

E.A.R.-CERTIFICATE

(ARTICLE 11 OF THE REGULATION (EU) 2017/745 ON MEDICAL DEVICES)

REF. NO.: MQ 1460-2021

ORDER NO.: MQ 8814-2020

DATE: 03/08/2021

MANUFACTURER:	ECO MEDI GLOVE SDN BHD Lot 23826, Jalan Tembaga Kuning, Kamunting Raya Industrial Estate, 34600 Taiping Perak, Malaysia	FACILITIES:	ECO MEDI GLOVE SDN BHD Lot 26910, Kawasan Perindustrian Kamunting Raya, Mukim Assam Kumbang, 34600 Taiping Perak, Malaysia
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PRODUCT CATEGORIES: Please See Annex to MDR EAR Certificate (10 Devices, 4 Pages)

MODELS: Please See Annex to MDR EAR Certificate (10 Devices, 4 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 January 1st 2020*, and the Mandate is signed by both parties in accordance with article 11.2 of the MDR (EU) 2017/745.



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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.



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ANNEX to MDR EAR Certificate

Order No.: MQ 8814-2020

Reference No.: MQ 1460-2021

Manufacturer: ECO Medi Glove Sdn. Bhd.

Country: Malaysia

#	GMDN/ EMDN	Generic device name (including BASIC UDI)	Commercial Name of device	Intended use	Class	Rule	Legacy (Y/N)	Mandated (Y/N)	Mandate starting date	Mandated Vigilance (Y/N)
1	56286	Powder Free Nitrile Examination Glove (EMNE Series) Basic UDI#: 955101241NIT-AD- NS-NLELG	ECO Powder Free Nitrile Examination Glove	A Nitrile Patient Examination Glove is a single use device intended for Medical Purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. Glove is a considered as an invasive device with respect to body orifices. It is not intended to be used during surgically invasive procedure. Surface contacting nature of subject devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.	1	5	N	N	-	Y
2	56286	Powder Free Nitrile Examination Glove (RSNE Series) Basic UDI#: 955101241NIT-AD- NS-NLELG	RS Safe Powder Free Nitrile Examination Glove	A Nitrile Patient Examination Glove is a single use device intended for Medical Purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. Glove is a considered as an invasive device with respect to body orifices. It is not intended to be used	1	5	N	N	-	Y

				<p>during surgically invasive procedure.</p> <p>Surface contacting nature of subject devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.</p>						
3	56286	<p>Powder Free Nitrile Examination Glove (RSNE Series)</p> <p>Basic UDI#: 955101241NIT-AD-NS-NLELG</p>	RS Blue Powder Free Nitrile Examination Glove	<p>A Nitrile Patient Examination Glove is a single use device intended for Medical Purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.</p> <p>Glove is a considered as an invasive device with respect to body orifices. It is not intended to be used during surgically invasive procedure.</p> <p>Surface contacting nature of subject devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.</p>	1	5	N	N	-	Y
4	47509	<p>Powder Free Latex Examination Glove (EMLE Series)</p> <p>Basic UDI#: 955101241LAT-AD-NS-NLE8N</p>	EMG Powder Free Latex Examination Glove	<p>A Latex Patient Examination Glove is a single use device intended for Medical Purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.</p> <p>Glove is a considered as an invasive device with respect to body orifices. It is not intended to be used during surgically invasive procedure.</p> <p>Surface contacting nature of subject devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.</p>	1	5	N	N	-	Y
5	56286	Powder Free Nitrile Examination Glove (RSNE Series)	RS Powder Free Nitrile	<p>A Nitrile Patient Examination Glove is a single use device intended for Medical Purpose that is worn on the</p>	1	5	N	N	-	Y

		Basic UDI#: 955101241NIT-AD-NS-NLELG	Examination Glove	<p>examiner's hand or finger to prevent contamination between patient and examiner.</p> <p>Glove is considered as an invasive device with respect to body orifices. It is not intended to be used during surgically invasive procedure.</p> <p>Surface contacting nature of subject devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.</p>						
6	47509	<p>Non Sterile Cleanroom Glove (RSNS 200 Series)</p> <p>Basic UDI#: 955101241LAT-AD-NS-NLE8N</p>	RS Latex Glove	Non Sterile Cleanroom Glove for Single used	1	5	N	N	-	Y
7	61631	<p>Powder Free Sterile Nitrile Examination Glove (RSNE Series)</p> <p>Basic UDI#: 955101241NIT-AD-S-NLEPW</p>	RSSAFE Sterile Nitrile Examination Glove	A Powder Free Sterile Nitrile Examination Glove, is a sterile disposable device of synthetic polymer that would not contain of any protein trace and is intended to be worn on the hand finger (s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.	1s	5	N	N	-	Y
8	56286	<p>Non Sterile Cleanroom Glove (RSNS 400 Series)</p> <p>Basic UDI#: 955101241NIT-AD-NS-NLELG</p>	RS Nitrilstat	Non Sterile Cleanroom Glove for Single used	1	5	N	N	-	Y
9	47509	<p>Powder Free Latex Examination Glove (RSLE Series)</p> <p>Basic UDI#: 955101241LAT-AD-NS-NLE8N</p>	RSCARE Powder Free Latex Examination Glove	A Latex Patient Examination Glove is a single use device intended for Medical Purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	I	5	N	N	-	Y

				Glove is a considered as an invasive device with respect to body orifices. It is not intended to be used during surgically invasive procedure.						
				Surface contacting nature of subject devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.						
10	47509	Powder Free NR Latex Surgical Glove (EMLS Series) Basic UDI#: 955101241LAT-HS-S-NLERY	EMG Powder Free NR Latex Surgical Glove	A Powder Free NR Latex Surgical Glove, Sterile is a disposable device intended for Medical Purpose that is worn on the examiner's hands or finger to prevent contamination patient and examiner.	Ila	6	N	N	-	Y

Date

CEO Of Obelis

Gideon Elkayam

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01 (Aug 12, 2021 14:52 GMT+2)

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