

EC DECLARATION OF CONFORMITY

Manufacturer	: Hartalega NGC Sdn. Bhd. No. 1, Persiaran Tanjung Kawasan Perindustrian Tanjung 43900 Sepang, Selangor Darul Ehsan, Malaysia
European Representative	: Medical Device Safety Service (MDSS) Schiffgraben 41, 30175 Hannover, Germany
Device Name	: Antimicrobial Nitrile Powder Free Examination Gloves Five fingered, chlorinated, powder free nitrile gloves, with textured fingers and beaded cuff. Thickness ≥ 2.2 mil 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 2777/11723-03/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.

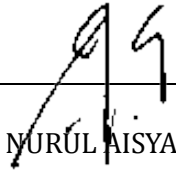
WE, HARTALEGA NGC SDN BHD HEREWITH DECLARE THAT THE ABOVE MENTIONED DEVICE IS IN CONFORMITY WITH REGULATION (EU) 2016/425 AND OTHER RELEVANT UNION LEGISLATION THAT PROVIDES FOR THE ISSUANCE OF THIS DECLARATION OF CONFORMITY. THIS DECLARATION IS ISSUED UNDER THE SOLE RESPONSIBILITIES OF THE MANUFACTURER.

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

EU Type – Examination Certificate Number : 2777/11723-03/E00-00

Place and Date of Issue : Hartalega NGC Sdn. Bhd./ 31st 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
Antimicrobial Nitrile Powder Free Examination Gloves (XS)	TBA
Antimicrobial Nitrile Powder Free Examination Gloves (S)	TBA
Antimicrobial Nitrile Powder Free Examination Gloves (M)	TBA
Antimicrobial Nitrile Powder Free Examination Gloves (L)	TBA
Antimicrobial Nitrile Powder Free Examination Gloves (XL)	TBA