

Meditech Gloves (BPG)

Medical Examination Grade Nitrile Gloves

PRODUCT SPECIFICATIONS

Material	Synthetic Nitrile Latex
Type	Non-sterile Powder-Free Ambidextrous; Fingertip textured; Beaded cuff; Blue
Quality Standards	Conforms to ASTM D6319 Manufactured under ISO 13485:2003 Quality Management System Manufactured from 100% nitrile (Acrylonitrile-Butadiene)
Glove Sizes	Extra-Small, Small, Medium, Large, Extra-Large Marked in the check box on the shipping carton
Storage	Store in a dry and cool place, the temperature not higher than 38°C

PHYSICAL DIMENSIONS

DIMENSIONS	Standards	
	BPG Nitrile Gloves (Meditech Gloves) <i>(Min Spec for Size M)</i>	ASTM D6319
Length (mm)	240 min	220 min (S) 230 min (M, L, XL)
Width (mm)	95 ± 3 (M)	80 ± 10 (S) 95 ± 10 (M) 110 ± 10 (L) 120 ± 10 (XL)
Thickness – Single wall (mm)	Fingers : 0.10 mm min Palm : 0.07 mm min	Fingers : 0.05 mm min Palm : 0.05 mm min

PHYSICAL PROPERTIES AND BIOCOMPATABILITY (SIZE M)

Sample Reference	Tensile Properties			
	Unaged		Aged (7days / 70°C)	
	Tensile Strength (MPa)	Ultimate Elongation (%)	Tensile Strength (MPa)	Ultimate Elongation (%)
QA/2019/0005/2.1	29.3	500	26.4	500
2.2	22.7	470	21.5	470
2.3	26.0	480	21.3	460
2.4	23.7	490	26.4	490
2.5	17.8	460	26.2	490
2.6	26.4	490	26.4	480
2.7	14.3	430	29.8	500
2.8	16.5	430	32.7	500
2.9	18.2	470	22.8	470
2.10	13.2	420	31.2	500
2.11	23.7	500	25.7	500
2.12	25.9	490	25.3	490
2.13	27.2	510	27.8	490
Powder Content	0.6 mg is the measured residual surface powder per glove 2 mg/glove maximum to conform			

Summary of Certification:i) **BSI – EU Type Examination Certificate****Applicable Standards:**

The following Harmonized European 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.

- ii) **BSI - Conformity To Type Based on Internal Production Control plus supervised product checks at random intervals**
- iii) **ISO 13485 - Quality Management**
- iv) **SMTL - EN 455 – 1-3**
- v) **SATRA - EN 420 + EN 16523 + EN ISO 374-1**
- vi) **SATRA – EN 374-2**
- vii) **ASTM D6319**
- viii) **ASTM D6124**
- ix) **FDA Certification (approved for sale in USA)**
- x) *(FDA 510(K) – USA Medical approval Imminent, registered on FDA website)*

Imagery:



Packaging/Measurements/Weight:

Cartons on a pallet :
Dimension of carton (L-W-H) : x x cm
Weight of carton : kg

The box size, as an individual unit:
1 Box = 100 gloves
Dimension of Box (L-W-H) : 24x12.5x5.5 cm
Weight of Box : 0.499kg (i.e. 1.10lb)

1 Carton = 10 boxes



Meditech Gloves Sdn Bhd



Dr. Effendi Tenang
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www.meditechgloves.com