

E.A.R.-CERTIFICATE

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

REF. NO.: FG 1346-2021

DATE: 29/04/2021

ORDER NO.: FG 9343-2020

MANUFACTURER:

Biomax Rubber Industries Sdn Bhd
Lot 3612, Off Jalan Kuala Selangor,
Batu 19, Mukim Darul SG Buloh,
47000 Sungai Buloh, Selangor,
Malaysia

FACILITIES:

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Bhd
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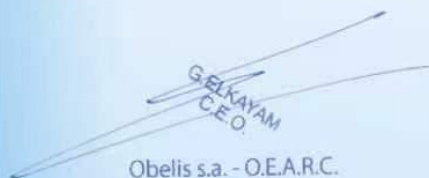
**PRODUCT
CATEGORIES:**

Please See Annex A - List of Devices (8 Devices, 4 Pages)

MODELS:

Please See Annex A - List of Devices (8 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 01/11/2019*, 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 PRRG

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



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V3 - ID: 00072720 - 15/01/2021

ANNEX to MDR EAR Certificate

Manufacturer: BIOMAX RUBBER INDUSTRIES SDN BHD

Country: MALAYSIA

Order No.: FG 9343-2020

Reference No.: FG 1346-2021

#	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	47173	Latex Medical Examination Gloves-Powdered SMALL-9555926400393 MEDIUM-9555926400409 LARGE-9555926400416	Biomed Latex Examination Gloves	Medical examination gloves are to be used by covering user's hand/donning by inserting the hand inside the gloves. Medical examination gloves are meant for single use only	1	5	N	N	N	N
2	56286	Nitrile Medical Examination Gloves-Powder Free SMALL-9555926400249 MEDIUM-9555926400256 LARGE-9555926400263	Biomed Nitrile Examination Gloves	Medical examination gloves are to be used by covering user's hand/donning by inserting the hand inside the gloves. Medical examination gloves are meant for single use only	1	5	N	N	N	N

6	63217	Protector BRI-Antimicrobial Latex Examination Gloves- Powder free SMALL-9555926400577 MEDIUM-9555926400584 LARGE-9555926400591	Protector BRI-Antimicrobial Latex Examination Gloves	Medical examination gloves are to be used by covering user's hand/doning by inserting the hand inside the gloves. Medical examination gloves are meant for single use only	1	5	N	N	N	N
7	63217	Protector BRI-Antimicrobial Latex Examination Gloves Premium- Powder free SMALL-9555926400638 MEDIUM-9555926400645 LARGE-9555926400652	Protector BRI-Antimicrobial Latex Examination Gloves Premium	Medical examination gloves are to be used by covering user's hand/doning by inserting the hand inside the gloves. Medical examination gloves are meant for single use only	1	5	N	N	N	N
8	47173	Tani Latex Medical Examination Gloves- Powdered SMALL-5206970001923 MEDIUM-520690001930 LARGE-520690001947	Tani Latex Examination Gloves	Medical examination gloves are to be used by covering user's hand/doning by inserting the hand inside the gloves. Medical examination gloves are meant for single use only	1	5	N	N	N	N

3	47173	Bluemax Latex Medical Examination Gloves-Powdered SMALL-9555926400300 MEDIUM-9555926400317 LARGE-9555926400324	Bluemax Latex Examination Gloves	Medical examination gloves are to be used by covering user's hand/doning by inserting the hand inside the gloves. Medical examination gloves are meant for single use only	1	5	N	N	N	N
4	47173	3R Latex Medical Examination Gloves-Powdered SMALL-9555926400218 MEDIUM-9555926400225 LARGE-9555926400232	3R Latex Examination Gloves	Medical examination gloves are to be used by covering user's hand/doning by inserting the hand inside the gloves. Medical examination gloves are meant for single use only	1	5	N	N	N	N
5	47172	BRI Latex Medical Examination Gloves- Powder Free SMALL-9555926400010 MEDIUM-9555926400027 LARGE-9555926400034	BRI Latex Examination Gloves	Medical examination gloves are to be used by covering user's hand/doning by inserting the hand inside the gloves. Medical examination gloves are meant for single use only	1	5	N	N	N	N

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