bsi.

By Royal Charter

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
Effective Date: 2022-04-23
Latest Revision Date: 2022-04-08
Expiry Date: 2025-04-22

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Digitally signed by Granaci Boris
Date: 2022.11.25 16:30:17 EET
Reason: MoldSign Signature
Location: Moldova

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

QS 16122016 CB 16

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Art & Science of Amazing Protection

ASAP INNOVATIONS LIMITED (625986)

Registered Address: 7 Saggart Lakes, Saggart, Dublin D24 PY01, Ireland
Office: Unit 17, Ace Enterprise Park, Bawnogue Road, Dublin D22 V272, Ireland
Tel: +353 1 466 1660 Website: www.whyasap.ie Email: info@whyasap.ie

CE

CERTIFICATE OF CE (MDD) NOTIFICATION

We: ASAP Innovations Ltd.
7 Saggart Lakes, Saggart, Dublin D24 PY01, Ireland

HPRA Registered number: IE/CA01/R/GM/1268

Performed all notification duties and responsibilities according to the European Council Directive 93/42/EEC as the Authorised representative (EC REP) of:

Manufacturer: ASAP International SDN BHD (1157980-X)
No. 1, Jalan Sitar 33/6, Seksyen 33, 40400 Shah Alam, Selangor, Malaysia.

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE

The Manufacturer declares that the Class I devices comply with the directive including all essential requirements.

The Manufacturer has provided ASAP Innovations Ltd. with all the appropriate declarations as per the European Council Directive 93/42/EEC article 14 requirements, including the EC Declaration of Conformity (according to Annex VII) confirming that their Class I medical devices, as stipulated here below, are fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

The notification of the following medical devices has been completed by ASAP Innovations Ltd. with the Health Products Regularity Authority in Ireland (www.hpra.ie) on the 24/4/2020 in compliance with the European Council Directive 93/42/EEC – article 14 requirements.

CLASS I MEDICAL DEVICES: Please see Annex A – List of Devices (1 page, 4 devices)

As of the 24/04/2020 and as long as the manufacturer will continue complying with the hereabove mentioned requirements, they therefore:

- Are required to affix the CE marking on these devices.
- May place these devices in the European Community territory.

Sean Keller

Mr S. Keller, Managing Director
(authorised signature)

Date of issue: 24/04/2020

ASAP INNOVATIONS LIMITED (625986)
Registered Address: 7 Saggart Lakes, Saggart, Dublin D24 PY01, Ireland
Office: Unit 17, Ace Enterprise Park, Bawnogue Road, Dublin D22 V272, Ireland
Tel: +353 1 466 1660 Website: www.whyasap.ie Email: info@whyasap.ie

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Annex A – List of devices

No.	Make	Generic Name	Description and intended use	HPRA Registration number	GMDN Code	Class
1.	ASAP	ASAP Powder Free Nitrile Examination Gloves	Non-sterile, Powder Free, Ambidextrous, Single Use, Beaded Cuff, Finger Textured Surface or Textured Surface, Nitrile Synthetic Rubber Examination Glove. A powder free nitrile examination glove is a disposable glove made of nitrile synthetic rubber intended to wear on the hand for medical purposes to provide a barrier against potentially infections materials and other contaminants. In addition, this product demonstrated reduced potential for sensitizing users to chemical activities.	IE/CA01/R/ GM/1268/15016	56286	I
2.	ASAP	ASAP Powdered Latex Examination Gloves	Non-sterile, Ambidextrous, Single Use, Beaded Cuff, Textured or Smooth Surface, Natural Rubber Latex Examination Gloves. A powdered latex examination glove is a disposable glove made of natural rubber latex intended to wear on the hand for medical purposes to provide a barrier against potentially infections materials and other contaminants.	IE/CA01/R/ GM/1268/15018	47173	I
3.	ASAP	ASAP Latex Powder Free Examination Gloves	Non-sterile, Powder Free Ambidextrous, Single Use, Beaded Cuff, Textured Surface, Natural Rubber Latex Examination Gloves A powder free latex examination glove is a disposable glove made of natural rubber latex intended to wear on the hand for medical purposes to provide a barrier against potentially infections materials and other contaminants	IE/CA01/R/ GM/1268/15017	47172	I
4.	ASAP	ASAP Face Mask	Non-sterile, Surgical Face Mask with Filter, 3 ply, Ear loops. Intended to be used as isolation face mask, procedure mask and dental face mask.	IE/CA01/R/ GM/1268/17491	35177	I

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
EC REP 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

Issued to:

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

Notified Body: 2777

SATRA customer number: P0130

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:

6	XS
7	S
8	M
9	L
10	XL

Classification:

EN ISO 374-1:2016/Type B	**Level**	**EN374-4:2013**
40% Sodium Hydroxide	1	-46.1%
65% Nitric Acid	2	30.9%
37% Formaldehyde	2	-93.8%
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.

JOB REF NO.: 2021-05-21-009
DATE RECEIVED: MAY 21, 2021
DATE REPORTED: JUNE 04, 2021

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

SIGNED FOR AND ON BEHALF OF
SGS (MALAYSIA) SDN BHD

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

****End of Report****

JOB REF NO.: 2021-05-21-009
DATE RECEIVED: MAY 21, 2021
DATE REPORTED: JUNE 04, 2021

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

		Force at Break, N	
SIZE	**SAMPLE NO.**	**BEFORE AGING**	**AFTER AGING**
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****

SIGNED FOR AND ON BEHALF OF
SGS (MALAYSIA) SDN BHD

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

JOB REF NO.: 2021-05-21-009
DATE RECEIVED: MAY 21, 2021
DATE REPORTED: JUNE 04, 2021

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

****End of Report****

SIGNED FOR AND ON BEHALF OF
SGS (MALAYSIA) SDN BHD

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

JOB REF NO.: 2021-05-21-009
DATE RECEIVED: MAY 21, 2021
DATE REPORTED: JUNE 04, 2021

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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SGS (MALAYSIA) SDN BHD

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

****End of Report****

JOB REF NO.: 2021-05-21-009
DATE RECEIVED: MAY 21, 2021
DATE REPORTED: JUNE 04, 2021
PAGE: **1 of 1**

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

****End of Report****

SIGNED FOR AND ON BEHALF OF
SGS (MALAYSIA) SDN BHD

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

Art & Science of Amazing Protection

LATEX POWDER FREE EXAMINATION GLOVES

DATA SHEET

Art & Science of Amazing Protection

LATEX POWDER FREE

EXAMINATION GLOVES

Features

Micro textured surface
Provides excellent grip in all conditions with micro textures on the surface of the gloves.

Superior Strength
Capable to withstand against physical damage and harmful chemicals for increased hand security.

Enhanced dexterity
The enhanced dexterity and flexibility improve hand comfort for comfortable long period wear.

Powder Free
Retains donning efficiency through the use of smooth polymer interior that improves moist or dry Donning.

Ambidextrous
Fits well on both hands making it convenient and economical.

100% Latex
Latex powder-free with low protein rate to minimize exposure to allergens and skin irritants.

Application
ASAP Latex Powder Free gloves are recommended to be used in industries that require:

- Handling chemicals and hazardous objects in medical and construction industries
- Protection from blood and other fluid contaminants
- Overall protection for workers such as nurses, caregivers and other healthcare providers

Industry icons:

Examination & Surgery (E&S)

Research & Development (R&D)

Building & Construction (B&C)

Hygiene Matters
At ASAP, we are committed to hygiene control and quality assurance. Proper hygiene standard is practiced throughout the development of all ASAP products – from raw materials handling, processing, production, inspection, to our finished product to deliver high quality products while limiting the risk of cross contamination.

Look for the Hygiene Matters logo, quality and hygiene you can trust.

Art & Science of Amazing Protection

Technical Specification Sheet

Product Information

Series Number	10390
Description	Latex, Powder Free, Examination Gloves
Material	100% Latex Powder
Design	Ambidextrous, Textured & Beaded Cuff
Color	Natural
Quality Assurance	ISO 9001 ISO 13485 ISO 14001
Quality Control	EN 455-1:2000 EN 455-2:2015 EN 455-3:2015 EN 455-4:2009
Food Safe	Tested in accordance with EU standard EN 1186 under Food Commission Regulation 10/2011
Acceptable Quality Level (AQL)	1.5
Packaging	100 pcs per box, 10 boxes per carton
Handling & Storage	Keep out of direct sunlight; store in a cool and dry place
Country of Origin	Malaysia

Physical Properties Specification

Dimension Specification

Test	Particular		Specification
Dimension (mm)	Palm Width	Extra Small	75 ± 5
		Small	85 ± 5
		Medium	95 ± 5
		Large	105 ± 5
		Extra Large	115 ± 5
	Length		Min. 240
	Thickness (Single wall)	Cuff (25 ± 5 from bead)	Min. 0.06
		Palm (centre of palm)	Min. 0.08
		Finger (13 ± 3 from tip)	Min. 0.10
Physical Properties	Force at break (N)	Before Aging	Min. 6.0
		After Aging	Min. 6.0
Physical Appearance	Rolled beaded cuff Natural Latex Colour Textured Surface Ambidextrous		

Art & Science of Amazing Protection

LATEX POWDER FREE
EXAMINATION GLOVES

Packaging Dimensions

Inner	220 x 110 x 65mm
Carton	340 x 230 x 230mm

Product Size Codes

Small	Medium	Large	Extra Large
10392	10393	10394	10395

Instructions for Use

Use

This guideline is to be used in combination with the specific information that is mentioned on each packaging. These gloves are designed as single and transient use gloves and should be disposed of after use. The gloves are liquid proof, and can therefore be used for splash protection against certain chemicals. Kindly ensure the gloves are used for the designated purposes only.

Precautions

This product contains latex rubber which may cause an allergic reaction in some individuals. Do not expose these gloves to any person with a known or suspected sensitivity to nitrile rubber. If allergic reaction occurs, discontinue use immediately and consult a physician. These gloves should not be used for thermal or harsh chemical protection. They are not intended for application involving prolonged direct exposure to harsh chemical where heavy-duty industrial gloves are required.

Variability in material thickness, gloves integrity, chemical concentration, temperature, and length of exposure to chemicals may affect performance. User is responsible for determining glove suitability for individual application. Before usage, inspect the gloves for any faults or deficiencies. If the gloves are ripped or punctured during use, dispose them immediately.

Storage

Store in a dry place at room temperature. Open product should be shielded from exposure to direct sunlight, intense artificial light, x-ray machines, and other sources of zone.

Disposal

Dispose according to Local Authority Regulations. Landfill or incinerate under controlled conditions.

ASAP INTERNATIONAL SDN BHD

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