DISPOSABLE LATEX GLOVES FOR EXAMINATION POWDER FREE TRADEMARK REFLEXX 57

1. NAME AND ADDRESS OF MANUFACTURER:

REFLEXX S.R.L.
Via Passeri, 2
46019 VIADANA (MN)
Tel. 0375 833164 Fax. 0375 464504

2. GENERAL DESCRIPTION OF PRODUCT:

 disposable glove inspection in natural rubber latex, with high sensitivity, dexterity and comfort.
 five-fingered glove with beaded cuff, ambidextrous in white-amber color with smooth surface..
 glove not sterile, powder-free inside 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 by testing for all procedures non-invasive and invasive procedures for temporary use.
 glove used as Personal Protective Equipment (PPE) against minimal risks.
 Unit For Sale in boxes of 100 gloves/pcs. in flat cardboard boxes recyclable
 Outer packagings containing n°10 packs made from recyclable corrugated cardboard

Imballo		
Cod./Taglie	100 Confezione	10 Cartone
R57/XS	8032891632901	8032891637906
R57/S	8032891632918	8032891637913
R57/M	8032891632925	8032891637920
R57/L	8032891632932	8032891637937
R57/XL	8032891632949	8032891637944

3. QUALITY AND COMPLIANCE WITH REGULATIONS

- As a PPE category I risk according to IT Legislative Decree 475/92 implementing Dir 89/686/EEC. The product is certified according to the EN 420 and EN 374

- 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

4. DIMENSIONS AND PERFORMANCE:

Dimensions (in mm.)	SIZE		Length (min.)	Width
	description size	size CE		
	XS	6	240	70-75
	S	7	240	80-85
	M	8	240	90-95
	L	9	240	100-105
	XL	10	240	110-115

Thickness (in mm.)	Cuff (± 0.03)	0.07
	Palm (± 0.03)	0.10
	Fingers (± 0.03)	0.13

EN 420	construction compliant	in compliance
	measures	in compliance
	donning	in compliance
	dexterity	minimum diameter of 5 mm peg collected

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

Gloves reflexx 57 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 AQL 4.0 (livello G1) 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. Disposable latex glove - PPE : Risk Category I against minimal risks (Directive 89/686/EEC) - glove for medical purposes - medical device class I to Directive 2007/47 EEC
4. The glove is a device subject to wear and tear so it is recommended the frequent replacement , and in all cases where visually you can see imperfections. Always wear gloves your hands are dry and clean
5. The product contains latex rubber. It may cause allergic reactions of type I hypersensitivity and delayed hypersensitivity type IV.
6. Avoid contact with aggressive substances such as fats , oils , acids, hydrocarbons and other chemical agents
7. Before using the product, test it in real conditions of use
8. Before use, remove the excess powder that may be present on the outside; after use, wash your hands carefully
9. Keep the packaging for further information and to ensure traceability
10. Keep the product in its original packaging in a dry place at a temperature not exceeding 40 ° C or below -10 ° C
11. Avoid exposure to sunlight and heat sources
12. The expiry date is indicated on the packaging and it is valid when the product must is properly stored
13. 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.

REFLEXX Srl
Via Passeri, 2 - 46019 VIADANA (MN)
P.I. e C.F. 02085450209
Tel. 0375.833164 - Fax 0375.464504
e-mail: info@reflexx.com