



E SEI IN MANI SICURE!

REFLEXX S.r.l.	INFORMATIVE NOTE	rev 10 del 29 giugno 2016
Product: reflexx 40 art. R40/ XS - art. R40/ S – art. R40/ M – art. R40/ L– art. R40/ XL		
<i>Emessa da G.Isetti – Amm.re Unico</i>		Pag.: 1/4

DISPOSABLE LATEX GLOVES FOR EXAMINATION

TRADEMARK REFLEXX 40

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.
- glove not sterile, with powder inside of vegetable origin (corn starch) for easy donning.
- five-fingered glove with beaded cuff, ambidextrous in white color and smooth surface.
- 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
R40 XS	8032891631324	XS	8032891636329
R40 S	8032891631331	S	8032891636336
R40 M	8032891631348	M	8032891636343
R40 L	8032891631355	L	8032891636350
R40 XL	8032891631362	XL	8032891636367



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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/387055 S/388913 M/388914 L/388916 XL/388917
- ❑ 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 (in mm.)	Palm (\pm 0.03)	0.09
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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%	2	>30'
	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)
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For the certification of PPE category III, gloves reflexx 40 are tested with the following chemicals (EN 374): 96% sulfuric acid, sodium hydroxide 40%, diethylamine, p-phenylenediamine 5% and are tested (legislation EN-388) for resistance to abrasion, to cutting by blade, for tearing and perforation.

Gloves reflexx 40 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 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. Before use, remove the excess powder that may be present on the outside; after use, wash your hands carefully
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. The product contains latex rubber. It may cause allergic reactions of type I hypersensitivity and delayed hypersensitivity type IV.
8. Keep the packaging for further information and to ensure traceability
9. Keep the product in its original packaging in a dry place at a temperature not exceeding 40 ° C or below -10 ° C
10. Avoid exposure to sunlight and heat sources
11. The expiry date is indicated on the packaging and it is valid when the product must is properly stored
12. 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

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