PRODUCT DETAILS
NATURAL RUBBER GLOVES
HIGH PROTECTION

Disposable glove in pure natural rubber latex. Sensitive and resistant. Finely powdered. Suitable for use in hospitals, outpatient and medication. Also recommended in the laboratory or in the food industry. White or green

GENERAL DESCRIPTION DEVICE

The product is certified as a medical device class 1. In compliance with the provisions of the GUIDELINES FOR THE DEFINITION OF STANDARD SAFETY AND HEALTH DEPARTMENT OF ENVIRONMENTAL OPERATORS drafted by ISPESL, the gloves were tested to determine the ability of 'be impermeable barrier and provide effective protection against viral agents and pathogens ensuring the impermeability of gloves to blood and body fluids that may contain these pests.

The product has also been tested by the EC Notified 0465 to protect against RISKS MECHANICAL, CHEMICAL AND BIOLOGICAL, in accordance with Legislative Decree No. 475: implementation of Directive 89/686 / EEC Directive with reference to the provisions of the aforesaid lines ISPESL guide.
The product does not bear the marking as PPE validity of the legislation which provides that the examination gloves are considered medical devices and does not allow a product can simultaneously be marked as medical device and which personal protective equipment (vds. Note Min . Health DGFDM III / P / 13228 / I 1c.r.)

REFERENCE STANDARDS

Legislative Decree no. 46/97, Directive 93/42
Legislative Decree. N. 475/92, Legislative Decree no. 626/94, Directive 89/686 / EEC
Italian Republic Pharmacopoeia Ed. Current European Pharmacopoeia Ed. Current
EN 455 I - II - III, EN 374 I - II - III, EN 420, EN 388, ASTM F1670, ASTM F1671
ISO 2859

INSTRUCTIONS FOR STORAGE AND WAREHOUSE

Store in cool, dry place. Do not store at temperatures above 40 ° C. Do not expose to direct sunlight, UV light and fluorescent lamps. If the packaging is damaged or wet you discard the product. Do not use beyond the expiration date printed on the packaging. Do not use beyond the expiration date printed on the package.

LIFE PRODUCT

5 years

PRECAUTIONS AND SAFETY

Attention: latex gloves can cause contact allergy in susceptible individuals.

In order to minimize the risks apply the following procedures:

- Do not use gloves with chemicals and incompatible products (see briefing notes available from the manufacturer)
- Frequent change gloves and wash and dry your hands thoroughly before use
- Discontinue use immediately in case of allergic reaction and / or inflammation
- Wash your hands thoroughly with soap and lukewarm water
- Consult your doctor if necessary
- Communicate to the supplier any particular side effects

Caution: the product is combustible, but does not generate heat. Fire may produce toxic fumes: carbon monoxide, carbon monoxide, organic acids.

Extinguishing media: water, powder, CO2.

COMPOSITION

Lattice

Natural rubber latex

Content of Additives

ZDEC (zinc diethyldithiocarbamate) <0.70%

ZDBC (zinc dibutyldithiocarbamate) <0.70%

The product contains no thiurams, mercaptans and other chemicals known to be toxic or harmful to health and to the environment.

Protein content of the milk

PROTEIN MILK REMAINING <300 □g / g according to Standard ASTM D5712 (Method Lowry)

Talcing

Modified corn starch (USP grade)

QUANTITY 'OF POWDER LUBRICANT REMAINING ASTM D6124 <200 mg / glove

MISURA DEI GUANTI

SIZE	LENGHT (mm)		WIDTH (mm)	THICKNESS (mm)					
				Palm		Finger		Wrist	
	MIN	STD	STD	MIN	STD	MIN	STD	MIN	STD
X-SMALL	240	240	<=80	0.09	-	0.12	-	0.07	-
SMALL	240	240	80±10	0.09	-	0.12	-	0.07	-
MEDIUM	240	240	95±10	0.09	-	0.12	-	0.07	-
LARGE	240	240	110±10	0.09	-	0.12	-	0.07	-
X-LARGE	240	240	>=110	0.09	-	0.12	-	0.07	-

Reference to EN 455-2 - ISO 2859-1 AQL 4

The values stated in the "standard" refers to the size required by the standards mentioned above; those in column "minimum" in the minimum actual product supplied

PACKAGE

PAPERBOARD 1000 PIECES TO FIT IN 10 BOXES / DISPENSER 100 PIECES

QUALITY CONTROL

DEFECTS HIGHLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE LEVEL OF QUALITY (AQL)
No Holes	EN 455-1 UNI EN 374	Kept filling with water	ISO 2859-1	1.5

PHYSICAL: BREAKING LOAD

DEFECTS HIGHLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE LEVEL OF QUALITY (AQL)
Tensile strength before and after accelerated aging	EN 455-2	Breaking load N as measured with a dynamometer	ISO 2859-1	4.0

MINIMUM BREAKING LOAD	N standard reference	N samples
Before accelerated aging	> 9	9
After accelerated aging	> 6	6

PHYSICAL: TENSILE STRENGHT

DEFECTS HIGHLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE LEVEL OF QUALITY (AQL)
Tensile strength before and after accelerated aging	ASTM D412 ASTM D573	Tensile strength in MPa measured with the dynamometer	ISO 2859-1	4.0

TRACTION RESISTANCE MINIMUM	MPa normative reference	MPa SAMPLE	% Elongation reference standard	% elongation sample
Before accelerated aging	18	20	650	700
After accelerated aging	14	16	500	500

VISIBLE DEFECTS

Critical defects: visible holes, tears, dirt is not removable, lumps, folds, stains
Minor defects: removable dirt, lumps, wrinkles, bad finish edge

DEFECTS HIGHLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE LEVEL OF QUALITY (AQL)
Critical defects	ASTM 3578 EN 420	visual inspection	ISO 2859-1	2.5
Minor defects	ASTM 3578 EN 420	visual inspection	ISO 2859-1	4.0

RESISTANCE TO PENETRATION OF MICRO AND CHEMICALS

DEFECTS HIGHLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE LEVEL OF QUALITY (AQL)
Production chemicals	EN 374-2	test of air leakage by immersion in water	ISO 2859-1	1.5 (see the instructions available on request)

RESISTANCE TO CHEMICALS

DEFECTS HIGHLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE LEVEL OF QUALITY (AQL)
Production chemicals	EN 374-3	determining passage time chemical for constant contact	EACH SAMPLE	See the instructions available for use as PPE

RESISTANCE TO PENETRATION OF BIOLOGICAL AGENTS - ISPESL REFERENCE GUIDELINES FOR THE DEFINITION OF STANDARD SAFETY AND HEALTH DEPARTMENT OF ENVIRONMENTAL OPERATORS

DEFECTS HIGHLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	RESULT
Penetration of biological agents	ASTM F1670	verifying the absence of penetration of the artificial blood	EACH SAMPLE	No penetration admitted

RESISTANCE TO MECHANICAL STRESS

DEFECTS HIGHLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE LEVEL OF QUALITY (AQL)
Resistance to damage caused by blunt instruments	EN 388	CIMAC	Each sample	N/A

BIOCOMPATIBILITY

As provided for by the ISO 10993-1 the product has been tested for biocompatibility with the tissues: devices in contact with the surface of the skin, mucous membranes, membranes, surfaces injured or compromised, longer contact time.

DEFECTS HIGHLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE LEVEL OF QUALITY (AQL)
Cytotoxicity	ISO 10993-5	In vitro	Each sample	Biocompatible
Sensitization	ISO 10993-10	In vitro	Each sample	Biocompatible
Irritation	ISO 10993-10	In vitro	Each sample	Biocompatible

WASTE PROCESSING / ALIEN SUBSTANCES

According to government regulations indicated the product has been tested to highlight the absence of cutting waste both chemical and biological.

DEFECTS HIGHLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE LEVEL OF QUALITY (AQL)
Chemical Additives	En 455, EN 374, Pharmacopoeia Italian Republic European Pharmacopoeia USP Ed. Current	chemical analysis	Each sample	absent / in the specifications
Bioburden	European Pharmacopoeia And USP. corr.	microbiological analysis	Each sample	<150 cfu/pz.

Results of analysis for residues of chemical compounds used (test liquid chromatography TLC)

ZDEC (zinc diethyldithiocarbamate)	< 0.50 %
ZDBC (zinc dibutyldithiocarbamate)	< 0.30 %
Wingsay L (phenol)	< 1.00 %

It is undetectable the presence of residues of other additives (detection limit 12:01%)

PRODUCTION PROCESS LATEX GLOVES

1. Preparation Intermediate.

a. preparation of sulfur dispersion

b. preparation dispersion main lot

c. preparation of lauric acid soap

d. preparation of latex bath

e. Preparation Solution Nitric Acid

f. preparation Alkaline Solution

g. preparation coagulant

h. preparing an aqueous suspension of corn starch

NOTE: the definition of the production batch is effected according to the batch preparation of the bath of latex2. 2.

2. Washing of the molds of ceramic

a. to. washing of the molds with nitric acid to remove the residue of

b. working

c. b. neutralizing residual acidic solution by rinsing in solution

d. alkaline

e. c. drying the molds in the oven to dry

3. Coagulation bath

a. deposit a uniform layer of gelling agent (calcium nitrate) and

b. anti-adhesive (calcium carbonate)

c. b. fix the coagulant to the molds by drying in an oven

4. Latex bath

a. submerge the molds with coagulant in the latex bath

b. dry the latex film until the formation of gel for the welt

c. strengthen the flap through the formation of the flange**5.**

5. Leaching I and II

a. submerge the molds in hot running water 60 ° - 65 ° C to eliminate the soluble proteins and the excess of chemicals machining**.**

6. Vulcanization

a. drying of the gel in the oven for 30 min. in the oven to dry at room temp. between 110°C and 130 ° C

7. Suspension of the powder

a. application of the powder of cornstarch by immersion in bath

b. aqueous

c. drying of the piece in a hot air oven

8. Packaging, labeling and packaging

a. tglove removal from the molds and breakdown by measure

b. packaging gloves multipack and labeling

c. identification product and lot number of production

d. cardboard packaging Shipping

9. Quality Control

a. product inspection during production

- Major and minor visible defects
- size

b. inspections after production

- Major and minor visible defects
- Verification of water tightness and physical properties
- size

c. Warehouse and Shipping

- Marking labels and packaging
- Major and minor visible defects
- Verification of water tightness and physical properties
- size
- Quantity per packaging unit

RULES 'OF DISPOSAL

To dispose hospital waste according to current legislation

TECNOLATTE S.R.L.

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