

PRODUCT CATALOGUE

PRODUCT : **NITRILE EXAMINATION GLOVES, NON STERILE, POWDER FREE**
 BRAND NAME : **IndiSAFE**
 COMPLYING STANDARDS : **ASTM D6319-2010 & EN455-I: 2000 and EN455-II: 2011**

Average weight : **4.0 gm /piece**

Specification

- Made from high quality 100% Synthetic Nitrile Latex.
- Free from Natural Rubber Latex.
- Colour: Blue/Lavender Blue.
- Ambidextrous
- Micro rough surface texture provides enhanced instrument grip.
- No protein that is contained in the Natural Rubber Latex.
- Ring rolled bead and extra length for extra protection.
- Quality standard as per ASTM D 6319-2010/EN455 II -2011.



Physical Dimensions

SIZE	x-SMALL	SMALL	MEDIUM	LARGE	X-LARGE	Tol.
Width (Palm) mm Min	70	80	95	110	120	±10
Length (mm) min	240					
Thickness at (mm) Min	Cuff	0.08±3	Palm	0.08±3	Finger	0.09±2

Physical Properties

Characteristics	Before Ageing	After Ageing
Tensile Strength	14 Mpa Min	14 Mpa Min
Ultimate Elongation	500 % Min	400 % Min
Characteristics		Powder Free Gloves
Powder Content (Max)		2mg/dm ²
Moisture Content % (Max)		0.8

Classification of medical device

Nitrile Examination Gloves –Non Sterile Powder Free- are classified as Class 1 Medical Device (Rule 5 of Annex IX as per MDD/93/42/EEC as amended.)

Performance criteria (Sampling plan as per ISO 2859)

Sr.No.	Characteristics	Related defects	Inspection Levels	AQL
01	Freedom from holes	Pin hole, cuff hole, palm holes	G-1	1.5
02	Physical Dimensions	Length, Width, Thickness	S-2	4.0
03	Physical Properties	Before & after ageing	S-2	4.0
04	Powder amount	Exceeds maximum amount	N=3	N/A

USE INSTRUCTIONS**MEDICAL DEVICE: NITRILE SURGICAL GLOVES –NON STERILE –POWDER FREE BRAND: IndiSAFE*****Intended applications.***

Nitrile examination gloves are disposable gloves intended for Medical Examinations / laboratory pupose etc.

Nitrile gloves are more puncture resistant than Latex Examination gloves; the barrier properties are stronger to dangerous viruses and other blood borne pathogens.

Nitrile rubber is more resistant than natural rubber to chemicals, oils and acids, and has superior strength, they have a vide application in the chemical Industry, and pharma sector.

Instructions for use

- Nitrile Examination Gloves- Non sterile - Powder Free- are not surgically invasive devices.
- Examination gloves are Ambidextrous.
- Must see the date of Manufacturing and expiry date, Lot/Batch No& Manufacturers address.
- Must see the product specification standard reference (ASTM/EN Standard) and AQL Level.
- Use micro roughened glove for added instrument grip.
- Limit "Touch Contamination" with soiled gloves.
- Do not store gloves exposed to direct sunlight, fluorescent lighting or under high Humidity areas and protect from Ozone atmosphere.
- Store gloves under cool dry place where temperature does not rise above 40°C.
- The device is for single use only.
- Disposal after use as per local, state, national regulatory rules.

Shelf life (Use before date)

The shelf life of the gloves is 3 years from the date of manufacture.

Packing

Nitrile Examination Gloves Powder Free, Non Sterile Gloves

100 Pieces per dispenser box. One master carton contains 1000 Pieces (10 Dispenser boxes).

1.4 Million Pieces on 20' STD container & 3.3 million pieces per 40'HC container.