

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 : Polyisoprene Powder Free Surgical Glove
Hand Specific, Polyisoprene, textured, powder free
surgical glove 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

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 AB0321/23144-01/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.

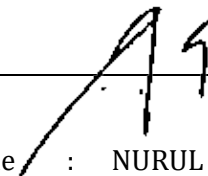
WE, HARTALEGA NGC SDN BHD HEREWITH DECLARE THAT THE ABOVE MENTIONED DEVICE IS IN CONFORMITY WITH REGULATION 2016/425 ON PERSONAL PROTECTIVE EQUIPMENT, AS AMENDED TO APPLY IN GB AND OTHER RELEVANT UNION LEGISLATION THAT PROVIDES FOR THE ISSUANCE OF THIS DECLARATION OF CONFORMITY. THIS DECLARATION IS ISSUED UNDER THE SOLE RESPONSIBILITIES OF THE MANUFACTURER.

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

UKCA Type - Examination Certificate : AB0321/23144-01/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
Polyisoprene Powder Free Surgical Glove (5.5)	TBA
Polyisoprene Powder Free Surgical Glove (7.5)	TBA
Polyisoprene Powder Free Surgical Glove (9)	TBA