



EU DECLARATION OF CONFORMITY

1. Product

Description : Powder Free Blue Nitrile Exam Gloves, Textured, Polymer Coated
Type : PPE Category III, in accordance with attachment I of the regulation and is identical with the PPE which was subject to the EU type examination certificate No. 2777/13656-02/E00-00 issued by notified body SATRA Technology Europe Limited (Identificate No. 2777).

2. Name and address of the manufacturer

Name : PT. Arista Latindo
Address : Jl. K. H. Moh. Mansyur No. 128 Jakarta 11210 INDONESIA.

3. This Declaration of Conformity is issued under the sole responsibility of the manufacturer :

PT. Arista Latindo
Jl. K. H. Moh. Mansyur No. 128 Jakarta 11210 INDONESIA

4. European Representative : MedNet GmbH Borkstrasse 10, 48163 Muenster, Germany

5. The product of the declaration described above is in conformity with the relevant Union Harmonization Legislation :

- Regulation (EU) 2016/425 of 9 March 2016 on personal protective equipment
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

6. This product is a Class I medical device according to the Council Directive 93/42/EEC to the Clasification in Annex IX

7. References to the relevant harmonized standards used or references to the specifications in relation to which conformity is declared :

- EN455 part 1
- EN455 part 2
- EN455 part 3
- EN1186-1
- RoHS Directive 2011/65/EU

Jakarta, 26 September 2020



Linga Sumarta, Marketing Manager

