



## 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

ECO MEDI GLOVE SDN BHD MANUFACTURER:

> 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,

DATE: 03/08/2021

34600 Taiping Perak, Malaysia

**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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Mr. G. Elkayam CEO 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

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## **ANNEX to MDR EAR Certificate**

Manufacturer: ECO Medi Glove Sdn. Bhd.

**Country:** Malaysia

Order No.: Mo	Q 8814-2020
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**Reference No.:**MQ 1460-2021

EMDN (including BASIC UDI) Name of device  1 56286 Powder Free Nitrile Examination Glove (EMNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  2 56286 Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile Examination Glove is a single use device intended for Medical Purpose that is worn on the examiner's hand or finger to prevent contamination 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 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 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 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 intended for Medical Purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.											
device    1   56286   Powder Free Nitrile Examination Glove (EMNE Series)   ECO Powder Free Nitrile Examination Basic UDI#: 955101241NIT-AD-NS-NLELG   ECO Powder Free Nitrile Examination Glove   1   5   N   N   -   Y	#	GMDN/	Generic device name	Commercial	Intended use	Class	Rule	Legacy	Mandated	Mandate	Mandated
Co Powder Free Nitrile Examination Glove (EMNE Series)		EMDN	(including BASIC UDI)	Name of				(Y/N)	(Y/N)	starting	Vigilance
1 56286 Powder Free Nitrile Examination Glove (EMNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG    Powder Free Nitrile Examination Glove (EMNE Series)   Sa 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   Glove   Surface contacting nature of subject devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.    Surface contacting nature of subject devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.    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.    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.    Solve   Solv			(manufacture)						( - , ,	_	_
Glove (EMNE Series) Basic UDI#: 955101241NIT-AD- NS-NLELG  Free Nitrile Examination Glove  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.  RS Safe Powder Free Nitrile Examination Glove (RSNE Series)  NS-NLELG  RS Safe Powder Free Nitrile Examination Glove is a single use device intended for Medical Purpose that is worn on the examination between patient and examiner.  Glove is a considered as an Glove is a considered as an examination between patient and examiner.	4	FC00C	Davidar Franklitvila Evansination		A Nitrila Dationt Evansination Clave	4	F	N	NI NI	uate	(1/14)
Basic UDI#: 955101241NIT-AD- NS-NLELG    Basic UDI#: 955101241NIT-AD-   Solve   Salve   Salve	1	56286				1	5	IN	I N	-	Y
Basic UDI#: 955101241NIT-AD-NS-NLELG  Glove   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.  2   56286   Powder Free Nitrile Examination Glove (RSNE Series)   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			Glove (Elvine Series)								
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 s24 Hours.  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 s24 Hours.  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			Pagia LIDI#: 055101241NIT AD								
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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.  Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile 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			INO-INELEG								
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.  Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile 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											
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during surgically invasive procedure.  Surface contacting nature of subject devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.  2 56286 Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile 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											
Surface contacting nature of subject devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.  2 56286 Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile 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								5A			
Surface contacting nature of subject devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.  2 56286 Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile 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					during surgically invasive procedure.						
devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.  2 56286 Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile 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					Surface contacting nature of subject						
a membrane. Contact Duration is limited for ≤24 Hours.  2 56286 Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile 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											
2 56286 Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD-NS-NLELG  RS Safe Powder Free Nitrile 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					membrane. Contact Duration is						
Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD- NS-NLELG  Powder Free Nitrile Examination Glove  Redical Purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.  Glove is a considered as an					limited for ≤24 Hours.						
Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD- NS-NLELG  Powder Free Nitrile Examination Glove  Redical Purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.  Glove is a considered as an				\							
Basic UDI#: 955101241NIT-AD- NS-NLELG  Nitrile Examination Glove  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	2	56286				1	5	N	N	-	Υ
Basic UDI#: 955101241NIT-AD- NS-NLELG  Examination Glove  examiner's hand or finger to prevent contamination between patient and examiner.  Glove is a considered as an			Glove (RSNE Series)						/		
NS-NLELG  Glove  contamination between patient and examiner.  Glove is a considered as an			D : UBW 05540404417 4B								
examiner.  Glove is a considered as an											
Glove is a considered as an			NS-NLELG	Glove							
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invasive device with respect to body					Glove is a considered as an						
					invasive device with respect to body						
orifices. It is not intended to be used											

			during surgically invasive procedure.
		RIZ	Surface contacting nature of subject devices. Intact skin and mucosal membrane. Contact Duration is limited for ≤24 Hours.
3	56286	Powder Free Nitrile Examination Glove (RSNE Series)  Basic UDI#: 955101241NIT-AD- NS-NLELG  RS Blue Powder Free Nitrile Examination Glove	Medical Purpose that is worn on the
4	47509	Powder Free Latex Examination Glove (EMLE Series)  Basic UDI#: 955101241LAT-AD- NS-NLE8N  EMG Powde Free Latex Examination Glove	is a single use device intended for
5	56286	Powder Free Nitrile Examination Glove (RSNE Series)  RS Powder Free Nitrile	A Nitrile Patient Examination Glove 1 5 N N - Y is a single use device intended for Medical Purpose that is worn on the

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		Basic UDI#: 955101241NIT-AD- NS-NLELG	Examination Glove	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.	Sin				
6	47509	Non Sterile Cleanroom Glove (RSNS 200 Series)  Basic UDI#: 955101241LAT-AD- NS-NLE8N	RS Latex Glove	Non Sterile Cleanroom Glove for Single used	1 5	SA I	N	-	Y
7	61631	Powder Free Sterile Nitrile Examination Glove (RSNE Series) Basic UDI#: 955101241NIT-AD-S- NLEPW	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		Y
8	56286	Non Sterile Cleanroom Glove (RSNS 400 Series)  Basic UDI#: 955101241NIT-AD- NS-NLELG	RS Nitrilstat	Non Sterile Cleanroom Glove for Single used	1 5	N	N	-	Y
9	47509	Powder Free Latex Examination Glove (RSLE Series) Basic UDI#: 955101241LAT-AD- NS-NLE8N	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.	1 5	N	N	-	Y

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	Ż		Glove is a considered as an invasive device with respect to body orifices. It is not intended to be used during surgically invasive procedure.	

				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.	lla	6 N	N	-	Y
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**Date** 

**CEO Of Obelis** 

**Gideon Elkayam** 

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