PRODUCT DETAILS
GLOVES NITRILE DOC ZERO
HIGH PROTECTION

Disposable nitrile ambidextrous glove. Suitable for sensitive skin. Sensitive and resistant. The textured surface on the fingertips ensures optimal grip. Finely powdered. Suitable for use in hospitals, outpatient and medication. Recommended for use even in the laboratories.

GENERAL DESCRIPTION

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 notified body CE0465 for protection from 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 aforementioned guidelines ISPESL.
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
Warning: 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

Nitrile

The material composition of the gloves is the acrylonitril/butadiene/acid metacriclico (XNBR) commonly known as nitrile.

Content of Additives

Additive	Main function	Content
ZDEC (zinc diethyldithiocarbamate)	Accelerator	0.10 - 0.50 %
ZDBC (zinc diethyldithiocarbamate)	Accelerator	0.10 - 0.50 %
SULPHUR	Curing agent	0.60 - 2.50 %
ZnO (zinc oxide)	Activator	0.50 - 3.00 %
Vultamolo	Dispersing Agent	0.30 - 0.50 %
Wingstay L, Nonox SP	Antioxidant	0.30 - 0.50 %
TiO2 (titanium dioxide)	Colorant	0.40 - 2.00 %
Teric 320	Stabilizing	0.10 - 0.20 %
Ammonia	PH regulator	0.10 - 0.60 %
KOH (potassium hydroxide)	PH regulator	0.05 - 0.20 %

With regard to the processing residues of chemicals used to see over point WASTE PROCESSING/ALIEN SUBSTANCES

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

It does not contain substances that are not compatible with food use (FDA and EEC legislation for intermittent contact plastics with food).

Lubricating powder
Talcing using corn starch modified conform to the USP Ed . Current

QUANTITY ' OF POWDER LUBRICANT REMAINING ASTM D6124 < 200 g / Glove

PH LUBRICANT COMPOSITION AND DUST RESIDUAL

	Values required for USP			Declared value
	Conf. USP	Min	Max	
Residual dry	%	/	<12.0	compliant
PH in suspension	Unit	10.0	10.8	compliant
Ashes	%	/	<3.0	compliant
Test sedimentation (purity)	ML	45.0	75.0	compliant
Magnesium oxide	%	/	<2.0	compliant
Residual heavy metals	PPM	/	<10	compliant
stability autoclave	Conf. USP	/	/	compliant
chlorides	ppm	/	/	< 1000
Residue 325 mesh	%	/	< 1.0	compliant
Residue 400 mesh	%	/	< 2.0	compliant
Total bacterial count	cfu/g	/	< 600	compliant
Molds	cfu/g	/	< 40	compliant
Yeasts	cfu/g	/	< 20	compliant
Coliforms	cfu/g	/	< 20	compliant
Escherichia coli	Absent 10g	/	/	compliant
Pseudomonas Aeruginosa	absent 10g	/	/	compliant
Staphylococcus Aureus	absent 10g	/	/	compliant

MISURA DEI GUANTI

Size	LENGHT (mm)		WIDTH (mm)	THICKNESS (mm)					
				Palm		Finger		Wrist	
	MIN	STD	STD	MIN	STD	MIN	STD	MIN	STD
SMALL	240	240	80±10	0.09	-	0.13	-	0.05	-
MEDIUM	240	240	95±10	0.09	-	0.13	-	0.05	-
LARGE	240	240	110±10	0.09	-	0.13	-	0.05	-
X-LARGE	240	240	>=110	0.09	-	0.13	-	0.05	-

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
NO HOLES

NUMBER OF DEFECTS	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE QUALITY LEVEL (AQL)
Holes	EN 455-1 UNI EN 374	Kept filling wit hwater	ISO 2859-1	1.5

PHYSICAL: BREAKING LOAD

DEFECTS HIGLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE QUALITY LEVEL (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
Before accelerated aging	> 9
After accelerated aging	> 6

PHYSICAL: TENSILE STRENGTH

DEFECTS HIGLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE QUALITY LEVEL (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	14	16	500	500
After accelerated aging	12	12	400	450

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

DEFECTS HIGLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE QUALITY LEVEL (AQL)
Critical defect	ASTM 3578 EN 420	Ispezione visiva	ISO 2859-1	2.5
Minor defect	ASTM 3578 EN 420	Ispezione visiva	ISO 2859-1	4.0

RESISTANCE TO PENETRATION OF MICRO AND CHEMICALS

DEFECTS HIGLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE QUALITY LEVEL (AQL)
penetration chemicals	EN 374-2	Test of air leakage by immersion in water	ISO 2859-1	1.5

ESISTANCE TO CHEMICALS PERMEATION

DEFECTS HIGLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE QUALITY LEVEL (AQL)
Permeation chemical products	EN 374-3	Determination time passing chemical for constant contact	Randomly	-

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

DEFECTS HIGLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE QUALITY LEVEL (AQL)
Penetration of biological agents	ASTM F1670	verifying the absence of penetration of the artificial blood	Randomly	No penetration
Penetration of biological agents	ASTM F1671	penetration testing bacteriophage Phi - X174	Randomly	No penetration

RESISTANCE TO MECHANICAL STRESS

DEFECTS HIGLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE QUALITY LEVEL (AQL)
Resistance to damage caused by blunt instruments	EN 388	CIMAC	Randomly	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 HIGLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE QUALITY LEVEL (AQL)
Cytotoxicity	ISO 10993-5	Vitro	Randomly	Biocompatible
Sensibilization	ISO 10993-10	Vitro	Randomly	Biocompatible
Irritation	ISO 10993-10	Vitro	Randomly	Biocompatible

RESIDUI DI LAVORAZIONE /SOSTANZE ESTRANEE

Secondo quanto previsto dalle normative indicate il prodotto è stato testato per evidenziare l'assenza di residui di lavorazione sia chimici che biologici.

DEFECTS HIGLIGHTED	REGULATIONS	METHOD TO TEST	SAMPLING PLAN	ACCEPTABLE QUALITY LEVEL (AQL)
Chemical additives	En 455, EN 374, Pharmacopoeia Italian Republic European Pharmacopoeia USP Current ed.	Chemical Analyses	Randomly	Absent / in the specifications
Residual EtO	Pharmacopoeia Italian Republic	Analysis by gas chromatography	Randomly	EtO below the limit of 10 ppm
Endotossine batteriche	Pharmacopoeia Italian Republic	LAL test	Randomly	Endotoxins below the limits
Bioburden	European Pharmacopoeia USP Current ed.	microbiological analysis	Randomly	<150 cfu/pz.

Results analysis of chemical compounds used (test liquid chromatography)

ZDEC (zinc diethyldithiocarbamate)	< 0.35%
ZDBC (zinc diethyldithiocarbamate)	< 0.35%
Nonox SP	< 0,40%

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

PRODUCTION PROCESS GLOVES NITRILE

1. Preparation of intermediate

a. Raw material preparation
b . Extrusion of the plastic film

NOTE : the definition of the production batch is done according to the batch of raw material preparation

2. Diving molds

a. Dipping the mold in the polymer
b . Automatic molding gloves

3. Lamination

a. Plasticization process in the oven at 220 ° - 250 ° C

4. Cooling

a. Solidification by cooling in a convection oven up to 100 ° C
b . Winding of the flange
c . Further cooling to 60 ° C

5. Suspension of dust

a. Application of the powder of cornstarch by immersion in aqueous bath
b . Drying of the piece in a hot air oven

6. Packaging , Labeling and Packaging

a. Glove removal from the molds and breakdown by measure
b . Packaging gloves multipack and labeling identification product and lot number of production
c . Cardboard packaging Shipping

7. Quality control

a. Product inspection during production
-Visible major and minor defects
-Sized
b . Inspections after production
-Visible major and minor defects
-Check waterproofing and physical properties
-Sized
-Storing and Shipping
-Marking labels and packaging
-Visible major and minor defects
-Check waterproofing and physical properties
-Sized
-Amount per unit of packaging

RULES 'OF DISPOSAL

To dispose hospital waste according to current legislation

TECNOLATTE S.R.L.

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