



Art & Science of Amazing Protection

ASAP INNOVATIONS LIMITED (625986)

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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.

Mr S. Keller, Managing Director
(authorised signature)

Date of issue: 24/04/2020



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	<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>	IE/CA01/R/ GM/1268/15016	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>	IE/CA01/R/ GM/1268/15018	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>	IE/CA01/R/ GM/1268/15017	47172	I
4.	ASAP	ASAP Face Mask	<p>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.</p>	IE/CA01/R/ GM/1268/17491	35177	I