



I N S A F E H A N D S

REFLEXX S.p.A. Unipersonale

INFORMATIVE NOTE

rev 09 del 28 ottobre 2018

Product: reflexx 78 art. R78/XS- art. R78/S- art. R78/M- art. R78/L- art. R78/XL

Emessa da G.Isetti – Amm.re Unico

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EXAMINATION GLOVES DISPOSABLE NITRILE POWDER FREE TRADEMARK 78Black

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, beaded cuff , ambidextrous , black color, textured surface
- ❑ 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, but also as a medical device and as Personal Protective Equipment (PPE) also against chemicals and microorganisms; particularly recommended for aesthetic treatment and tinctures.
- ❑ Unit For Sale in boxes of 100 gloves / pcs.
- ❑ Outer packagings containing n ° 10 packs.



Imballo - Pack

100		10	
Taglia Size	Articolo Article	Taglia Size	Cartone Carton
R78 S	8032891631928	S	8032891636923
R78 M	8032891631935	M	8032891636930
R78 L	8032891631942	L	8032891636947
R78 XL	8032891631959	XL	8032891636954

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 B 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 T01020204 – NITRILE GLOVES –PROGRESSIVE NUMBER SYSTEM
ATTRIBUTED TO DM: mis. XS/1564830 S/1543992 M/1543993 L/1543994
XL/1543995



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 min. (mm)	Width mm (± 5)
R78/ XS (6)	240	80
R78/ S (7)	240	85
R78/ M (8)	240	95
R78/ L (9)	240	106
R78/ XL (10)	240	116

Thickness mm	Palm (+/- 0.02)	0.08
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EN 420:2003 + A1 2009	construction	
	compliant	in compliance
	measures	in compliance
	donning	in compliance

EN 455-2:2009/A1	Tensile strength	≥ 6 N (min)
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EN ISO 374-1:2016

Chemical compound :	EN 16523-1:2015 TYPE B			EN 374-4:2013
	COD	Performance level	Breakthrough time	% degradation
Sulfuric acid 96 %	L	2	>30'	95%
Sodium hydroxide 40%	K	3	>60'	47%
Diethylamine	G	2	>30'	73%
p- phenylenediamine 5%		3	>60'	51%

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

ISO 2859		
AQL 1.5 (level G1) Freedom from holes	AQL 2.5 (level G1) Major defects	AQL 4 (level G1) Minor defects

5. WARNINGS FOR USE AND STORAGE

- Please read carefully the information note before using the glove
- Please keep this information note for the duration of the useful life of the glove
- The product does not contain natural rubber latex
- In rare cases, you may encounter transient skin reactions and hypersensitivity reactions. In case of a reaction discontinue use . Nitrile gloves Reflexx 78 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
- 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
- Avoid contact with aggressive substances such as fats , oils , acids, hydrocarbons and other chemical agents.
- 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.





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8. Before using the product, try it in the real condition of use
9. Keep the packaging for further information and ensure traceability
10. Store the gloves in their original packaging in a dry place
11. Do not expose to direct sunlight and heat sources
12. The expiry date is 3 years from the date of manufacture indicated on the sales package, and is valid for the product properly stored
13. Gloves must be disposed of according to local regulations

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