

UK DECLARATION OF CONFORMITY

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

UK Responsible Person : MDSS-UK RP Ltd.
6 Wilmslow Road, Rusholme,
Manchester M14 5TP,
United Kingdom

Device Name : Nitrile Powder Free Examination Gloves
≥ 2.5mil Powder Free Nitrile disposable five fingered
glove. Available in a standard minimum 240mm
length or a longer cuff variant of 280mm. Available in
sterile and 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 approved body SATRA Technology Centre with Approved Body Number of 0321 performed the UKCA type-examination (Module B) and issued the UKCA type-examination certificate AB0321/16710-02/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 Approved Body SATRA Technology Centre with Approved Body Number of 0321.

WE, HARTALEGA NGC SDN. BHD. HEREWITH DECLARE THAT THE ABOVE MENTIONED DEVICE IS IN CONFORMITY WITH REGULATION 2016/425 ON PERSONAL PROTECTIVE EQUIPMENT, AS AMENDED TO APPLY IN GB 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.



Innovation & Quality

Approved Body : SATRA Technology Centre Limited/ AB No. 0321
Wyndham Way, Telford Way,
Kettering, Northamptonshire,
NN16 8SD, United Kingdom

UKCA Type – Examination Certificate : AB0321/16710-02/E00-00
Number

Place and Date of Issue : Hartalega NGC Sdn. Bhd./ 22nd January 2024

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