Art & Science of Amazing Protection

ASAP INNOVATIONS LIMITED (625986)
Registered Address: 7 Saggart Lakes, Saggart, Dublin D24 PY01, Ireland
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Tel: +353 1 466 1660 Website: www.whyasap.ie Email: info@whyasap.ie

CE

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 territory**

Digitally signed by Graur Boris
Date: 2023.11.15 12:01:25 EET
Reason: MoldSign Signature
Location: Moldova

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	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.	955589090ASAPPFN4L	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.	955589090ASAPPPL5E	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	955589090ASAPPFL4G	47172	I
4.	ASAP	ASAP Face Mask	Non-sterile, Medical Face Mask with Filter. Intended to be used as isolation, procedure and dental face mask.	955589090ASAP-FMTG	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.