

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 :	BPG Nitrile Examination Gloves, Powder Free (MNEPF1) Meditech Nitrile Examination Gloves, Powder-Free (MNEPF1)
Classification :	Class I
UDI-DI :	Nitrile Examination Gloves, Powder Free (9555752LEPFAT)
Description :	Nitrile Butadiene Rubber latex examination gloves, powder-free & non-sterile. Ambidextrous gloves with beaded cuff, available in blue colour.
Intended Purpose :	The gloves are intended to be 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 : **Meditech Gloves uses the following procedures for the CE-labelling of our Route products according the Regulation (EU) MDR 2017/745:**

Class I (Non-sterile) : EU conformity assessment according to Annex II and Annex III.

Common Specifications : **ASTM 6319**
(CS)

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. 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.



FOR REFERENCE ONLY