



E SEI IN MANI SICURE!

REFLEXX S.p.A.

INFORMATIVE NOTE

rev 02 del 10 novembre 2017

Product: reflexx N79plus art. N79P/S – art. N79P/M– art. N79P/L– art. N79P/XL

Emessa da G.Isetti - Amm.re Unico

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## EXAMINATION GLOVES DISPOSABLE NITRILE POWDER FREE

### TRADEMARK REFLEXX N79plus

#### 1. NAME AND ADDRESS OF MANUFACTURER

REFLEXX S.p.A.

Via Passeri, 2

46019 VIADANA (MN)

Tel. 0375 758891 Fax. 0375 464504

#### 2. GENERAL DESCRIPTION OF PRODUCT

- disposable nitrile synthetic glove with five fingers, with long cuff, beaded cuff, ambidextrous, black 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 50 gloves / pcs.
- Outer packagings containing n °10 packs

Codici	Pack	Cartone
N79P/S	8032891633533	8032891638538
N79P/M	8032891633540	8032891638545
N79P/L	8032891633557	8032891638552
N79P/XL	8032891633564	8032891638569

#### 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 420:2003 + A1 2009, EN 374-1:2016 TYPE B, EN 374-2:2015, EN 374-4:2013 and EN 374-5:2016

- 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



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in accordance with the EN 455 1-2-3 and 4. CND T01020204 – non surgical nitrile gloves\_ mis. S/1555786 M/ 1555785 L/ 1555788 XL/ 1555789

#### 4. DIMENSIONS AND PERFORMANCE

Dimensions (mm)	Size		Length (mm)	Width
	description size	size CE		
	S	7	300±20	80-89
	M	8	300±20	90-99
	L	9	300±20	100-109
	XL	10	300±20	110-119

Thickness (mm)	Palm (± 0.03)	0.14
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EN 420:2003 + A1 2009	construction	in compliance
	measures	in compliance
	donning	in compliance
	dexterity	minimum diameter of 5 mm peg collected

EN 374	test water loss	passed
	test of air leak	passed

EN 374-1:2016 TYPE B		Performance level of permeation	Breakthrough time (permeation)
		Sulfuric acid 96 %	2
	Sodium hydroxide 40%	3	>60'
	diethylamine	2	>30'
	p- phenylenediamine 5%	3	>60'
EN 374-4:2013	Degradation index		
		Sulfuric acid 96 %	96%
		Sodium hydroxide 40%	59%
		diethylamine	73%
	p- phenylenediamine 5%	51%	

EN 455-2:2009/A1	Tensile strength	≥6 N. (min)
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For the certification of PPE category III, gloves reflexx N79plus are tested for permeation and degradation with the following chemicals (EN 374-1:2016; EN 374-4:2013): 96% sulfuric acid, sodium hydroxide 40%, diethylamine, p-phenylenediamine.

The gloves reflexx N79plus 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 product
2. Please keep this information note for the duration of the useful life of the product
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 N79plus are designed in order to eliminate allergic 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. Carefully read the times and levels of protection indicated for chemicals
7. Do not use gloves when there is a risk of getting caught in the moving parts of machinery
8. 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
9. Keep the packaging for further information and to ensure traceability
10. Keep the product in its original packaging in a dry place
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. Dispose of in accordance with applicable national, regional and local regulations

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