Hartalega Innovation & Quality

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, antimicrobial powder free nitrile gloves, with textured fingers and beaded cuff. Thickness ≥2.2mil. Refer to Attachment I for Trade Name
Device Classification	:	Category III (Type C)
Standard Reference	:	EN 420: 2003+A1: 2009 EN ISO 374 – 1:2016+A1:2018 EN ISO 374 – 5:2016

The notified body SATRA Technology Europe Limited with Notified Body Number of 2777 are responsible for EU type-examination (Module B) certificate 2777/11723-01/E05-01 and the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module C2).

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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	:	2777/11723-01/E05-01
Place and Date of Issue	:	Hartalega NGC Sdn. Bhd./ 26th October 2022
Signed on Behalf of Hartalega NGC Sdn. Bhd.	:	

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

Rev 00

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ATTACHMENT I

Product or Trade Name	Reference Number
NITRIL LIOX	XS: 2284XS S: 2284S M: 2284M L: 2284L XL: 2284XL

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