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

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 REPRESENTANTE

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: 47172 LATEX EXAMINATION GLOVE - NON-STERILE – POWDER-FREE
Basic UDI-DI: 489712016CCIR-007015Q

Classification:

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

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 006 Rev.00
  Standards applied: EN 455-1:2020/A1:2022, EN 455-2:2015, UNE-EN 455-3:2015.

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House Street, Central Hong Kong

The MD certificates have been issued by:

- TÜV SÜD PSB Pte LTD (DM)
  15 International Business Park – SINGAPORE

Echo Zhang
Quality manager

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