



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
(955589090ASAPPL5E)
- 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





Art & Science of Amazing Protection

ASAP INNOVATIONS LIMITED (625986)

Registered Address: 7 Saggart Lakes, Saggart, Dublin D24 PY01, Ireland

Office: Unit 7, The Courtyard, Fonthill Business Park, Dublin D22 XA07, Ireland

Tel: +353 1 466 1660

Website: www.whyasap.ie

Email: info@whyasap.ie



CERTIFICATE OF CE (MDR) NOTIFICATION

This is to certify that we: **ASAP Innovations Ltd.**
7 Saggart Lakes, Saggart, Dublin D24 PY01, Ireland

EUDAMED SRN: **IE-AR-000002548**

Performed all notification duties and responsibilities according to Regulation (EU) 2017/745 as the European 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.

EUDAMED SRN: **MY-MF-000004500**

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED REGULATION

The Manufacturer declares that the Class I devices comply with the Regulation including all general safety and performance requirements.

The Manufacturer has provided ASAP Innovations Ltd. with all the appropriate declarations as per the Regulation (EU) 2017/745 article 52 requirements, including the EU Declaration of Conformity (according to Annex IV) confirming that their Class I medical devices, as stipulated here below, are fulfilling the applicable requirements of the Regulation (EU) 2017/745 .

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 01/07/2021 in compliance with the Regulation (EU) 2017/745.

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

As of the 01/07/2021 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 Union and EEA territory

Mr S. Keller, Managing Director
(authorised signature)

Date of issue: 01/07/2021





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

Annex A – List of devices

No.	Make	Generic Name	Description and intended use	Basic UDI-DI	GMDN Code	Class
1.	ASAP	ASAP Powder Free Nitrile Examination Gloves	<p>Non-sterile, Powder Free, Ambidextrous, Single Use, Beaded Cuff, Finger Textured Surface or Textured Surface, Nitrile Synthetic Rubber Examination Glove.</p> <p>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.</p>	955589090ASAPP FN4L	56286	I
2.	ASAP	ASAP Powdered Latex Examination Gloves	<p>Non-sterile, Ambidextrous, Single Use, Beaded Cuff, Textured or Smooth Surface, Natural Rubber Latex Examination Gloves.</p> <p>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.</p>	955589090ASAPP PL5E	47173	I
3.	ASAP	ASAP Latex Powder Free Examination Gloves	<p>Non-sterile, Powder Free Ambidextrous, Single Use, Beaded Cuff, Textured Surface, Natural Rubber Latex Examination Gloves</p> <p>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</p>	955589090ASAPP FL4G	47172	I
4.	ASAP	ASAP Face Mask	<p>Non-sterile, Medical Face Mask with Filter. Intended to be used as isolation, procedure and dental face mask.</p>	955589090ASAP-FMTG	35177	I



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

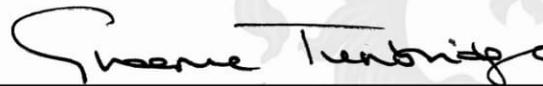
Holds Certificate No:

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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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 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.

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/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

SIGNED FOR AND ON BEHALF OF
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/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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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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