E.A.R.-CERTIFICATE

(Article 11 of the REGULATION (EU) 2017/745 on Medical Devices)

ref. no.: TMV 1232-2021

Order No.: OG 1058-2021

date: 14/04/2021

Manufacturer:	Longcane Industries Sdn Bhd Lot 5783, Jalan Seladang, Alma, 14000 Bukit Mertajam, Penang Malaysia	Facilities:	Longcane Industries Sdn Bhd Lot 5783, Jalan Seladang, Alma, 14000 Bukit Mertajam, Penang Malaysia

Product Categories: Please See Annex A - List of Devices (3 Devices, 2 Pages)

Models: Please See Annex A - List of Devices (3 Devices, 2 Pages)

The European Authorized Representative Center Obelis s.a. declares it will assume the role of European Authorised Representative of the aforementioned manufacturer, provided that the manufacturer complied with the terms and conditions set out in the EAR Services Agreement, which entered into force on 1 March 2021, and the Mandate is signed by both parties in accordance with article 11.2 of the MDR (EU) 2017/745.

G. ELKAYAM C.E.O.

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Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified.

*This certificate is not a confirmation of product notification nor an approval to place products on the market.
**This certificate will become void automatically upon termination of the EAR agreement or rejection of the products from Obelis PRRC

* This is not a CE mark and is only provided as a template for informational purposes.

Order No.: OG 1058-2021
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Annex A - List of Devices

(REGULATION (EU) 2017/745 on medical devices)

#	GMDN/EMDN	Generic device name (including BASIC UDI)	Commercial Name	Intended use	Class	Legacy (Y/N)	Mandated	Mandate Starting Date	Mandated Vigilance (Y/N)
1.	56286	955548260800LG	Nitrile examinaton glove, powder free	To protect hands from external factor, for medical, cleaning, examination, disposable purposes.	1	N	N	n/a	Y
2.	34020	955548260850LX	Latex examination glove, powder free	To protect hands from external factor, for medical, cleaning, examination, disposable purposes.	1	N	N	n/a	Y
3	34020	955548260880M8	Latex examination glove, powdered	To protect hands from external factor, for medical, cleaning, examination, disposable purposes.	1	N	N	n/a	Y

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (Annex VII - REGULATION (EU) 2017/745)

Signature:

Date:

Stamp: