Manufacturer:	Pharma Lab International Ltd.	
Single Registration Number:	*TBA*	
Address:	Unit 2102, CC Wu Building, 302-308 Hennessy Road, Wan Chai, Hong Kong	
European Authorized Representative:	Obelis s.a Bd. Général Wahis 53, 1030 Brussels, Belgium	
Basic UDI-DI:	366496515103GA	
Product:	Latex Examination Gloves	
Type:	Powdered	
Product Codes:	**Pharma Lab Int'l Codes**	**Size**
	GLXP-S	S
	GLXP-M	M
	GLXP-L	L
Classification:	Class I according to Medical Device Regulation 2017/745 Category III according to PPE Regulation (EU) 2016/425	

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.

The conformity assessment is based on Annex II and Annex III; Classification accordingly to rule 5, Annex VIII.

Applied standards: EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009

We hereby declare under sole responsibility that the CE 2777 marked products mentioned above are in conformity with the provisions of PPE Regulation (EU) 2016/425 and are identical to the PPE, which are the subject of EC certificate of conformity no. *2777/10905-01/E05-01* issued on 22 Feb 2019 by the Notified Body:

SATRA Technology Europe Limited (Notified Body No: 2777)

Bracetown Business Park,

Clonee, D15YN2P,

Republic of Ireland

These devices are subject to the procedure set out in ANNEX VII of PPE Regulation (EU) 2016/425 under the supervision of the Notified Body:

SATRA Technology Europe Limited (Notified Body No: 2777)

Bracetown Business Park,

Clonee, D15YN2P,

Republic of Ireland

Applied standards: EN 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4 :2013, EN ISO 374-5 :2016 and EN ISO 21420:2020

Anthony Guchet

Managing Director

Issued: Hong Kong, 01 Mar, 2021