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

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

EC REP
EU REPRESENTATIVE
LOTUS NL B.V., Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
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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: EN 455-1:2020/A1:2022, EN 455-2:2015 et 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 UKCA type examination certificate AB0321/25476-01/E00-00

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- 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.

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