

11. Declaration of Conformity

MEDITECH GL+VES SDN BHD (580515-T)
Registration No. 200201012852

PT 3345, JALAN PERMATA 1/3,
ARAB MALAYSIAN INDUSTRIAL PARK,
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NEGERI SEMBILAN DARUL KHUSUS,
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MEDICAL DEVICE DIRECTIVE 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 (UK) Ltd.,**
103 Carrickasticken Road, Forkhill,
Newry, County Down, BT35 9RL,
Northern Ireland, United Kingdom.

Model : **BPG Nitrile Examination Gloves, Powder-free (MNEPF1)**

Classification : **Class I**

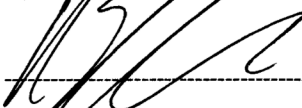

Description : **Nitrile Butadiene Rubber latex examination gloves, powder-free & non-sterile. Ambidextrous gloves with beaded cuff, available in blue colour.**

Standards Applied:

EN 374-2:2014	EN ISO 374-1:2016	EN 455-1	EN 455-3
EN 374-4:2013	EN 420:2003+A1:2009	EN 455-2	EN 455-4

MEDITECH GLOVES SDN. BHD. declares that the device described above conforms to the relevant provision of **Directive 93/42/EEC**, and complies with the relevant Essential Requirements of the Annex V and is manufactured in accordance with the **ISO 13485: 2016** Medical Device Quality Management System (QMS).

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


4/6/2020


DR. MOHAMMED EFFENDI MOHAMMED TENG

Managing Director

Meditech Gloves Sdn. Bhd.

MEDITECH GLOVES SDN. BHD

BPG Nitrile Examination Gloves Powder Free (MNEPF1) (PPE Regulation (EU) 2016/425) Technical File Rev1

**Section 11:
DRAFT EU DECLARATION OF CONFORMITY**

**ANNEX VI
EU DECLARATION OF CONFORMITY**

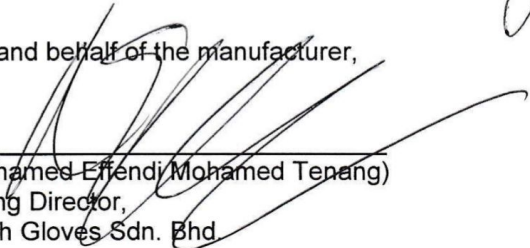
The manufacturer or his authorised representative established in the Meditech Gloves Sdn. Bhd, Jalan Permata 1/3, Arab Malaysian Industrial Park, 71800 Nilai Negeri Sembilan , Malaysia declares that the new PPE described hereafter BPG Nitrile Examination Gloves (MNEPF1) is in conformity with the provisions of PPE Regulation (EU) 2016/425 and, where such is the case, with the national standard transposing harmonized standard EN 16523-1:2016, EN 420:2003 + A1:2009, EN 374-2:2014, EN 374-1:2016 and EN 374-4:2013 is identical to the PPE which is the subject of EU Type Examination certificate of conformity No CE 698568 & CE 698569 and EU Quality Control system for final product No.CE 615886 issued by BSI Group, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.

Meditech Gloves Sdn Bhd is subject to the procedure set out in Module C2 of PPE Regulation (EU) 2016/425 under the supervision of the approved body BSI Group.

Done at Meditech Gloves Sdn Bhd on

15th July 2019

Signed and behalf of the manufacturer,



(Dr. Mohamed Effendi Mohamed Tenang)
Managing Director,
Meditech Gloves Sdn. Bhd