



## Precious Mountain Ent. Corp.

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To Whom It May Concern

Date Dec. 07, 2020

### EU DECLARATION OF CONFORMITY

We, PRECIOUS MOUNTAIN ENT. CORP., located at 2F No.68, Sec 1., Neihu rd., Neihu Dist., Taipei City 114, Taiwan

declares under our sole responsibility that the medical devices described hereafter as:

“ALVITA” Label, Nitrile 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 TÜV SÜD America Inc; TÜV SÜD Product Service GmbH.
- Our Authorized Representative is MedNet EC-REP GmbH.

Manager of Quality Assurance Center

(Title of authorized officer)

Dennis Chang

(Name of authorized officer)

*Dennis Chang*  
 (Signature of authorized officer)

DEC.07.2020

(Date of issue)