

Reference No: BSB/RA/030-23

## EU DECLARATION OF CONFORMITY

We, Bergamot Sdn Bhd, located at No. 7 & 8, Jalan Sinaran 6, Kawasan Perindustrian Sinaran, 43000 Kajang, Selangor, Malaysia, hereby described product hereafter:

**Brand:** Bergamot

**Product:** Nitrile Powder Free Examination Gloves, Non-Sterile

**Model:** X Series

**Size:** XS, S, M, L and XL

**Basic UDI-DI:** 9555904NPFMA

It is declared that the above product:

- is in conformity with the provisions of Personal Protective Equipment Regulation (EU) 2016/425, under Category III risk per set out in Annex I, complying with the European standards EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 and EN ISO 374-5:2016. It is identical to PPE which is subject to the EU Type Examination (Module B) according to Annex V under certificate number 2777/23594-01/E00-00, issued by SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, D15 YN2P, Ireland (CE 2777).
- is subject to the conformity assessment procedure Module C2 set out in Annex VII of Regulation (EU) 2016/425, under the surveillance of the notified body SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, D15 YN2P, Ireland (CE 2777).

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, Bergamot Sdn Bhd.



Name: Kartika Hamdan  
Designation: Regulatory Affairs Manager  
Bergamot Sdn Bhd  
Place: Selangor, MALAYSIA  
Date: 11<sup>th</sup> September 2023



EU Authorized Representative:  
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