MEDITECH GLOVES SDN BHD (580515-T)
Registration No. 200201012852

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MEDICAL DEVICE REGULATIONS (EU) 2017/745
EC DECLARATION OF CONFORMITY

Manufacturer/ Supplier	:	**MEDITECH GLOVES SDN. BHD.** **PT 3345, Jalan Permata 1/3, Arab Malaysian Industrial Park, 71800 Nilai, Negeri Sembilan, Malaysia**
Authorised Representative:		**Best Putra Gloves (Global) Ltd.,** **4 Haddington Terrace, Dun Laughaire,** **Dublin, A96 DX80,** **Republic of Ireland.**
Notified Body	:	**British Standards Institution (BSI)** **BSI, Say Building, John M. Keynesplein 9,** **1066 EP Amsterdam The Netherlands.**
Notified Body Number	:	**2797**
Model	:	**Polycare Latex Examination Gloves, Powder Free (MEPF3)**
Classification	:	**Class I**
Basic UDI-DI	:	**Latex Examination Gloves Powder Free (9555752LEPFAT)**
Description	:	**Natural Rubber latex examination gloves, powder-free & non-sterile. Ambidextrous gloves with beaded cuff, available in off-white to light yellow colours.**
Intended Purpose	:	**A non-sterile device made of Hevea natural rubber latex (NRL) intended as a protective barrier when worn on the hands of healthcare and similar personnel only once for medical purposes while doing examination of patients for diagnostic, surface contact and non-invasive examination, in order to prevent the cross contamination between the user and the patient.; it does not include antimicrobial agents/materials. The device is used mainly as a two-way barrier to protect both the patient and the staff against various contamination.**

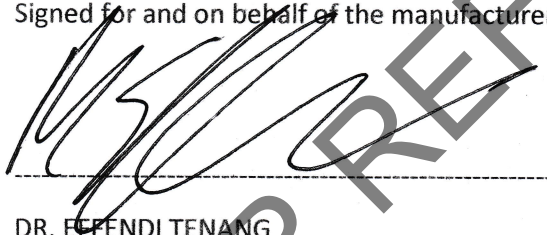
Conformity Assessment : Route	**Meditech Gloves uses the following procedures for the CE-labelling of our products according the Regulation (EU) MDR 2017/745:**
	<u>Class I (Non-sterile)</u> : EU conformity assessment according to Annex II and Annex III.
Common Specifications : (CS)	**ASTM 3578**

Standards Applied :

EN ISO 13485:2016	**EN 455-1:2020**	**EN 455-2:2015**
EN 455-3:2015	**EN 455-4:2009**	**ISO 14971:2019**

MEDITECH GLOVES SDN. BHD. declares that the device described above conforms to the relevant provision of **Regulations (EU) MDR 2017/745** for medical devices and fulfil the requirements. This declaration is supported by Quality System approval to ISO 13485 : 2016. All supporting documentation is retained at the premises of the manufacturer.

Signed for and on behalf of the manufacturer, Meditech Gloves Sdn. Bhd.:



26 MAY 2021

DR. EFFENDI TENANG
Managing Director
Meditech Gloves Sdn. Bhd.