

## **EU DECLARATION OF CONFORMITY**

Manufacturer : Bergamot Sdn Bhd  
No. 7 & 8, Jalan Sinaran 6, Kawasan Perindustrian  
Sinaran, 43000 Kajang, Selangor, Malaysia  
SRN: MY-MF-000004005

EU Authorised : ASAP INNOVATIONS LIMITED  
Representative B3A Airport Business Park, Swords,  
Co. Dublin, K67 Y2E1, IRELAND  
SRN: IE-AR-000002548

Brand : Bergamot

Devices : Chemtough Nitrile Powder Free Examination Gloves

Model : X2260GR

GMDN : 56286

Size : XS, S, M, L and XL

Basic UDI-DI : 9555904NPFMA

Intended use : The nitrile examination glove is intended for medical purposes such as conducting medical examination, diagnostic and therapeutic procedures that is worn on the examiner's hand to prevent contamination between the examiner and patient. They are not intended for surgical work, i.e. as a substitute for surgeon's gloves. The medical device is intended for single use.

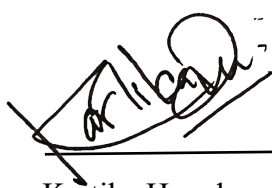
Declares under sole responsibility that the above medical devices are in conformity assessment route:

### **MDR**

- It is declared that the above product conforms with the provisions of Medical Device Regulations (EU) 2017/745, under Class I, Rule 5 of Annex VIII, complying with the European standards EN 455-1:2020, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009.

### **PPE**

- It is declared that the above product conforms 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 2777/23594-02/00-00, 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).



Kartika Hamdan  
Regulatory Affairs Manager  
Bergamot Sdn Bhd  
Place: Selangor, MALAYSIA  
Date: 16<sup>th</sup> December 2025

