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.

Digitally signed by Granaci Boris
Date: 2023.08.25 14:55:43 EEST
Reason: MoldSign Signature
Location: Moldova

Mr S. Keller, Managing Director
(authorised signature)

Date of issue: 24/04/2020

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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)
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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

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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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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