



## EC Declaration of Conformity

Form : MDR\_DOC  
Version: 0  
Revision Date: 2021-03-01

<b>Manufacturer:</b>	Pharma Lab International Ltd.
<b>Single Registration Number:</b>	HK-MF-000013674
<b>Address:</b>	Unit 2102, CC Wu Building, 302-306 Hennessy Road, Wan Chai, Hong Kong
<b>Authorized Representative Name:</b>	Obelis s.a
<b>Authorized Representative Address:</b>	Bd. Général Wahis 53, 1030 Brussels, Belgium
<b>Name of the Device(s):</b>	Latex Examination Gloves, Powder-free
<b>Product Codes:</b>	GLXNP-S, GLXNP-M, GLXNP-L
<b>Basic UDI-DI</b>	366496515102G8
<b>Classification:</b>	Class I according to Medical Device Regulation 2017/745 Annex VIII Rule 5
<b>Notified Body Name:</b>	N/A
<b>Notified Body Address:</b>	N/A
<b>Notified Body Identification Number:</b>	N/A
<b>Conformity Assessment Route:</b>	Medical Device Regulation 2017/745, Annex II and Annex III
<b>First CE Marking Date:</b>	08/02/2022
<b>CE Certificate Number</b>	N/A
<b>Certificate Expiry Date:</b>	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

<b>Manufacturer:</b>	Pharma Lab International Ltd.
<b>Address:</b>	Unit 2102, CC Wu Building, 302-306 Hennessy Road, Wan Chai, Hong Kong
<b>European Representative:</b>	Pharma Lab SAS
<b>European Representative Address:</b>	1 bis Rue du Havre, 75008 Paris, France
<b>Name of the Device(s):</b>	Latex Examination Gloves
<b>Model number:</b>	GLXNP-S, GLXNP-M, GLXNP-L
<b>Type:</b>	Powder-free
<b>Notified Body Name:</b>	SATRA Technology Europe Limited
<b>Notified Body Address:</b>	Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland
<b>Notified Body Identification Number:</b>	2777
<b>Conformity Assessment Route:</b>	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).
<b>CE Certificate Number</b>	2777/10906-02/E03-01
<b>Certificate Expiry Date:</b>	19/07/2023
<b>Place, Issue date of the certificate:</b>	Republic of Ireland, 22/02/2019

We hereby declare under sole responsibility that the Latex 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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