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).

Heruntergeladen von Gast (IP 216.73.217.10) am 22.11.2026 um 18:15 Uhr · sana.swiss

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

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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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