



E SEI IN MANI SICURE!

<b>REFLEXX S.p.A.</b>	<b>INFORMATIVE NOTE</b>	<b>rev. 11 del 06 marzo 2018</b>
Product: REFLEXX 30 art. R30/S– art. R30/M – art. R30/L – art. R30/XL		
<i>Emessa da G.Isetti – Amm.re Unico</i>		Pag.: 1/3

## DISPOSABLE VINYL GLOVES FOR EXAMINATION TRADEMARK REFLEXX 30

### 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 Vinyl (PVC) Glove, with five fingers, beaded cuff, ambidextrous, white color and smooth surface
- glove not sterile, with powder inside of vegetable origin (corn starch) for easy donning
- 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) for minimal risks only
- unit For Sale in boxes of 100 gloves / pcs.
- outer packagings containing n ° 10.



#### Imballo - Pack

100		10	
Taglia Size	Articolo Article	Taglia Size	Cartone Carton
R30 S	8032891631386	S	8032891636381
R30 M	8032891631393	M	8032891636398
R30 L	8032891631409	L	8032891636404
R30 XL	8032891631416	XL	8032891636411



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### 3. QUALITY AND COMPLIANCE WITH REGULATIONS

-As a PPE category I risk according to IT Legislative Decree 475/92 implementing Dir 89/686/EEC. The product is certified according to the EN 420 , EN 374

- 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 T01020201 NON SURGICAL GLOVES VINYL. PROGRESSIVE SYSTEM ATTRIBUTED TO DM: mis. S/419452 M/419522 L/419523 XL/419526.

- 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 (± 5mm)
	description size	size CE		
	S	7	240	85
	M	8	240	95
	L	9	240	105
	XL	10	240	115

Thickness ( in mm.)	Palm (± 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



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		mm peg collected
EN 374	test water loss	passed
	evidence of air leak	passed
EN 455-2:2009/A1	Tensile strength	≥3.6 N (min)

The gloves reflexx 30 are controlled according to the sampling method ISO 2859 AQL 1.5 ( G1 level ) for freedom from holes.

## 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. The product does not contain nickel
5. Avoid contact with aggressive substances such as fats, oils, acids, hydrocarbons, ketone solvents and other chemical agents
6. Before using the product, test it in real conditions of use
7. Before use, remove the excess powder that may be present on the outside; after use, wash your hands carefully. The glove is a device subject to wear so it is recommended frequent replacement and in all cases in which you can see visually imperfections. Wear gloves always with clean, dry hands after use and accurately wash the hands
8. Keep the packaging for further information and to ensure traceability
9. Keep the product in its original packaging in a dry place
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 be properly stored
12. Dispose of in accordance with applicable national, regional and local regulations

**REFLEXX S.p.A.**  
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