



I N S A F E H A N D S

REFLEXX S.p.A. Unipersonale

INFORMATIVE NOTE

rev 09 del 12 novembre 2019

Product: reflexx 98HR art. R98/ S – art. R98/ M – art. R98/ L– art. R98/ XL– art. R98/ XXL

Emessa da G.Isetti - Amm.re Unico

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DISPOSABLE LATEX GLOVES HIGH RESISTANCE TRADEMARK REFLEXX 98

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 glove high resistance in natural rubber latex
- ❑ glove with five fingers, ambidextrous, dark blue with long cuff, micro textured surface, beaded cuff and textured fingers
- ❑ glove non sterile, powdered free and internally chlorinated for easy donning and reduce the risk of allergies
- ❑ multipurpose glove to protect the hand and/or the product handled. It can be used for general purposes
- ❑ glove used as a medical device for examination, even invasive, intended for temporary use
- ❑ glove used as Personal Protective Equipment (PPE) also against chemicals and microorganisms
- ❑ unit For Sale in boxes of 50 gloves/pcs
- ❑ outer packagings containing n°10 packs



Imballo - Pack

50		10	
Taglia Size	Articolo Article	Taglia Size	Cartone Carton
R98 S	8032891631836	S	8032891636831
R98 M	8032891631843	M	8032891636848
R98 L	8032891631850	L	8032891636855
R98 XL	8032891631867	XL	8032891636862

3. QUALITY AND COMPLIANCE WITH REGULATIONS



- As a PPE category III risk according to Reg UE 2016/425 (ANCI_CIMAC, corso Brodolini, 19 27029 Vigevano (PV): Authorized Ministerial Body n. 0465). The product is certified according to the EN ISO 374-1:2016 TYPE A and EN ISO 374-5:2016

- Medical Device CLASSE I - Dir. 93/42/CEE – Dir 2007/47/CEE – EN 455 1,2,3, & 4
CND T010201 NON SURGICAL LATEX GLOVES - PROGRESSIVE NUMBER SYSTEM ATTRIBUTED TO DM: mis. S/1541982 - M/1541983 - L/1541984 - XL/1541985 – XXL/1541986



Reg CE 1935/2004 – Reg UE 10/2011 - DM 21/03/1973

To such use carefully read the declaration of suitability for food contact (DICA).





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4. DIMENSIONS AND PERFORMANCE:

DIMENSIONS		
Cod./Size	Length (mm)	Width (mm)
R98/ S (7)	280	80-89
R98/ M (8)	280	90-99
R98/ L (9)	280	100-109
R98/ XL (10)	280	110-119
R98/ XXL (11)	280	120-129

Thickness mm	Palm (+/- 0.06)	0.33
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ISO 2859		
AQL 1.5 (level G1) Freedom from holes	AQL 2.5 (level G1) Major defects	AQL 4 (level G1) Minor defects

EN 455-2:2009/A1	Tensile strength	≥6 N (min)
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EN 420:2003 + A1 2009	construction compliant	in compliance
	measures donning	in compliance
	dexterity	minimum diameter of 5 mm peg collected

EN 374-2:2014	test water loss	passed
	evidence of air leak	passed

EN ISO 374-1:2016				
Chemical compound :	COD	EN 16523-1:2015 TYPE A		EN 374-4:2013
		Performance level	Breakthrough time	% degradation
Sulfuric acid 96%	L	2	>30'	89%
Sodium hydroxide 40%	K	3	>60'	40%
Diethylamine	G	2	>30'	32%
Nitric acid 65%	M	2	>30'	90.2%
Formaldehyde 37%	T	3	>60'	51.3%
Hydrogen peroxide 30%	P	3	>60'	40.4%
p- phenylenediamine 5%		3	>60'	37%
Methanol		1	>10'	89%

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. The glove is a device subject to wear, so frequent replacement is recommended and in all cases where imperfections are observed. Wear gloves with dry, clean hands
4. The product contains latex rubber. It may cause allergic reactions of type I hypersensitivity and





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- delayed hypersensitivity type IV. In case of reaction, discontinue use and consult a doctor
5. Avoid contact with aggressive substances such as fats , oils , acids, hydrocarbons and other chemical agents.
 6. The glove is suitable for contact with pure chemical products for less than the permeation time indicated in the chemical resistance table. Results are obtained under laboratory conditions and may not reflect actual working time.
 7. Before using the product, try it in the real condition of use
 8. Keep the packaging for further information and ensure traceability
 9. Store the gloves in their original packaging in a dry place
 10. Do not expose to direct sunlight and heat sources
 11. The expiry date is 3 years from the date of manufacture indicated on the sales package, and is valid for the product properly stored
 12. Gloves must be disposed of according to local regulations

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