

**EC DECLARATION OF CONFORMITY**

Manufacturer : Hartalega NGC Sdn. Bhd.  
No. 1, Persiaran Tanjung  
Kawasan Perindustrian Tanjung  
43900 Sepang, Selangor Darul Ehsan,  
Malaysia

European Representative : MDSS GmbH,  
Schiffgraben 41, 30175 Hannover,  
Germany

Device Name : Biodegradable Nitrile Powder Free Examination  
Gloves  
Five fingered, ambidextrous, powder free,  
biodegradable, nitrile examination gloves with beaded  
cuff  
  
Refer to Attachment I for Trade Name

Device Classification : Category III (Type B)

Standard Reference : EN ISO 21420:2020  
EN ISO 374-1:2016+A1:2018  
EN ISO 374-5:2016  
EN 421: 2010 (Radioactive contamination only)

**The notified body SATRA Technology Centre with Notified Body Number of 2777 performed the EU type-examination (Module B) and issued the EU type-examination certificate 2777/25664-02/E00-00.**

**The PPE is subject to the conformity assessment procedure conformity to type based on quality assurance of the production process (Module D) under surveillance of the Notified body SATRA Technology Centre with Notified Body Number of 2777.**

**WE, HARTALEGA NGC SDN BHD HEREWITH DECLARE THAT THE ABOVE MENTIONED DEVICE IS IN CONFORMITY WITH REGULATION (EU) 2016/425 AND OTHER RELEVANT UNION LEGISLATION THAT PROVIDES FOR THE ISSUANCE OF THIS DECLARATION OF CONFORMITY. THIS DECLARATION IS ISSUED UNDER THE SOLE RESPONSIBILITIES OF THE MANUFACTURER.**

Notified Body : SATRA Technology Europe Limited/ NB No. 2777  
Bracetown Business Park,  
Clonee D15YN2P,  
Republic of Ireland.

EU Type – Examination Certificate Number : 2777/25664-02/E00-00

Place and Date of Issue : Hartalega NGC Sdn. Bhd./ 2<sup>nd</sup> June 2026

Signed on Behalf of Hartalega NGC Sdn. :  
Bhd.

  
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Name : NURUL ASYIAH KONG  
Function : GENERAL MANAGER – QUALITY  
ASSURANCE

**ATTACHMENT I**

| <b>Product or Trade Name</b>                              | <b>Reference Number</b> |
|-----------------------------------------------------------|-------------------------|
| Biodegradable Nitrile Powder Free Examination Gloves (XS) | TBA                     |
| Biodegradable Nitrile Powder Free Examination Gloves (S)  | TBA                     |
| Biodegradable Nitrile Powder Free Examination Gloves (M)  | TBA                     |
| Biodegradable Nitrile Powder Free Examination Gloves (L)  | TBA                     |
| Biodegradable Nitrile Powder Free Examination Gloves (XL) | TBA                     |