

PRODUCT CATALOGUE

PRODUCT	: LATEX EXAMINATION GLOVES, NON-STERILE/STERILE, POWDERED/POWDER FREE
BRAND NAME	: AGE.CARE
COMPLYING STANDARDS	: ASTM D 3578/ EN 455
Average weight	: 4.5 /5.0 gm /piece

Specification

- Made from high quality natural rubber latex
- Natural white/pale yellow color
- Ambidextrous
- Micro rough surface texture provides enhanced instrument grip
- Substantially low protein level to minimize the risk of allergen
- Chlorinated / Polymer Coated for Powder Free
- E.T.O Sterilized for Sterile Products
- Ring rolled bead and extra length for extra protection
- Quality standard as per ASTM D 3578/EN455
- Complies with International Standard ASTM D3578/ EN 455



Physical Dimensions

SIZE	x-SMALL	SMALL	MEDIUM	LARGE	X-LARGE	Tol.
Width (Palm) mm Min	70	80	95	111	114	±10
Length (mm) min	240					
Thickness at (mm) Min	Cuff	0.08	Palm	0.08	Finger	0.08

Physical Properties

Characteristics	Before Ageing	After Ageing
Tensile Strength	14 Mpa Min ≥9 Newton	14 Mpa Min ≥6 Newton
Ultimate Elongation	700 % Min	500 % Min
Characteristics	Powdered Gloves	Powder Free Gloves
Aqueous Soluble Protein Content (Max)	200µg/dm ²	50µg/dm ²
Powder Content (Max)	10mg/dm ²	2mg/dm ²
Moisture Content % (Max)	0.8	0.8

Classification of Medical Device

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

Latex Examination Rubber Gloves –Non Sterile Powdered /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	2.5
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: LATEX SURGICAL GLOVES -STERILE –POWDER FREE BRAND: AGE.CARE****Intended applications:**

Latex examination gloves are disposable gloves intended for Medical Examinations and procedures that help prevent cross-contamination between caregivers and patients

Contra indications:

- Latex Surgical gloves are manufactured from NATURAL RUBBER LATEX

CAUTION!

“This product contains natural rubber latex which may cause allergic reaction to some individuals. If any allergic reaction is observed discontinue the use and consult a physician”

Instructions for use

- Latex Examination Gloves- Non sterile -Powdered / Powder Free- are not surgically invasive devices.
- Examination gloves are Ambidextrous.
- Do not use the sterilized gloves if package is opened or damaged.
- Do not re-sterilize damaged or opened pouches.
- 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.
- For powdered gloves after donning remove powder by wiping gloves thoroughly with wet sterile cloth/sponge or other effective method.
- Make sure the powder does not contaminate the sterile working area.
- 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**Latex Examination Gloves Powdered & Powder Free -Non Sterile Gloves**

100 Pieces Per dispenser boxes. 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

Latex Examination Gloves Powdered & Powder Free - Sterile Gloves

One pair of gloves is packed in paper wallet and packed in Paper Pouch.

50 Pairs per Dispenser boxes and 500 Pairs in One Master Carton