

## ASAP INTERNATIONAL SDN. BHD. (1157980-X)

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## 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 Wena

Senior Global Business Development Manager















