



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

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



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

ASAP International Sdn. Bhd.
No.1 , Jalan Sitar 33/6
Seksyen 33
Shah Alam
Selangor
40400
Malaysia

Holds Certificate No:

FM 676151

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Manufacture, Marketing and Distribution of latex and nitrile examination gloves, face masks and sterile surgical gloves.



For and on behalf of BSI:

Michael Lam - Managing Director Assurance, APAC

Original Registration Date: 2017-11-13

Latest Revision Date: 2022-03-28

Effective Date: 2022-04-25

Expiry Date: 2025-04-24

Page: 1 of 1



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Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ASAP International Sdn. Bhd.
No.1 , Jalan Sitar 33/6
Seksyen 33
Shah Alam
Selangor
40400
Malaysia


Holds Certificate No:

MD 676150

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Manufacture, Marketing and Distribution of latex and nitrile examination gloves, face masks and sterile surgical gloves.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-12-13

Latest Revision Date: 2022-04-08

Effective Date: 2022-04-23

Expiry Date: 2025-04-22

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Certificate of Registration

ENVIRONMENTAL MANAGEMENT SYSTEM - ISO 14001:2015

This is to certify that:

ASAP International Sdn. Bhd.
No.1 , Jalan Sitar 33/6
Seksyen 33
Shah Alam
Selangor
40400
Malaysia

Holds Certificate No:

EMS 719589

and operates an Environmental Management System which complies with the requirements of ISO 14001:2015 for the following scope:

Provision in marketing and distribution of surgical gloves, examination gloves and face masks.



For and on behalf of BSI:

Michael Lam - Managing Director Assurance, APAC

Original Registration Date: 2019-12-27

Latest Revision Date: 2022-11-20

Effective Date: 2022-12-27

Expiry Date: 2025-12-26

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