



# 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  $\geq 2.2$ 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

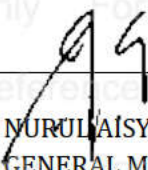
**WE, HARTALEGA NGC SDN. BHD. HEREWITH DECLARE THAT THE ABOVE MENTIONED DEVICE IS IN CONFORMITY WITH REGULATION (EU) 2016/425 AND OTHER RELEVANT UNION LEGISLATION THAT PROVIDES FOR THE ISSUANCE OF THIS DECLARATION OF CONFORMITY. THIS DECLARATION IS ISSUED UNDER THE SOLE RESPONSIBILITIES OF THE MANUFACTURER.**

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./ 26<sup>th</sup> 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<br>S: 2284S<br>M: 2284M<br>L: 2284L<br>XL: 2284XL |