



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: Powder Free Nitrile Examination Gloves

Series: ASAP X-Tra Lite & Lite Series

Basic UDI- DI: 955589090ASAPPFN4L

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 455-1:2020 EN 455-2:2015 EN 455-3:2015 EN 455-4:2009 |
| EU Regulation: | Personal Protective Equipment Regulation (EU) 2016/425 |
| Category: | CAT I |
| Harmonised Standards: | EN ISO 21420:2020 EN 374-1:2016+A1:2018 EN 374-4:2019 EN 374-5:2016 |

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 |
|---|--------|--------------|
| X-Tra Lite Series | | |
| X-Tra Lite True Blue Nitrile Powder Free Examination Gloves (100's) | XS-XL | 20611-20615 |
| X-Tra Lite True Blue Nitrile Powder Free Examination Gloves (200's) | XS-XXL | 20681-20686 |
| X-Tra Lite True Blue Nitrile Powder Free Examination Gloves (300's) | XS-XL | 20621-20625 |
| X-Tra Lite True Blue Nitrile Powder Free Examination Gloves (400's) | XS-XL | 20381-20385 |
| Lite Series | | |
| Lite Light Blue Nitrile Powder Free Examination Gloves (100's) | XS-XL | 20541-20545 |
| Lite Light Blue Nitrile Powder Free Examination Gloves (200's) | XS-XL | 20741-20745 |
| Lite Cobalt Blue Nitrile Powder Free Examination Gloves (100's) | XS-XL | 20551-20555 |
| Lite Cobalt Blue Nitrile Powder Free Examination Gloves (300's) | XS-XL | 20081-20085 |
| Lite Black Nitrile Powder Free Examination Gloves (100's) | XS-XL | 20271-20275 |
| Lite White Nitrile Powder Free Examination Gloves (100's) | XS-XL | 20851-20855 |

