

**EC DECLARATION OF CONFORMITY**

Manufacturer	: Hartalega Sdn. Bhd. C-G-9, Jalan Dataran SD1, Dataran SD, PJU 9, Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia
Facility	: Hartalega Sdn. Bhd. No. 7, Kawasan Perusahaan Suria, 45600 Bestari Jaya, Selangor Darul Ehsan, Malaysia
European Representative	: Medical Device Safety Service (MDSS) Schiffgraben 41, 30175 Hannover, Germany
Device Name	: Latex Polymer Coated Powder Free Examination Glove 5.5mil thickness latex polymer coated, powder free examination glove  Refer to Attachment I for Trade Name
Device Classification	: Category III (Type B)
Standard Reference	: EN 420: 2003+A1: 2009 EN ISO 374 - 1:2016+A1:2018 EN ISO 374 - 5:2016

**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 2777/12985-02/E00-00.**

**The PPE is subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the Notified body SATRA Technology Centre with Notified Body Number of 2777.**

**WE, HARTALEGA 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 : 2777/12985-02/E00-00

Place and Date of Issue : Hartalega Sdn. Bhd./ 16<sup>th</sup> February 2021

Signed on Behalf of Hartalega Sdn. Bhd. :



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Name : KUAN EU JIN  
Function : QUALITY MANAGEMENT  
REPRESENTATIVE