



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 Latex Examination Gloves
Basic UDI- DI: 955589090ASAPPFL4G

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

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 Powder Free Examination Gloves (100's)	XS-XL	10241-10245
Latex Powder Free Examination Gloves (100's)	XS-XL	10391-10395
Latex Powder Free Examination Gloves (200's)	XS-XL	10141-10145
Thick Latex Powder Free Examination Gloves (100's)	XS-XL	10431-10435
Thick Latex Powder Free CL Examination Gloves (100's)	XS-XL	10511-10515
X-Tra Thick Latex Powder Free Examination Gloves (100's)	XS-XL	10251-10255
Super Thick Latex Powder Free Examination Gloves (100's)	XS-XL	10261-10265
Super Thick Latex Powder Free DC Examination Gloves (100's)	XS-XL	10501-10505
Vitamin E Latex Powder Free Examination Gloves (100's)	XS-XL	10401-10405
X-Tra Lite X-Tended Latex Powder Free Examination Gloves (100's)	XS-XL	10271-10275
Lite X-Tended Latex Powder Free Examination Gloves (100's)	XS-XL	10281-10285
X-Tended Latex Powder Free Examination Gloves (100's)	XS-XL	10441-10445
Thick X-Tended Latex Powder Free Examination Gloves (100's)	XS-XL	10451-10455
X-Tra Thick X-Tended Latex Powder Free Examination Gloves (100's)	XS-XL	10301-10305
Pro X-Tended Latex Powder Free Examination Gloves (50's)	S-XXL	10112-10116

