

ASAP INTERNATIONAL SDN. BHD. (1157980-X)

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EU DECLARATION of CONFORMITY

ASAP International Sdn. Bhd. Manufacturer:

No. 1, Jalan Sitar 33/6, Seksyen 33,

40400 Shah Alam, Selangor, Malaysia.

SRN: MY-MF-000004500

ASAP INNOVATIONS LIMITED EC REP

7 Saggart Lakes, Saggart, European Authorized Dublin, D24 PY01, Ireland. Representative:

SRN: IE-AR-000002548

Products: Powder Free Nitrile Examination Gloves

ASAP X-Tra Lite & Lite Series Series:

955589090ASAPPFN4L Basic UDI- DI:

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

CAT I Category:

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















