BERGAMOT SDN BHD (1153028-V)
No. 7 & 8, Jalan Sinaran 6,
Kawasan Perindustrain Sinaran,
43000 Kajang, Selangor,
Malaysia
info@bergamot.com.my
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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
Brand:	Bergamot
Product Type & Basic UDI-DI:	Latex Powdered Examination Gloves (9555904LPSMS) Latex Powder Free Examination Gloves (9555904LPFLY) Nitrile Powder Free Examination Gloves (9555904NPFMA) Vinyl Powder Free Examination Gloves (9555904VPFNJ)
Classification and Rules:	Medical Device Regulations (EU) 2017/745, under Class I, Rule 5 of Annex VIII
European Standards:	EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009
EU Authorized Representative:	ASAP INNOVATIONS LIMITED 7, Saggart Lakes, Saggart, County Dublin, D24PY01, Ireland SRN: IE-AR-000002548

This EU declaration of conformity is issued under the sole responsibility of manufacturer, Bergamot Sdn. Bhd. We hereby declare that device covered by the present declaration is in conformity with the Medical Device Regulation (EU) 2017/745 and with the above-mentioned standards. All supporting documentation is retained at the premises of the manufacturer.

Place, Date of Declaration: MALAYSIA, 25th November 2021

Signature:

Mr. Chin Tze Kai
General Manager