/CC/B,

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SPC0325101/2201/1, CHM0344738/2308/1, CHM0341399/2248/1,
CHM0341399/2248/2, CHM0341399/2248/3, CHM0341399/2248/4.

- Applied standards: EN ISO 21420:2020, EN ISO 374-1:2016+A1 :2018 (Type B), 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



Echo Zhang
Quality manager

Hong Kong, March 7, 2024
Valid until March 6, 2027