



EC Declaration of Conformity

Doc. No.: MDR_DOC_GLXNP
Revision: 0
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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: 366496515102G8
Product: Latex Examination Gloves
Type: Powder Free
Product Codes:

Pharma Lab Int'l Codes	Size
GLXNP-S	S
GLXNP-M	M
GLXNP-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. 2777/10906-02/E03-01 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 21420:2020

Anthony Guchet
Managing Director

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