



EC Declaration of Conformity

Form : MDR_DOC
Version: 0
Revision Date: 2021-03-01

Manufacturer:	Pharma Lab International Ltd.
Single Registration Number:	HK-MF-000013674
Address:	Unit 2102, CC Wu Building, 302-306 Hennessy Road, Wan Chai, Hong Kong
Authorized Representative Name:	Obelis s.a
Authorized Representative Address:	Bd. Général Wahis 53, 1030 Brussels, Belgium
Name of the Device(s):	Nitrile Examination Gloves, Powder-free
Product Codes:	GNTNP-S, GNTNP-M, GNTNP-L
Basic UDI-DI	366496515104GC
Classification:	Class I according to Medical Device Regulation 2017/745 Annex VIII Rule 5
Notified Body Name:	N/A
Notified Body Address:	N/A
Notified Body Identification Number:	N/A
Conformity Assessment Route:	Medical Device Regulation 2017/745, Annex II and Annex III
First CE Marking Date:	24/03/2022
CE Certificate Number	N/A
Certificate Expiry Date:	N/A

We hereby declare under sole responsibility that the CE marked products mentioned above conform to the general safety and performance requirement (Annex I) of the Medical Device Regulation 2017/745.

All supporting documentation is retained under the premises of the manufacturer.



Anthony Guchet

Managing Director

Issued: Hong Kong, 13/04/2022



EC Declaration of Conformity

Form: PPER_DOC
Version: 0
Revision Date: 2022-03-22

Manufacturer:	Pharma Lab International Ltd.
Address:	Unit 2102, CC Wu Building, 302-306 Hennessy Road, Wan Chai, Hong Kong
European Representative:	Pharma Lab SAS
European Representative Address:	1 bis Rue du Havre, 75008 Paris, France
Name of the Device(s):	Nitrile Examination Gloves
Model number:	GNTNP-S, GNTNP-M, GNTNP-L
Type:	Powder free
Notified Body Name:	SATRA Technology Europe Limited
Notified Body Address:	Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland
Notified Body Identification Number:	2777
Conformity Assessment Route:	Based on the Annex V: EU type-examination (Module B) and the Annex VII: Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2).
CE Certificate Number	2777/11521-02/E03-01
Certificate Expiry Date:	09/11/2023
Place, Issue date of the certificate:	Republic of Ireland, 21/10/2020

We hereby declare under sole responsibility that the Nitrile Examination Gloves are in the compliance with the Personal Protective Equipment Regulation (EU) 2016/425.

Standard Applied:

EN 374-1:2016, EN 16523-1:2015, EN 374-4 :2013, EN ISO 374-5 :2016 and EN ISO 21420:2020

Signed for and on behalf of Pharma Lab International Ltd.

Name: Anthony Guichet

Position: Managing Director

Place and Date of Issue: Hong Kong, 14/04/2022

Pharma Lab International Ltd.

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