EXAMINATION GLOVES DISPOSABLE NITRILE POWDER FREE TRADEMARK 78Black

1. NAME AND ADDRESS OF MANUFACTURER:

REFLEXX S.R.L.
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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

Taglia *Size*	Articolo *Article*	Taglia *Size*	Cartone *Carton*
	100		10
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 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 T01020299 – NITRILE GLOVES - PROGRESSIVE SYSTEM ATTRIBUTED TO DM: mis. S/720929 M/720930 L/720933 XL/720936.

4. DIMENSIONS AND PERFORMANCE:

Dimensions (in mm.)	size		Length (min.)	Width
	description size	size CE		
	S	7	240	84
	M	8	240	94
	L	9	240	105
	XL	10	240	113

Thickness (mm.)	Palm (±0.03)	0.08

EN 420	construction compliant	in compliance
	measures	in compliance
	donning	in compliance
	dexterity	minimum diameter of 5 mm peg collected

EN 374	test water loss	passed
	evidence of air leak	passed

EN 374-3		Performance level of permeation	Breakthrough time (permeation)

	Sulfuric acid 96 %	2	>30’
	Sodium hydroxide 40%	3	>60’
	diethylamine	2	>30’
	p- phenylenediamine 5%	3	>60’

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

EN 455-2:2009/A1	Tensile strength	≥6 N. (min)

For the certification of PPE category III, gloves reflexx 78 are tested with the following chemicals (EN 374): 96% sulfuric acid, sodium hydroxide 40%, diethylamine, p-phenylenediamine 5% and are tested (legislation EN-388) for resistance to abrasion, to cutting by blade, for tearing and perforation.
Gloves reflexx 78 are controlled according to the sampling method ISO 2859 AQL 1.5 (level G1) for freedom from holes AQL 2.5 (level G1) for more defects and AQL 4.0 (level G1) for minor defects.

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 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 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

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.

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.