

EU 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 : Nitrile Powder Free Examination Gloves
≥ 2.2 mil Powder Free Nitrile disposable five fingered
glove. Available in a standard minimum 240mm length
or a longer cuff variant of 280mm, available as sterile
(Gamma & X-ray) or non-sterile

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 (excluding clause 4.3)

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 2777/11578-04/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.

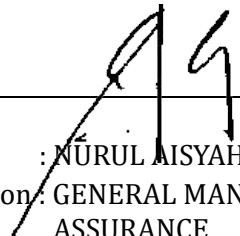
WE, HARTALEGA NGC SDN. BHD. HERewith DECLARE THAT THE ABOVE MENTIONED DEVICE IS IN CONFORMITY WITH REGULATION (EU) 2016/425 AND OTHER RELEVANT UNION LEGISLATION THAT PROVIDES FOR THE ISSUANCE OF THIS DECLARATION OF CONFORMITY. THIS DECLARATION IS ISSUED UNDER THE SOLE RESPONSIBILITIES OF THE MANUFACTURER.

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

EU Type – Examination Certificate Number : 2777/11578-04/E00-00

Place and Date of Issue : Hartalega NGC Sdn. Bhd./ 14th April 2025

Signed on Behalf of Hartalega NGC Sdn. :
Bhd.



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

ATTACHMENT I

Product or Trade Name	Reference Number
Nitrile Powder Free Examination Gloves (XS)	TBA
Nitrile Powder Free Examination Gloves (S)	TBA
Nitrile Powder Free Examination Gloves (M)	TBA
Nitrile Powder Free Examination Gloves (L)	TBA
Nitrile Powder Free Examination Gloves (XL)	TBA
Nitrile Powder Free Examination Gloves (XXL)	TBA