



E SEI IN MANI SICURE!

REFLEXX S.p.A.	INFORMATIVE NOTE	rev 00 del 9 marzo 2017
Product: reflexx 77 art. R77100/XS - art. R77100/ S – art. R77100/ M – art. R77100/ L– art. R77100/ XL		
<i>Emessa da G.Isetti – Amm.re Unico</i>		Pag.: 1/4

DISPOSABLE EXAMINATION NITRILE POWDER FREE GLOVES TRADEMARK REFLEXX 77

1. NAME AND ADDRESS OF MANUFACTURER:

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

2. GENERAL DESCRIPTION OF PRODUCT:

- ❑ disposable nitrile synthetic glove with five fingers, beaded cuff , ambidextrous , light blue color, textured surface and Textured fingertips
- ❑ non-sterile gloves, powder free, internally chlorinated for easy donning and to reduce the risk of allergies.
- ❑ multi-purpose glove to protect the hand and / or the product and can be used for general purposes.
- ❑ glove used as a medical device by examination, even invasive , intended for temporary use
- ❑ glove can be used as Personal Protective Equipment (PPE) also against chemicals and micro-organisms
- ❑ Unit For Sale in boxes of 100 gloves / pcs.
- ❑ Outer packagings containing n ° 10 packs



Imballo		
Cod./Taglie	Confezione	Cartone
R77100/XS	8032891633465	8032891638460
R77100/S	8032891633472	8032891638477
R77100/M	8032891633489	8032891638484
R77100/L	8032891633496	8032891638491
R77100/XL	8032891633502	8032891638507



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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 T01020204 – NITRILE GLOVES – PROGRESSIVE SYSTEM ATTRIBUTED TO DM: : mis. XS/1528659 S/1528660 M/1528658 L/1528656 XL/1528657.
- ❑ 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 (+/-5)
	description size	size CE		
	XS	6	230	75
	S	7	230	85
	M	8	240	95
	L	9	250	106
	XL	10	260	116

Thickness (in mm.)	Palm (± 0.03)	0.06
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EN 420	construction compliant	in compliance
	measures	in compliance
	donning	in compliance
	dexterity	minimum diameter of 5



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		mm peg collected
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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)
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For the certification of PPE category III, gloves reflexx 77 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 77 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.

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. Avoid contact with aggressive substances such as fats, oils, acids, hydrocarbons and other chemical agents; has low resistance to ketone solvents
4. Before using the product, test it in real conditions of use



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5. 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
6. Keep the packaging for further information and to ensure traceability
7. Keep the product in its original packaging in a dry place at a temperature not exceeding 40 ° C or below -10 ° C
8. Avoid exposure to sunlight and heat sources
9. The expiry date is indicated on the packaging and it is valid when the product must is properly stored
10. 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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