



ASAP INTERNATIONAL SDN. BHD. (1157980-X)

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

Tel: +6 03 5191 0166

Fax: +6 03 5191 0702

Website: www.whyasap.com

Email: info@whyasap.com

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

Unit 7, The Courtyard, Fonthill Road,
Fonthill Business Park, D22 XA07, Dublin, Ireland
SRN: IE-AR-000002548

Products: Powder Free Nitrile Examination Gloves

Series: ASAP X-Tra Thick & Super Thick Series

Basic UDI- DI: 955589090ASAPPFN4L

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 III (Type C)
Harmonised Standards: EN ISO 21420:2020
EN ISO 374-1:2016+A1:2018
EN ISO 374-4:2019
EN ISO 374-5:2016

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 above European regulations and standards.

The product is in conformity with PPE (EU) Regulation 2016/425 with the EU Type Examination (Module B) and the conformity assessment procedure (Module C2) under Certificate Number: 2777/18245-02/E00-00 issued by Notified Body:





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SATRA Technology Europe Limited,
Bracetown Business Park, Clonee,
Dublin D15 YN2P, Republic of Ireland
Notified Body: 2777

Place, Date of Declaration: Malaysia., August 01, 2024

Signature:

Nurul Farhana
Regulatory Affairs





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ANNEX I

| PRODUCT BRAND | SIZE | PRODUCT CODE |
|--|-------|--------------|
| ASAP X-Tra Thick T-Grip | | |
| ASAP X-tra Thick Nitrile Powder Free Examination Gloves (Black) | XS-XL | 21181-21185 |
| ASAP X-tra Thick Nitrile Powder Free Examination Gloves (Blue) | XS-XL | 20711-20715 |
| ASAP X-tra Thick Nitrile Powder Free Examination Gloves (Black) Chemo Tested | XS-XL | 20101-20105 |
| ASAP X-Tra Thick X-Tended Nitrile Powder Free Examination Gloves (Black) | XS-XL | 20841-20845 |
| ASAP X-Tra Thick X-Tended Nitrile Powder Free Examination Gloves (Blue) | XS-XL | 20961-20965 |

