

SPECIFICATIONS

NIT-ROMED EXAMINATION GLOVES, POWDERFREE

REF: NITROM-800, NITROM-805, NITROM-810, NITROM-815



Applicable harmonized standard: EN 455-1,-2,-3, 4, EN ISO 374-1, -5, EN 16523-1
 Medical device conform MDR (EU) 2017/745
 Personal Protective Equipment conform (EU) 2016/425 PPE

Disposable medical examination gloves, non-sterile, powderfree, latex free, with a texture and softness similar to the nitrile gloves.

Sizes: small, medium, large and extra-large

DESCRIPTION:

Intended use	:	Medical examination
Class	:	Class I medical device
Category	:	Category III PPE (EN ISO 374-1 Type C – level 6 permeation resistance against 40% Sodium Hydroxide, EN ISO 374-5 protection against viruses, bacteria and fungi)
Primary material	:	Synthetic Polymer with flexible formulation
Latex protein content	:	A latex free glove and chemical accelerator-free compound
Powder	:	No powder lubricant added
Colour	:	Blue
Design and feature	:	Ambidextrous, smooth surface, beaded cuff
Packing	:	100 pieces in a dispenser box (90 pieces for the XL gloves), 10 dispenser boxes in an export carton

DIMENSIONS

Glove size	Palm width (mm)	Length (mm)
Small	85 ± 5	≥240
Medium	95 ± 5	≥240
Large	105 ± 5	≥240
Extra large	115 ± 5	≥240

TYPICAL THICKNESS (single wall thickness)

Location of thickness measurements	mm
Finger	≥0.05
Palm	≥0.05

PHYSICAL PROPERTIES

Criteria	
Tensile strength	>3.6 N Before Aging >3.6 N After Aging
Elongation	>350% Before Aging >350% After Aging

PERFORMANCE REQUIREMENTS

Criteria	Insp. level	AQL
1000 ml water leak test	G-1	1.5
Physical properties	S-2	4.0
Dimension	S-2	4.0
Visual inspection	S-2	4.0 Major 2.5 Minor 1.0 Critical

Additional use: Food contact materials

The Romed medical examination gloves are chemically acceptable for use in slaughtering, processing, transporting or storage areas in direct contact with meat or poultry food product prepared under Federal inspection.

This acceptance is valid as long as the composition and use remain as described. No endorsement of the material or of any concomitant claims is intended

Packing

100 pieces in a dispenser box (90 pieces for the XL gloves), 10 dispenser boxes in an export carton