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## EU Declaration of Conformity

We, **Meditech Gloves Sdn Bhd**, hereby declare that the following Personal Protective Equipment (PPE):

1. Model & Description: MNEPF1 - BPG Nitrile Examination Gloves Powder-free
2. Glove sizes: XS, S, M, L and XL
3. Manufacturer: **Meditech Gloves Sdn Bhd**  
PT 3345 Jalan Permata 1/3, Arab Malaysian Industrial Park,  
71800 Nilai, Negeri Sembilan  
Tel: +606-799 7742 / 7746
4. Classification: Category III-Complex
5. It is in conformance with the Regulation (EU) No 2016/425 of the European Parliament and of the Council and national standards in some cases, in conformance with the harmonized standards conversion.
6. It is in conformance with the essential requirements of Medical Device Directive (MDD) 93/42/EEC as amended by Directive 2007/47/EC for Class I medical devices.
7. The notified body BSI (Number: 2797) performed the EU type-examination certificate number is CE 698568 (Module B).
8. Product Standards: BS EN 455 Parts 1, 2 and 3 Total Extractable Protein and Residual Powder. Additionally, ASTM D6319 and ASTM D6124 standards.
9. The object of this declaration described in point 4 is in conformity with the relevant Union harmonization legislation: EN420:2003+A1:2009, EN374-1:2016, EN ISO 374-5:2016.
10. Europe Standard
  - ✓ EN ISO 374-1:2016
  - ✓ EN ISO 374-4:2013
  - ✓ EN 16523-1:2015
  - ✓ EN 374-2:2014
  - ✓ EN ISO 374-5:2016
  - ✓ EN420:2003+A1:2009



# MEDITECH GLOVES SDN BHD (580515-1)

Registration No: 200201012852

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The declaration is valid for the above product in its original and unmodified packaging.

For and on behalf of

Meditech Gloves Sdn Bhd



Dr. Effendi Tenang

Managing Director

Date: Oct. 16, 2020