



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

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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/1380

Performed all notification duties and responsibilities according to the European Council Directive 93/42/EEC as the Authorised representative (EC REP) of:

Manufacturer: Bergamot Sdn. Bhd(1153028-V)

No. 31, Jalan Balakong Jaya 4, Taman Industri Balakong Jaya, 43300 Seri Kembangan, 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 25/5/2020 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 25/05/2020 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: 25/05/2020





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Annex A – List of devices

No.	Make	Generic Name	Description and intended use	HPRA Registration number	GMDN Code	Class
1.	Bergamot	Bergamot 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/1380/17593	56286	I
2.	Bergamot	Bergamot 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/1380/17594	47173	I
3.	Bergamot	Bergamot 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/1380/17595	47172	I
4.	Bergamot	Bergamot 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/1380/17596	35177	I

