



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





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ASAP INNOVATIONS LIMITED (625986)

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

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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





ASAP INTERNATIONAL SDN. BHD. (1157980-X)

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Website: www.whyasap.com

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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

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





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: P20198

EU Type-Examination Certificate

Certificate number: 2777/18244-01/E00-00

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: ASAP REGULAR & THICK
Description: Five finger powder free nitrile examination glove.

Sizes:
6 – 10

Classification:	Level	EN 374-4: 2019 Degradation %
EN ISO 374-1: 2016+ A1		
2018/Type C		
40% Sodium hydroxide (K)	5	-17.7
30% Hydrogen peroxide (P)	0	12.9
37% Formaldehyde (T)	4	-22.7

EN ISO 374-5: 2016	Result
Protection against bacteria and fungi	Pass
Protection against viruses	Pass

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHM0303515/2042/LH/B, CHM0297929/2020/EN/F, CHM02979/2020/EN/A, CHM0297929/2020/SPT, CHM0303515/2042/LH/A

Signed on behalf of SATRA:

Geoff Graham

Date first issued: 26/08/2021
Date of issue: 26/08/2021
Expiry date: 26/08/2026

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. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified 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 manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. 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, or UK government.
9. 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.
10. SATRA 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 the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.



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PRODUCT SPECIFICATION

- Product Series** : ASAP Nitrile Powder Free Examination Glove
- Material** : Nitrile
- Features** : Nitrile Examination Glove, Powder Free, Non-Sterile, Ambidextrous, Finger Textured, Beaded Cuff, Single-Used Only
- Color** : Black / Light Blue / Light Violet
- Available Sizes** : Extra Small, Small, Medium, Large, Extra-Large
- Packing Mode** : 100 pieces per box, 10 boxes per carton
- Shelf Life** : 3 years

Test	Particular	Specification	Standard Compliance	
Dimension (mm)	Palm Width	Extra Small	75 ± 5	EN 455 Part 2: 2015
		Small	85 ± 5	
		Medium	95 ± 5	
		Large	105 ± 5	
		Extra Large	115 ± 5	
	Length	Min. 240		
	Thickness (Single wall)	Cuff (25 ± 5 from bead)	0.06 ± 0.02	In-house
Palm (center of palm)		0.07 ± 0.02	In-house	
Finger (13 ± 3 from tip)		0.09 ± 0.02	In-house	
Physical Properties*	Force at Break (N)	Before Ageing	Min. 6	EN 455 Part 2: 2015
		After Ageing	Min. 6	
Powder Content*	Powder free (mg/glove)	Max. 2	EN 455 Part 2: 2015	
Physical Appearance	Rolled beaded cuff Finger Textured Ambidextrous			

**Remark: Results applicable upon request

Handling and Storage

Store in a cool, dry and dust free facility or at room temperature. Exposed product should be shielded from humidity, direct sunlight, and fluorescent lighting.

Caution

This product contains substance 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. This product is not made with natural rubber latex.



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

SATRA reference: CHM0297929/2020/EN
/A

Your reference:

Date of report: 7th August 2020

Samples received: 13th July 2020

Date(s) work carried out: 28th July to 6th August
2020

TECHNICAL REPORT

Subject:

Chemical innocuousness testing in accordance with EN ISO 21420:2020 on gloves described as Nitrile Powder Free Examination Gloves, ASAP NPF.

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked \neq fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor $k=2$, which provides a coverage probability of approximately 95%.

Report signed by: Emma Norris
Position: Technologist Team Leader
Department: Chemical & Analytical Technology

WORK REQUESTED:

Samples of gloves described as Nitrile Powder Free Examination Gloves, ASAP NPF were received on the 13th July 2020 for testing in accordance with the innocuousness requirements of EN ISO 21420:2020 - Protective Gloves - General Requirements and Test Methods.

SAMPLE SUBMITTED:



Samples described as Nitrile Powder Free Examination Gloves, ASAP NPF- Blue Nitrile Powder Free 2.5g



Samples described as Nitrile Powder Free Examination Gloves, ASAP NPF- Black X-Tra Thick Nitrile Powder Free 5.0g



Samples described as Nitrile Powder Free Examination Gloves, ASAP NPF- Pink Nitrile Powder Free 3.8g



Samples described as Nitrile Powder Free Examination Gloves, ASAP NPF- Violet Blue Nitrile Powder Free 3.5g

- Blue Nitrile Powder Free 2.5g
- Black X-Tra Thick Nitrile Powder Free 5.0g
- Pink Nitrile Powder Free 3.8g
- Violet Blue Nitrile Powder Free 3.5g

CONCLUSIONS:

The samples of gloves described as Nitrile Powder Free Examination Gloves, ASAP NPF were assessed in accordance with the innocuousness requirements of EN ISO 21420:2020 and were found to meet with the requirement for pH value and PAHs.

Full results are reported in the following tables.

TESTS REQUIRED:

- EN ISO 21420:2020 - Clause 4.2 c) pH Value (EN ISO 3071:2006 - Textiles - Determination of pH of aqueous extract).
- EN ISO 21420:2020 - Clause 4.2 f) Polycyclic aromatic hydrocarbons (PAHs) (≠PD CEN ISO/TS 16190:2013 - Footwear - Critical substances potentially present in footwear and footwear components. Test method to quantitatively determine polycyclic aromatic hydrocarbons (PAH) in footwear materials in accordance with SATRA SOP CAT-047 (modified for the detection of those PAH listed in the appendices)).

RESULTS AND REQUIREMENTS:

EN ISO 3071:2006 - Textiles - Determination of pH of aqueous extract.

Date of determination: 28th July 2020

Sample	Method	pH Value	UoM	Pass/Fail
Blue, black, pink and violet blue gloves combined	ISO 3071:2006 (water extraction)	6.7	± 0.1	Pass
Requirement	pH value greater than 3.5 and less than 9.5			

The extraction solution temperature was 23°C and at pH 7.4

#PD CEN ISO/TS 16190:2013 - Footwear - Critical substances potentially present in footwear and footwear components. Test method to quantitatively determine polycyclic aromatic hydrocarbons (PAH) in footwear materials in accordance with SATRA SOP CAT-047 (modified for the detection of those PAH listed in the appendices)

Testing completed 31st July 2020

Analysed by Gas Chromatography with Mass Spectrometry (GC-MS)

Sample	PAHs detected (mg/kg)	Pass/Fail
Blue, pink and violet blue gloves combined	0.3mg/kg of benzo(b)fluoranthene detected <0.2 of each remaining PAH listed in the appendices	Pass
Black gloves	<0.2 (of each PAH listed in the appendices)	Pass
Requirement	≤ 1mg/kg (0.0001% by mass of this component) of each PAH listed in the appendices	

APPENDICES:

Restricted polycyclic aromatic hydrocarbons (PAHs)

PAH	CAS Number
Benzo[a]pyrene	50-32-8
Benzo[e]pyrene	192-97-2
Benzo[a]anthracene	56-55-3
Chrysene	218-01-9
Benzo[b]fluoranthene	205-99-2
Benzo[j]fluoranthene	205-82-3
Benzo[k]fluoranthene	207-08-9
Dibenzo[a,h]anthracene	53-70-3

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

- 1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- 1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.
- 1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing
- 1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.
- 1.5 All references in these terms and conditions to:
 - (a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
 - (b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
 - (c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).
- 1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.
- 1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

- 2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- 2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.
- 2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.
- 2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.
- 2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- 2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- 2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.
- 2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

- 3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.
- 3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.
- 3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.
- 3.4 The Client agrees and acknowledges that SATRA retains any and all proprietary rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.
- 3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionsitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

- 4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.
- 4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Client's failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

- 5.1 Reports are issued on the basis of information, documents and/or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- 5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:
 - (a) death or personal injury caused by its negligence or the negligence of its employees or agents;
 - (b) fraud or fraudulent misrepresentation;
 - (c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
 - (d) defective products under the Consumer Protection Act 1987; or
 - (e) any other liability which cannot be limited or excluded by applicable law.
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- 5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

6. MISCELLANEOUS

- 6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- 6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.
- 6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- 6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

- 7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.
 - 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
 - 7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.
 - 7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.
 - 7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

- 8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

- Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.
- 9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.
- 10. PROVISION OF SERVICES**
- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.
- 10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.
- 10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.
- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- 10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.
- 10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.
- Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.
- Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.
- 10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.
- 10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.
- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.
- 11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES**
- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.
- 11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.
- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.
- 11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.
- 12. DELIVERY AND NON-DELIVERY OF GOODS**
- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- 12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.
- 12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.
- 12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- 12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).
- 13. RISK/TITLE OF GOODS**
- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
- b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when: -
- a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
- b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- a) hold the Goods as SATRA's bailee;
- b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
- c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
- b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
- c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.
- 13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.
- 14. PATENTS**
- 14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.
- 15. WARRANTY OF GOODS**
- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.
- 16. DEFECTIVE GOODS**
- 16.1 Subject to clauses 16.6 and 16.7 if:
- a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
- b) SATRA is given a reasonable opportunity of examining such Goods; and
- c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
- b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or
- c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
- b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

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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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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**** End of Report ****



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

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