

EU DECLARATION OF CONFORMITY

Regulatory basis. This Declaration of Conformity is issued under the sole responsibility of the manufacturer in accordance with Regulation (EU) 2016/425 on personal protective equipment.

Manufacturer

Name & address
ASAP International Sdn. Bhd.
No. 1, Jalan Sitar 33/6, Seksyen 33,
40400 Shah Alam, Selangor, Malaysia

Single Registration Number (SRN) MY-MF-000004500

EU Authorised Representative

Name & address
CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo, 18, 29006 Málaga, Spain

Single Registration Number (SRN) ES-AR-000000293

PPE identification

Personal Protective Equipment
ASAP Nitrile Powder Free Examination Glove
(models listed in Annex I)

PPE Category Category III (Type C)

Harmonised Standards
EN ISO 21420:2020
EN ISO 374-1:2016+A1:2018
EN ISO 374-4:2019
EN ISO 374-5:2016

Intended use (PPE)
Single-use protective gloves to protect the wearer against
chemical and microbiological risks (within IFU limitations).

Regulatory statement. The manufacturer declares that the Personal Protective Equipment specified above and listed in Annex I conforms to the applicable provisions of Regulation (EU) 2016/425 and the standards/specifications referenced herein. All supporting documentation is retained at the premises of the manufacturer.

The PPE described above is in conformity with Regulation (EU) 2016/425 on personal protective equipment. EU type-examination (Module B) has been carried out and the EU type-examination certificate No. 2777/18177-02/E00-00 has been issued by the notified body:

SATRA Technology Europe Limited
Bracetown Business Park, Clonee,
Dublin D15 YN2P, Republic of Ireland
Notified Body: 2777

The PPE is subject to the conformity assessment procedure Module C2 (conformity to type based on internal production control plus supervised product checks at random intervals) under the surveillance of Notified Body 2777.

Place and date of issue: Shah Alam, Malaysia — 13 April 2026

Signed by ASAP International Sdn. Bhd. designated representative:

Name / Title: Nurul Farhana / Regulatory Affairs Specialist

Signature: 

ANNEX I

PRODUCT MODEL	SIZE	PRODUCT CODE
ASAP Lite Nitrile Powder Free Examination Gloves (Blue)	XS-XL	20541-C3 – 20545-C3
ASAP Lite Nitrile Powder Free Examination Gloves (White)	XS-XL	20851-C3 – 20855-C3
ASAP Nitrile Powder Free Examination Gloves (Blue)	XS-XL	20571-C3 – 20575-C3
ASAP Nitrile Powder Free Examination Gloves (Black)	XS-XL	20531-C3 – 20535-C3
ASAP Nitrile Powder Free Examination Gloves (Pink)	XS-XL	20661-C3 – 20665-C3