PHARMALAB INTERNATIONAL	**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):	Latex Examination Gloves, Powdered
Product Codes:	GLXP-S, GLXP-M, GLXP-L
Basic UDI-DI	366496515103GA
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:	08/02/2022
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

PHARMALAB INTERNATIONAL	**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):	Latex Examination Gloves
Model number:	GLXP-S, GLXP-M, GLXP-L
Type:	Powdered
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	2777/10905-01/E05-01
Certificate Expiry Date:	19/07/2023
Place, Issue date of the certificate:	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 Guchet

Position: Managing Director

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