



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 ≥ 2.2 mil.

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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Growing Global

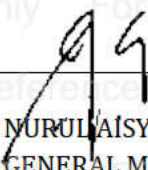
WE, HARTALEGA NGC SDN. BHD. HEREWITH DECLARE THAT THE ABOVE MENTIONED DEVICE IS IN CONFORMITY WITH REGULATION (EU) 2016/425 AND OTHER RELEVANT UNION LEGISLATION THAT PROVIDES FOR THE ISSUANCE OF THIS DECLARATION OF CONFORMITY. THIS DECLARATION IS ISSUED UNDER THE SOLE RESPONSIBILITIES OF THE MANUFACTURER.

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

ATTACHMENT I

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