

EC Declaration of Conformity

We, the manufacturer

Hartalega NGC Sdn. Bhd.,
No. 1, Persiaran Tanjung,
Kawasan Perindustrian Tanjung,
43900 Sepang,
Selangor Darul Ehsan,
Malaysia

with European Representative

Medical Device Safety Service (MDSS)
Schiffgraben 41, 30175 Hannover,
Germany

Declares that the new PPE described hereafter

Category III

Laurel

≥ 2.2 mil Powder Free Nitrile disposable five fingered glove. Available in a standard minimum 240mm length or a longer cuff variant of 280mm

is in conformity with the relevant Union harmonisation legislation

PPE Regulation (EU) 2016/425

where such is the case, with the national standard transposing harmonized standard number

EN 420: 2003+A1: 2009

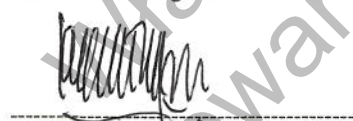
EN ISO 374 - 1:2016

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 2777/11578-01/E13-01.

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.

Done at Hartalega NGC Sdn. Bhd. on 01st August 2019.



Kuan Eu Jin
Quality Management Representative