

PRODUCT SPECIFICATION

PRODUCT : **TEXTURED POWDER FREE
LATEX EXAMINATION GLOVE**

PRODUCT DESCRIPTION

PRODUCT TYPE : Textured Latex Examination Gloves
STERILITY : Non-sterile
INTENDED USE : Medical Activities
MDD 93/42/EEC STATUS : Class I Medical Device
ORIENTATION : Ambidextrous
CUFF : Beaded end
COLOUR : Natural color
BASIC MATERIAL : Natural Rubber Latex
STORAGE CONDITION : Keep in Dry Cool Place, Avoid Ozone
SHELF LIFE : The gloves shall have shelf life of 3 years from the date of manufacturing with the above storage condition.

PACKAGING : 100 pieces per box, 10 boxes per case

 : 100 pieces per plastic bag, 50 bags per sack

Physical Dimensions

Palm Width and Length

Size	Palm Width (mm)	Length (minimum in mm)
<i>X-Small</i>	≤ 80	235
<i>Small</i>	80 ± 10	235
<i>Medium</i>	95 ± 10	235
<i>Large</i>	110 ± 10	235
<i>X-Large</i>	<i>Min 110</i>	235

Thickness (Single Wall)

Location of Thickness Measurement	Single Wall Thickness (mm)
<i>Fingertip (at 13 ± 3 mm from the extreme tip)</i>	<i>0.13 min.</i>
<i>Palm (at centre of palm)</i>	<i>0.11 min.</i>
<i>Cuff (at 25 mm from cuff end)</i>	<i>0.08 min.</i>

Physical Properties

Characteristics	Reference Standard	Before Ageing	After Ageing 7 days @ 70 °C ± 2 hours
<i>Tensile Strength (MPa)</i>	<i>Internal standard</i>	<i>21 min.</i>	<i>16 min.</i>
<i>Ultimate Elongation (%)</i>	<i>Internal standard</i>	<i>700 min.</i>	<i>500 min.</i>

Protein level

Not more than 50 µg water extractable protein *per gram* of glove.

Powder Content

Not more than 2 mg per glove

Quality Assurance For Glove Performance Requirements

Characteristics	Inspection Level & Sampling Plan	AQL and Acceptance Limit
<i>Barrier Non-conformities (Critical Defect)</i>	<i>G-1</i>	<i>1.5</i>
<i>Major Visual Non-conformities (Major Defect)</i>	<i>G-1</i>	<i>2.5</i>
<i>Physical Properties Related Non-conformities</i>	<i>S-2</i>	<i>4.0</i>
<i>Physical Dimensions</i>	<i>S-2</i>	<i>4.0</i>
Average Powder Content	<i>As per ASTM D3578</i>	<i>Below 2 mg per glove</i>
Water Extractable Protein	<i>As per ASTM D3578</i>	<i>Below 50 µg <u>per g.glove</u></i>

Reference Requirement

- 1.1 EN 455 – 1
- 1.2 EN 455 – 2
- 1.3 ASTM D3578
- 1.4 ASTM D412
- 1.5 ASTM D5712
- 1.6 ASTM D5151