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 and EEA territory**

Mr S. Keller, Managing Director
(authorised signature)

Date of issue: **01/07/2021**

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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