DISPOSABLE LATEX GLOVES HIGH RESISTANCE

TRADEMARK REFLEXX 98

1. NAME AND ADDRESS OF MANUFACTURER:

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2. GENERAL DESCRIPTION OF PRODUCT:

- disposable glove high resistance in natural rubber latex
- glove with five fingers, ambidextrous, dark blue with long cuff, micro textured surface, beaded cuff and textured fingers
- glove non sterile, powdered free and internally chlorinated for easy donning and reduce the risk of allergies
- multipurpose glove to protect the hand and/or the product handled. It can be used for general purposes
- glove used as a medical device for examination, even invasive, intended for temporary use
- glove used as Personal Protective Equipment (PPE) also against chemicals and microorganisms
- unit For Sale in boxes of 50 gloves/pcs.
- outer packagings containing n°10 packs

Imballo - Pack

Taglia *Size*	Articolo *Article*	Taglia *Size*	Cartone *Carton*
R98 S	8032891631836	S	8032891636831
R98 M	8032891631843	M	8032891636848
R98 L	8032891631850	L	8032891636855
R98 XL	8032891631867	XL	8032891636862

3. QUALITY AND COMPLIANCE WITH REGULATIONS

- As a PPE category III risk according to IT Legislative Decree 475/92 implementing Dir 89/686/EEC (CIMAC, authorized Ministerial: 0465). The product is certified according to the EN 420 , EN 374 part I, II and III and EN 388.

- As Medical Device Class I fall in between devices by invasive examination also intended for temporary use in accordance with Directive 93/42/EEC and subsequent Legislative Decree 37/2010 on the implementation Dir 2007/47/EEC. The product is in accordance with the EN 455 1-2 and 3. CND T010201 GLOVES NON SURGICAL LATEX PROGRESSIVE SYSTEM ATTRIBUTED TO DM: -S/866734 - M/866736 - L/866737 - XL/866738

- The product may come into contact, for industrial use, with food as it complies with the relevant legislation: IT Directives 82/711/EEC, 85/572/EEC, 93/8/EEC, 97/48/EC, 2002/72/EC and subsequent amendments, regulations 1935/2004/EC, 1895/2005/CE, EU n.10/2011, DM 21/03/1973 and subsequent updates and changes, Presidential Decree 777/82 and subsequent updates and changes in accordance with the relevant regulations UNI EN 1186 1-15:2003. To such use carefully read the declaration of suitability for food contact (DICA).

4. DIMENSIONS AND PERFORMANCE:

Dimensions (in mm.)	SIZE		Length (min.)	Width
	description size	size CE		
	S	7	270	85
	M	8	270	95
	L	9	270	106
	XL	10	270	116

Thickness (mm)	Palmo (± 0.03)	0.33

EN 420	construction compliant	in compliance
	measures	in compliance
	donning	in compliance

	dexterity	minimum diameter of 5 mm peg collected

EN 374	test water loss	passed
	evidence of air leak	passed

EN 374-3		Performance level of permeation	Breakthrough time (permeation)
	Sulfuric acid 96 %	2	>30’
	Sodium hydroxide 40%	3	>60’
	diethylamine	2	>30’
	p-phenylenediamine 5%	3	>60’

EN 388		Protection Levels
	Resistance to abrasion, blade cut, tear , perforation	0
	Dexterity	5

EN 455-2:2009/A1	Tensile strength	≥6 N. (min)

For the certification of PPE category III, gloves reflexx 98RH are tested with the following chemicals (EN 374): 96% sulfuric acid, sodium hydroxide 40%, diethylamine and p-phenylenediamine 5% and are tested (legislation EN-388) for resistance to abrasion, to cutting by blade, for tearing and perforation.
Gloves reflexx 98RH are controlled according to the sampling method ISO 2859 AQL 1.5 (level G1) for freedom from holes AQL 2.5 (level G1) for major and for minor defects.

5. INSTRUCTIONS FOR USE AND STORAGE:

1. Please read carefully the information note before using the glove
2. Please keep this information note for the duration of the useful life of the glove
3. The product contains latex rubber. It may cause allergic reactions of type I hypersensitivity and delayed hypersensitivity type IV.
5. Avoid contact with aggressive substances such as fats , oils , acids, hydrocarbons and other chemical agents ; has low resistance to ketone solvents.
6. Before using the product, test it in real conditions of use.
7. Keep the packaging for further information and to ensure traceability.
8. Keep the product in its original packaging in a dry place at a temperature not exceeding 40 °C or below -10 °C.
9. Avoid exposure to sunlight and heat sources.
10. The expiry date is indicated on the packaging and it is valid when the product must is properly stored.
11. As a medical device and PPE can come into contact with organic material potentially infected. In this situation, the disposal must follow the procedures for the disposal of special waste. If the use is not in contact with potentially infectious materials disposal will have to follow the common rules of waste.

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