



Alliance Rubber Products Sdn. Bhd. (52446-U)

Lot 2716 & 2720, Mk 7, Kawasan Perindustrian Bukit Panchor, 14300 Nibong Tebal, Pulau Pinang, Malaysia.
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EC DECLARATION OF CONFORMITY

Manufacturers Name and Address: Alliance Rubber Products Sdn. Bhd.

Lot 2716 & 2720, MK 7,

Kawasan Perindustrian Bukit Panchor,

14300 Nibong Tebal, Pulau Pinang, Malaysia

SRN (Single Registration Number): MY-MF-000008415

Authorized Representative Name and Address (if applicable): Obelis s.a.

Bd. Général Wahis 53

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We, Alliance Rubber Products Sdn. Bhd. hereby declare under our sole responsibility that the product(s) listed in Annex comply(ies) with the provisions of the European Medical Device Regulation-MDR 2017/745.

The devices are Class 1 following Rule 1 of Annex VIII of the European Medical Device Regulation-MDR 2017/745.

We hereby also declare under our sole that the product(s) listed in Annex comply(ies) with the provisions of PPE Regulation (EU) 2016/425.

The present declaration is in conformity with European Medical Device Regulation-MDR 2017/745 and PPE Regulation (EU) 2016/425.

Pulau Pinang, Malaysia, 18th August 2021

Issue place and date


<Chua Hooi Koon>
<CEO>



Attachments – DoC MDR – ID # 00060320 – V2 – xxx/2020

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Products are PPE approved
under Regulation (EU)
2016/425 Module D



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Annex - List of Devices Covered by the Declaration of Conformity

#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN/ CND code
1	Powder Free Nitrile Examination Gloves	NGPF	Powder Free Nitrile Examination Gloves	The device is a sheath made by carboxylated butadiene acrylonitrile copolymer that fits over the fingers and palm area to provide barrier protection for both the donned person and the person / material that is handled	I	I	955586710NGPFR8	56286
2	Powder Free Latex Examination Gloves	LGPF	Powder Free Latex Examination Gloves	The device is a sheath made by thin natural rubber latex that fits over the fingers and palm area to provide barrier protection for both the donned person and the person / material that is handled	I	I	955586710LGPFQS	47172
3	Powdered Nitrile Examination Gloves	NG	Powdered Nitrile Examination Gloves	The device is a sheath made by carboxylated butadiene acrylonitrile copolymer that fits over the fingers and palm area to provide barrier protection for both the donned person and the person / material that is handled	I	I	955586710NG4J	56287
4	Powdered Latex Examination Gloves	LG	Powdered Latex Examination Gloves	The device is a sheath made by thin natural rubber latex that fits over the fingers and palm area to provide barrier protection for both the donned person and the person / material that is handled	I	I	955586710LG4C	47173

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