



E SEI IN MANI SICURE!

REFLEXX S.p.A.

INFORMATIVE NOTE

rev 01 del 12 dicembre 2017

Prodotto: reflexx N70plus art. N70P/S – art. N70P/M – art. N70P/L– art. N70P/XL– art. N70P/XXL

Emessa da G.Isetti - Amm.re Unico

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EXAMINATION GLOVES DISPOSABLE NITRILE POWDER FREE

TRADEMARK REFLEXX N70plus

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 nitrile synthetic glove with five fingers, ambidextrous with long cuff, beaded cuff, 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 can be used as Personal Protective Equipment (PPE) also against chemicals and micro-organisms
- ❑ glove used as a medical device by examination, even invasive, intended for temporary use
- ❑ Unit For Sale in boxes of 100 gloves / pcs.
- ❑ Outer packagings containing n °10 packs



Codici	Pack	Cartone
N70P/S	8032891633403	8032891638408
N70P/M	8032891633410	8032891638415
N70P/L	8032891633427	8032891638422
N70P/XL	8032891633434	8032891638439
N70P/XXL	8032891633441	8032891638446



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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 T01020299 – non surgical nitrile gloves

- 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 (mm)	Size		Length (min.) ±10	Width
	description size	size CE		
	S	7	290	80-89
	M	8	290	90-99
	L	9	290	100-109
	XL	10	290	110-119
	XXL	11	290	120-129

Thickness (mm)	Palm (± 0.03)	0.10
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EN 420	construction	in compliance
	measures	in compliance
	donning	in compliance
	dexterity	minimum diameter of 5 mm peg collected



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EN 374	test water loss	passed
	test 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 N70plus 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.

The gloves reflexx N70plus are controlled according to the sampling method ISO 2859 AQL 1.5 (G1 level) for freedom from holes AQL 2.5 (G1 level) for more defects and AQL 4.0 (G1 level) for minor defects.

5. INSTRUCTIONS FOR USE AND STORAGE

1. It is recommended to read carefully the information note before the use of the glove
2. Please keep this information note for the duration of the useful life of the glove
3. The product does not contain natural rubber latex
4. In rare cases, you may encounter transient skin reactions and hypersensitivity reactions. In case of a reaction discontinue use . Nitrile gloves Reflexx N70plus are designed in order to eliminate allergic



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reactions associated with latex proteins . The absence of dust enables the use of the glove even to people who suffer from irritations caused by allergies to corn starch or a particularly sensitive skin

5. Before using the product, test it in real conditions of use
6. Do not use gloves when there is a risk of getting caught in the moving parts of machinery
7. 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 when your hands are dry and clean and wash your hands thoroughly
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.

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