



PT. UNIVERSAL GLOVES



Certified Company  
Cert No :  
16 00 G 12083



Certified Company  
Cert No.:  
44 221 120909

To Whom It May Concern

Date : December 05, 2020

### EU DECLARATION OF CONFORMITY

We, PT. UNIVERSAL GLOVES, located at Jl. Pertahanan No. 17 Patumbak 20361, Deli Serdang, Sumatera Utara, Indonesia.

Declares under our sole responsibility that the Medical Devices described hereafter as:

“ALVITA” Label, Latex Powdered and Powder-Free Examination Gloves (Non Sterile)

- Are in conformity with the general safety and performance requirements of Annex I Medical Device Regulation (EU) 2017/745 for Class I Medical Device;
- Classification: Class I based on Rule 5 transient use, Annex VIII of Medical Device Regulation (EU) 2017/745;
- Are in conformity with the European harmonized standard EN 455-1, EN 455-2, EN455-3 and EN455-4;
- The gloves are manufactured according to ISO 9001:2015 and EN ISO 13485:2016 Quality Management Systems and certified by TUV NORD;
- Our Authorized Representative is Obelis s.a., located at Bd. General Wahis 53, 1030 Brussels, Belgium.

Authorized Signature,  
PT. Universal Gloves

Trixie  
*Marketing Manager*