

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

Page: 1 of 1



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Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +603 9212 9638.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 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 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 679348

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:

Poon Cheong Yuen, Managing Director

Original Registration Date: 2017-11-13

Latest Revision Date: 2022-03-28

Effective Date: 2022-04-25

Expiry Date: 2025-04-24

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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.

Malaysia Headquarters: Suite 29.01, Level 29, The Gardens North Tower, Mid Valley City, Lingkaran Syed Putra, 59200 Kuala Lumpur.

A Member of the BSI Group of Companies.



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

Medical Devices &
Basic UDI- DI:

- Powdered Latex Examination Gloves
(955589090ASAPPPL5E)
- Powder Free Latex Examination Gloves
(955589090ASAPPFL4G)
- Powder Free Nitrile Examination Gloves
(955589090ASAPPFN4L)

Classification:

Class I Medical Devices according to Medical Device
Regulation (EU) 2017/745, Annex VIII

Harmonised Standards:

EN455-1:2000, EN 455-2:2015, EN455-3:2015,
EN455-4:2009



European Authorized
Representative:

ASAP INNOVATIONS LIMITED

7 Saggart Lakes, Saggart,
Dublin, D24 PY01, Ireland.

SRN: IE-AR-000002548

This EU declaration of conformity is issued under the sole responsibility of manufacturer, ASAP International Sdn. Bhd. We hereby declare that device covered by the present declaration is in conformity with the Medical Device Regulation (EU) 2017/745 and with the above-mentioned standards. All supporting documentation is retained at the premises of the manufacturer.

Place, Date of Declaration: Malaysia., May 26, 2021

Signature:

Mr. Chin Tze Weng
Senior Global Business Development Manager



EU Type-Examination Certificate

Certificate number: 2777/11077-01/E03-01

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:

Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference: AS LPF
Description: Latex Examination powder free gloves.

Sizes:		Classification:		
6	XS	EN ISO 374-1:2016/Type B	Level	EN374-4:2013
7	S	40% Sodium Hydroxide	1	-46.1%
8	M	65% Nitric Acid	2	30.9%
9	L	37% Formaldehyde	2	-93.8%
10	XL	40% Hydrofluoric Acid	2	X
		EN ISO 374-5:2016		
		Resistance to Bacteria and Fungi	Pass	
		Resistance to Virus	Pass	

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHM0265590/1750/CL/A, CHM0265590/1750/CL/B, CHM0265590/1750/SPT
TUV: 7191154274-CHM16-01-RC

Signed on behalf of SATRA:



Hannah Coe



Geoff Graham

Date of issue: 17/04/2019**Expiry date:** 14/08/2023

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the certification and product are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
8. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
9. SATRA Technology reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.

EU Type-Examination Certificate

Certificate number: 2777/10648-04/E04-01

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
 Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

AS NPF

Description:

Nitrile examination powder free gloves

Sizes:

6 (XS) – 10 (XL)

Classification:

EN ISO 374-1:2016/Type B	Level	EN374-4:2013
37% Formaldehyde	6	3.1%
40% Sodium Hydroxide	6	-25.6%
30% Hydrogen Peroxide	2	17.0%

EN ISO 374-5:2016

Resistance to Bacteria and Fungi	Pass
Resistance to Virus	Pass

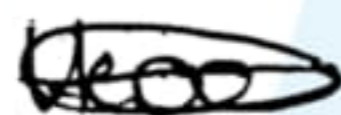
Standards/Technical specifications applied:

EN 420: 2003+A1: 2009; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:

SATRA: CHM0265112/1749/EN/A, CHM0265112/1749/EN/B, CHM0265112/1749/SPT, CHM0272621/1826/JS, CHM0275215/1836/LH, CHM0275215/1836/LH/E, CHM0275215/1836/LH/D, CHM0275215/1836/LH/A/Final
 TUV: 7191143339-CHM16-01-RC

Signed on behalf of SATRA:



Hannah Coe



Geoff Graham

Date of issue: 17/04/2019

Expiry date: 25/06/2023

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the certification and product are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
8. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
9. SATRA Technology reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.

Test Report No : CPSA/210663477-CA64942
Company : ASAP International Sdn. Bhd.
No.1, Jalan Sitar 33/6, Seksyen 33,
40400 Shah Alam, Selangor,
Malaysia.

TEST REPORT

Sample Description : Powder Free Latex Examination Gloves,
Device Basic UDI-DI: 955589090ASAPPFL4G
Brand Name : ASAP
Country of Origin : Malaysia
Country of Destination : All countries
Size : M
Quantity Tested : 200 pieces
Test Conducted : Freedom from holes
Test Method : EN455 Part 1:2020
Testing Period : 21 May 2021 – 04 June 2021

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5 Accept : 7 Found : 4

Result : Within AQL

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SGS (MALAYSIA) SDN BHD

****End of Report****



CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

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Test Report No : CPSA/210663478-CA64943
Company : ASAP International Sdn. Bhd.
No.1, Jalan Sitar 33/6, Seksyen 33,
40400 Shah Alam, Selangor,
Malaysia.

TEST REPORT

Sample Description : Powder Free Latex Examination Gloves,
Device Basic UDI-DI: 955589090ASAPPFL4G
Brand Name : ASAP
Country of Origin : Malaysia
Country of Destination : All countries
Size : M
Quantity Tested : 13 pieces per test
Test Conducted : Force at Break During Shelf Life and After Challenge
Test Method : EN 455 Part 2:2015
Ageing : 70 ± 2 Deg C for 168 hrs
Testing Period : 21 May 2021 – 04 June 2021

SIZE	SAMPLE NO.	Force at Break, N	
		<u>BEFORE AGING</u>	<u>AFTER AGING</u>
M	1	10.7	8.8
	2	10.7	10.0
	3	10.3	9.1
	4	11.1	9.5
	5	9.8	9.1
	6	10.6	9.8
	7	10.1	9.1
	8	10.7	9.1
	9	10.0	9.4
	10	10.7	10.0
	11	10.7	9.1
	12	9.4	8.4
	13	8.9	9.0
Median		10.6	9.1
Requirement		≥ 6.0	≥ 6.0

****End of Report****

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Test Report No : CPSA/210663479-CA64944
Company : ASAP International Sdn. Bhd.
No.1, Jalan Sitar 33/6, Seksyen 33,
40400 Shah Alam, Selangor,
Malaysia.

TEST REPORT

Sample Description : Powder Free Latex Examination Gloves,
 Device Basic UDI-DI: 955589090ASAPPFL4G
 Brand Name : ASAP
 Country of Origin : Malaysia
 Country of Destination : All countries
 Size : M
 Quantity Tested : 13 pieces
 Test Conducted : Dimensions
 Test Method : EN 455 Part 2:2015
 Testing Period : 21 May 2021 – 04 June 2021

Based on submitted samples, the following results obtained :-

Size	M	M	M	M	M	M	M	M	M	M	M	M	M	Median
Width Median: 95±10mm	95	94	95	95	94	95	94	95	95	95	95	94	95	95
Length Median: ≥ 240mm	251	248	251	252	252	254	250	252	252	251	251	250	251	251

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Test Report No : CPSA/210663480-CA64945
Company : ASAP International Sdn. Bhd.
 No.1, Jalan Sitar 33/6, Seksyen 33,
 40400 Shah Alam, Selangor,
 Malaysia

TEST REPORT

Sample Description : Powder Free Latex Examination Gloves,
 Device Basic UDI-DI: 955589090ASAPPFL4G
 Brand Name : ASAP
 Country of Origin : Malaysia
 Country of Destination : All countries
 Size : M
 Quantity Tested : 8 pieces
 Test Conducted : Aqueous Extractable Protein Content
 Test Method : EN455 Part 3:2015
 Testing Period : 21 May 2021 – 04 June 2021

EXTRACTABLE PROTEIN CONTENT

Analysis had been carried out as per your request. We report the following results:

SIZE	AQUEOUS EXTRACTABLE PROTEIN CONTENT, µg/g
M	23

Note: Detection limit = 10 µg/g

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Test Report No : CPSA/210663481-CA64946
Company : ASAP International Sdn. Bhd.
No.1, Jalan Sitar 33/6, Seksyen 33,
40400 Shah Alam, Selangor,
Malaysia.

TEST REPORT

Sample Description : Powder Free Latex Examination Gloves,
Device Basic UDI-DI: 955589090ASAPPFL4G
Brand Name : ASAP
Country of Origin : Malaysia
Country of Destination : All countries
Size : M
Quantity Tested : 5 pieces
Test Conducted : Powder Content
Test Method : EN455 Part 3:2015
Testing Period : 21 May 2021 – 04 June 2021

On testing the samples, the following results were obtained:-

SIZE

Average Powder Mass per Glove

M

0.12 mg

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Test Report No : CPSA/210663482-CA64947
Company : ASAP International Sdn. Bhd.
No.1, Jalan Sitar 33/6, Seksyen 33,
40400 Shah Alam, Selangor,
Malaysia

TEST REPORT

Sample Description : Powder Free Nitrile Examination Gloves,
Device Basic UDI-DI: 955589090ASAPPFN4L
Brand Name : ASAP
Country of Origin : Malaysia
Country of Destination : All countries
Size : M
Quantity Tested : 200 pieces
Test Conducted : Freedom from holes
Test Method : EN455 Part 1:2020
Testing Period : 21 May 2021 – 04 June 2021

Based on submitted samples, the following results obtained:-

Acceptable Quality Limit (AQL) : 1.5 Accept : 7 Found : 3

Result : Within AQL

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Test Report No : CPSA/210663483-CA64948
Company : ASAP International Sdn. Bhd.
No.1, Jalan Sitar 33/6, Seksyen 33,
40400 Shah Alam, Selangor,
Malaysia

TEST REPORT

Sample Description : Powder Free Nitrile Examination Gloves,
Device Basic UDI-DI: 955589090ASAPPFN4L
Brand Name : ASAP
Country of Origin : Malaysia
Country of Destination : All countries
Size : M
Quantity Tested : 13 pieces per test
Test Conducted : Force at Break During Shelf Life and After Challenge
Test Method : EN 455 Part 2:2015
Ageing : 70 ± 2 Deg C for 168 hrs
Testing Period : 21 May 2021 – 04 June 2021

SIZE	SAMPLE NO.	Force at Break, N	
		<u>BEFORE AGING</u>	<u>AFTER AGING</u>
M	1	8.4	8.1
	2	8.6	8.3
	3	9.1	8.9
	4	7.5	9.8
	5	8.2	8.8
	6	8.6	9.9
	7	8.9	8.9
	8	8.7	8.2
	9	8.1	8.2
	10	7.9	8.6
	11	9.4	9.1
	12	8.9	9.3
	13	8.5	9.3
Median		8.6	8.9
Requirement		≥ 6.0	≥ 6.0

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Test Report No : CPSA/210663484-CA64949
Company : ASAP International Sdn. Bhd.
 No.1, Jalan Sitar 33/6, Seksyen 33,
 40400 Shah Alam, Selangor,
 Malaysia

TEST REPORT

Sample Description : Powder Free Nitrile Examination Gloves,
 Device Basic UDI-DI: 955589090ASAPPFN4L
 Brand Name : ASAP
 Country of Origin : Malaysia
 Country of Destination : All countries
 Size : M
 Quantity Tested : 13 pieces
 Test Conducted : Dimensions
 Test Method : EN 455 Part 2:2015
 Testing Period : 21 May 2021 – 04 June 2021

Based on submitted samples, the following results obtained :-

Size	M	M	M	M	M	M	M	M	M	M	M	M	M	Median
Width Median: 95±10mm	96	96	96	96	96	96	96	96	96	95	95	96	96	96
Length Median: ≥ 240mm	245	240	246	244	241	245	241	246	242	240	248	249	245	245

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**** End of Report ****



CHEE TUCK CHOON
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Test Report No : CPSA/210663485-CA64950
Company : ASAP International Sdn. Bhd.
No.1, Jalan Sitar 33/6, Seksyen 33,
40400 Shah Alam, Selangor,
Malaysia

TEST REPORT

Sample Description : Powder Free Nitrile Examination Gloves,
Device Basic UDI-DI: 955589090ASAPPFN4L
Brand Name : ASAP
Country of Origin : Malaysia
Country of Destination : All countries
Size : M
Quantity Tested : 5 pieces
Test Conducted : Powder Content
Test Method : EN455 Part 3:2015
Testing Period : 21 May 2021 – 04 June 2021

On testing the samples, the following results were obtained:-

<u>SIZE</u>	<u>Average Powder Mass per Glove</u>
M	0.08 mg

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SGS (MALAYSIA) SDN BHD

**** End of Report ****



CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

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