



E SEI IN MANI SICURE!

REFLEXX S.r.l.

INFORMATIVE NOTE

rev 09 del 29 giugno 2016

Product: reflexx 46 art. R46/ XS - art. R46/ S – art. R46/ M – art. R46/ L– art. R46/ XL

Emessa da G.Isetti - Amm.re Unico

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## DISPOSABLE LATEX GLOVES FOR EXAMINATION POWDER FREE TRADEMARK REFLEXX 46

### 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 textured surface and textured fingers.
- glove not sterile, powder-free inside and internally chlorinated for easy donning and reduce the risk of allergies.
- glove with protein content of less than 50 mg/dm<sup>2</sup> (Lowry method, according to EN 455-3).
- 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) also against chemicals and microorganisms.
- Unit For Sale in boxes of 100 gloves/pcs.
- Outer packagings containing n°10 packs



Imballo - Pack

100		10	
Taglia Size	Articolo Article	Taglia Size	Cartone Carton
R46 XS	8032891631614	XS	8032891636619
R46 S	8032891631621	S	8032891636626
R46 M	8032891631638	M	8032891636633
R46 L	8032891631645	L	8032891636640
R46 XL	8032891631652	XL	8032891636657

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Capitale Sociale 300.000 euro (i.v.) Partita Iva 02085450209 R.E.A. 23166 - e-mail: [info@reflexx.com](mailto:info@reflexx.com) [www.reflexx.com](http://www.reflexx.com)



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### 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: mis. XS/392641 S/392643 M/392650 L/392652 XL/392655
- 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		
	XS	6	240	70-79
	S	7	240	80-89
	M	8	240	90-99
	L	9	240	100-109
	XL	10	240	110-119

  

Thickness (mm.)	Palm ( $\pm$ 0.03)	0.10
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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'

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

EN 455-2:2009/A1	Tensile strength	≥6 N. (min)
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For the certification of PPE category III, gloves reflexx 46 are tested with the following chemicals (EN 374): 96% sulfuric acid, sodium hydroxide 40%, diethylamine and are tested (legislation EN-388) for resistance to abrasion, to cutting by blade, for tearing and perforation.

Gloves reflexx 46 are controlled according to the sampling method ISO 2859 AQL 1.5 (level G1) for freedom from holes AQL 2.5 (level G1) for more defects and AQL 4.0 (level G1) for minor defects.



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## 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 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
4. 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 be 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.

