GLOVES DISPOSABLE VINYL POWDER FREE
TRADEMARK REFLEXX 38 STRETCH

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

- Glove Non Sterile Disposable Vinyl (PVC) powder free.
- Glove with five fingers, with beaded cuff, ambidextrous, 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 examination, even invasive, intended for temporary use.
- Glove 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 cardboard

Imballo - Pack

100		10	
Taglia *Size*	Articolo *Article*	Taglia *Size*	Cartone *Carton*
R38 S	8032891631973	S	8032891636978
R38 M	8032891631980	M	8032891636985
R38 L	8032891631997	L	8032891636992
R38 XL	8032891632000	XL	8032891636008

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 T01020201 NON SURGICAL GLOVES VINYL. PROGRESSIVE SYSTEM ATTRIBUTED TO DM: mis. S/419534 M/419535 L/419536 XL/419537.

- Il prodotto può essere utilizzato, per uso industriale, con alimenti in quanto certificato secondo la legislazione di riferimento: DPR 777 del 23/08/1982 e DM 108 del 25/01/1992, DM 21/03/1973 e successivi aggiornamenti e modifiche; direttive 82/711/CEE, 85/572/CEE, 93/8/CEE, 97/48/CE; regolamenti (EU) 10/2011, 321/2011, 1282/2011, regolamenti (CE) 1935/2004, 1895/2005, in accordo con la normativa di riferimento: UNI EN 1186 1-15:2003. Per tale utilizzo leggere attentamente la dichiarazione di idoneità al contatto alimentare (DICA).

4. DIMENSIONS AND PERFORMANCE

Dimensions (mm)	Size		Length (min.)	Width
	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

EN 420	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 374-3		Performance level of permeation	Breakthrough time (permeation)
	Sulfuric acid 96 %	2	>30’
	Sodium hydroxide 40%	2	>30’
	diethylamine	2	>30’

EN 388		Protection Levels
	Resistance to abrasion, blade cut, tear, perforation	0
	Dexterity	5

EN 455-2:2009/A1	Tensile strength	≥3.6 N (min)

The gloves reflexx 38 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. The product does not contain nikel
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. Avoid contact with aggressive substances such as fats, oils, acids, hydrocarbons and other chemical agents; has low resistance to ketone solvents
7. Before using the product, test it in real conditions of use

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
Via Passeri, 2 - 46019 VIADANA (MN)
P.I. e C.F. 02085450209
Tel. 0375.833164 - Fax 0375.464504
e-mail: info@reflexx.com