



ASAP INTERNATIONAL SDN. BHD. (1157980-X)

No. 1, Jalan Sitar 33/6, Seksyen 33, 40400 Shah Alam, Selangor, Malaysia.

Tel: +6 03 5191 0166

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EU DECLARATION of CONFORMITY



Manufacturer:

ASAP International Sdn. Bhd.

No. 1, Jalan Sitar 33/6, Seksyen 33,
40400 Shah Alam, Selangor, Malaysia.

SRN: MY-MF-000004500



European Authorized
Representative:

ASAP INNOVATIONS LIMITED

7 Saggart Lakes, Saggart,
Dublin, D24 PY01, Ireland.

SRN: IE-AR-000002548

Products: Powdered Latex Examination Gloves
Basic UDI- DI: 955589090ASAPPPL5E

This EU declaration of conformity is issued under the sole responsibility of manufacturer. We hereby declare that the above product and as listed in Annex I is in conformity with the following European regulations and standards:

EU Regulation: Medical Device Regulation (EU) 2017/745
Classification: Class I according to Rule 1 and Rule 5 in Medical Device Regulation (EU) 2017/745, Annex VIII
Harmonised Standards: EN 455-1:2000
EN 455-2:2015
EN 455-3:2015
EN 455-4:2009
EU Regulation: Personal Protective Equipment Regulation (EU) 2016/425
Category: CAT I

Place, Date of Declaration: Malaysia., June 30, 2021

Signature:

Mr. Chin Tze Weng
Senior Global Business Development Manager





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ANNEX I

| PRODUCT BRAND | SIZE | PRODUCT CODE |
|---|-------|--------------|
| Lite Latex Powdered Examination Gloves (100's) | XS-XL | 10221-10225 |
| Lite Latex Powdered Examination Gloves (200's) | XS-XL | 10161-10165 |
| Latex Powdered Examination Gloves (100's) | XS-XL | 10411-10415 |
| Thick Latex Powdered Examination Gloves (100's) | XS-XL | 10421-10425 |
| X-Tra Thick Latex Powdered Examination Gloves (100's) | XS-XL | 10001-10005 |
| Super Thick Latex Powdered Examination Gloves (100's) | XS-XL | 10231-10235 |
| Fit Latex Powdered Examination Gloves (100's) | XS-XL | 10461-10465 |
| Green Latex Powdered Examination Gloves (100's) | XS-XL | 10471-10475 |
| Green Mint Latex Powdered Examination Gloves (100's) | XS-XL | 10131-10135 |

