

EU Type Examination Certificate

This is to certify that:

Meditech Gloves Sdn. Bhd.
PT 3345, Jalan Permata 1/3
Arab Malaysian Industrial Park
Nilai
Negeri Sembilan, Darul Khusus
71800
Malaysia

Holds Certificate Number:

CE 698568

In respect of:

**Natural rubber gloves for personal protection- models MEPF3 & MSPF2
(NBR) Nitrile Butadiene Rubber Latex gloves for personal protection- model MNEPF1.
To EN 420:2003+A1:2009, EN ISO 374-1:2016 & EN ISO 374-5:2016.**

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified
Body for the above Regulation
(Notified Body Number 0086):


Chris Lewis - Certification Director, Product Certification

First Issued: 2019-05-02
Latest Issue: 2019-05-02

Effective Date: 2019-05-02
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...making excellence a habit.™

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Product Specification:

The PPE equipment Protective Gloves that are covered by the scope of this Module B Certificate and the Harmonized European Standards and technical specifications to which the products are approved are to the following specifications:

Model:	MEPF3 Polycare Latex Examination Gloves
Classification:	Protective gloves for use against microorganisms and general applications.
Description:	Natural rubber latex examination gloves, powder free and non-sterile. Ambidextrous gloves with beaded cuff, available in off-white to light yellow colours.
Size Range:	XS to XL
Product codes:	MEPF3-XS, MEPF3-S, MEPF3-M, MEPF3-L and MEPF3-XL.

Product Specification

Performance: **Resistance to penetration to EN 374-2:2014**
Pass

Resistance to degradation to EN 374-4:2013
Tested for degradation against the chemical listed below.
Sodium Hydroxide 40% (CAS:1310-73-2)
Mean Degradation: -84.3%

Resistance to chemical permeation to EN ISO 374-1:2016 (Test method EN 16523-1:2015) **Type C**

Chemical	Level
Sodium Hydroxide 40% (K)	6

General requirements for gloves to EN 420:2003+A1:2009

Dexterity: Level 5
pH: 7.5
Protein Content: 84.5 µg/g

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Product Specification continued:

Model: MSPF2 - ExcellPC Sterile Latex Surgical Gloves Powder Free

Classification: Protective gloves for use against microorganisms and general applications.

Description: Natural rubber latex sterile polymer coated Surgical Gloves, powder free, disposable single use, sterilized by Gamma Irradiation, beaded cuff and anatomical shape., available in off-white to light yellow colours.

Size Range: 5.5 to 9.0

Product codes: MSPF2-5.5, MSPF2-6.0, MSPF2-6.5, MSPF2-7.0, MSPF2-7.5, MSPF2-8.0, MSPF2-8.5 and MSPF2-9.0.

Product Specification

Performance: **Resistance to penetration to EN 374-2:2014**
Pass

Resistance to degradation to EN 374-4:2013
Tested for degradation against the chemical listed below.
Sodium Hydroxide 40% (CAS:1310-73-2)
Mean Degradation: -78.9%

Resistance to chemical permeation to EN ISO 374-1:2016 (Test method EN 16523-1:2015) **Type C**

Chemical	Level
Sodium Hydroxide 40% (K)	6

General requirements for gloves to EN 420:2003+A1:2009

Dexterity: Level 5
pH: 7.2
Protein Content: 123.5 µg/g

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Model: **MNEPF1 – BPG Nitrile Examination Gloves Powder-free**

Classification: Protective gloves for use against microorganisms and general applications.

Description: NBR (Nitrile Butadiene Rubber Latex) examination gloves, powder free and non-sterile. Ambidextrous gloves with beaded cuff, available in blue colour.

Size Range: S to L

Product codes: MNEPF1-S, MNEPF1-M and MNEPF1-L.

Product Specification

Performance: **Resistance to penetration to EN 374-2:2014**
Pass

Resistance to degradation to EN 374-4:2013
Tested for degradation against the chemical listed below.
Sodium Hydroxide 40% (CAS:1310-73-2)
Mean Degradation: -21.6%

Resistance to chemical permeation to EN ISO 374-1:2016 (Test method EN 16523-1:2015) **Type C**

Chemical	Level
Sodium Hydroxide 40% (K)	6

General requirements for gloves to EN 420:2003+A1:2009

Dexterity: Level 5
pH: 6.2
Protein Content: N/A

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Applicable

The following Harmonized European Standards:

Standards:

EN 420:2003+A1:2009 Protective gloves. General requirements.

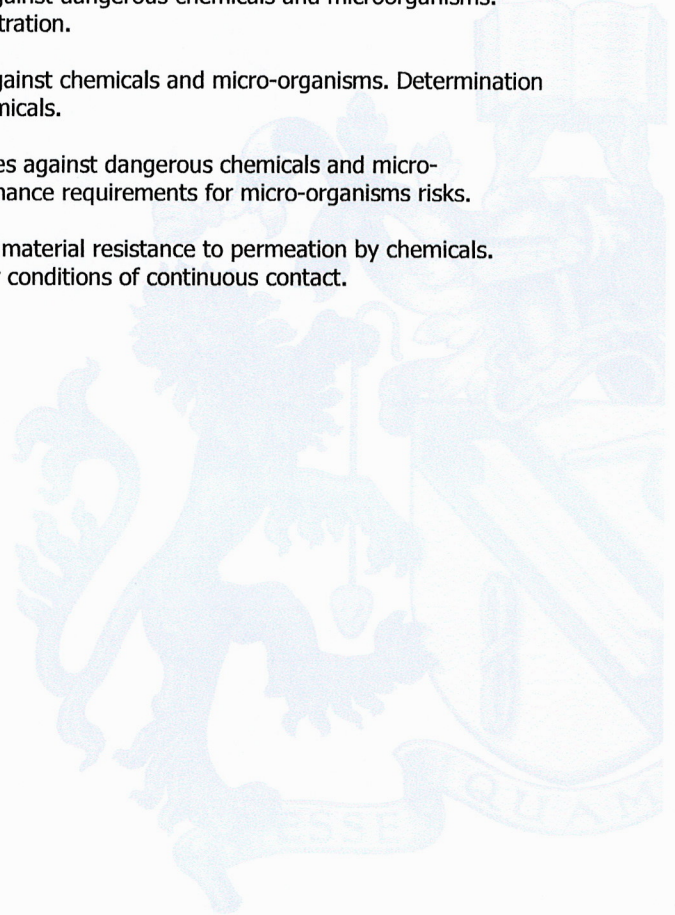
EN ISO 374-1:2016. Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN 374-2:2014. Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.

EN 374-4:2013. Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals.

EN ISO 374-5:2016. Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.

EN 16523-1:2015. Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact.



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Certificate Administration Details

Manufacturer's technical file reference: MEPF3 v1, MSPF2 v0 and MNEPF1 v0 Technical Files.

Certificate Amendment Record:

Issue Date	Comments	Internal BSI Project Number
May 2019	Transition of PPE Directive, Article 10 CE 684183. Model: MEPF3. Addition on new models MNEPF1 & MSPF2.	0086:19:9640615

Note: The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall processes utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

Monitoring of manufactured PPE:

The validity of the Certificate is also dependent on the conformity to the type based on the internal production control plus supervised product checks at random intervals (Annex VII, Module C2), for the specific standards/product that are referenced in the BSI issued Module C2 Certificate Number CE 615886.

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