# DISPOSABLE LATEX GLOVES FOR EXAMINATION

# TRADEMARK REFLEXX 51

## 1. NAME AND ADDRESS OF MANUFACTURER:

REFLEXX S.R.L.
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## 2. GENERAL DESCRIPTION OF PRODUCT:

 disposable glove inspection in natural rubber latex, with high sensitivity, dexterity and comfort.
 glove not sterile, with powder inside of vegetable origin (corn starch) for easy donning.
 five-fingered glove with beaded cuff, ambidextrous in white color and smooth surface.
 multipurpose glove to protect the hand and/or the product handled. It can be used for general purposes and may come into contact with different foods.
 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) against minimal risks.
 Unit For Sale in boxes of 100 gloves/pcs. in flat cardboard boxes recyclable.
 Outer packagings containing n°10 packs made from recyclable corrugated cardboard.

| Imballo | | |
|---|---|---|
| Cod./Taglie | 100 Confezione | 10 Cartone |
| **R51/XS** | 8032891632994 | 8032891637999 |
| **R51/S** | 8032891633007 | 8032891638002 |
| **R51/M** | 8032891633014 | 8032891638019 |
| **R51/L** | 8032891633021 | 8032891638026 |
| **R51/XL** | 8032891633038 | 8032891638033 |

## 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 and 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 T010201 GLOVES NON SURGICAL LATEX -
- The product can be used with foods, as certified by the relevant legislation: DM 21/03/1973 and subsequent updates and changes, Regulation 1935/2004/EC, in accordance with the relevant regulations: UNI EN 1186-1-15:2003. For such use, follow the instructions for use

## 4. DIMENSIONS AND PERFORMANCE:

| | SIZE | | Length (min.) | Width |
|---|---|---|---|---|
| Dimensions (in mm.) | description size | size CE | | |
| | XS | 6 | 240 | 76 +/- 3 |
| | S | 7 | 240 | 84 +/- 3 |
| | M | 8 | 240 | 94 +/- 3 |
| | L | 9 | 240 | 105 +/- 3 |
| | XL | 10 | 240 | 113 +/- 3 |

| | | |
|---|---|---|
| Thickness ( in mm.) | Cuff (± 0.03) | 0.09 |
| | Palm (± 0.03) | 0.08 |
| | Fingers (± 0.03) | 0.11 |

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

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

Gloves reflexx 51 are controlled according to the sampling method ISO 2859 AQL 1.5 (level G1) for freedom from holes AQL 2.5 (level G1) for major and 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. Disposable latex glove - PPE : Risk Category I against minimal risks (Directive 89/686/EEC ) - glove for medical purposes - medical device class I to Directive 2007/47 EEC
4. On the basis of tests performed glove Reflexx 51 can come into contact with aqueous foods, for which it is expected the use of the simulant A for 30 minutes at 40 ° C. The product is not suitable for

contact with acid foods with pH <4.5, alcoholic and oily or fatty foods, for which it is provided the use of simulants B, C, D1 and D2 for 30 minutes at 40 ° C. The glove may then meet for example with non-alcoholic beverages with pH> 4.5; Whole fruit, fresh or chilled, unpeeled; Whole vegetables, fresh or chilled; spices and seasonings in the natural state with pH> 4.5. In case of contact with specific foods and / or special conditions of use require the supplier information to the specific conditions of use.

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. Before use, remove the excess powder that may be present on the outside; after use, wash your hands carefully
7. Avoid contact with aggressive substances such as fats , oils , acids, hydrocarbons and other chemical agents ; has low resistance to ketone solvents .
8. Before using the product, test it in real conditions of use
9. The product contains latex rubber. It may cause allergic reactions of type I hypersensitivity and delayed hypersensitivity type IV.
10. Keep the packaging for further information and to ensure traceability
11. Keep the product in its original packaging in a dry place at a temperature not exceeding 40 ° C or below -10 ° C
12. Avoid exposure to sunlight and heat sources
13. The expiry date is indicated on the packaging and it is valid when the product must is properly stored
14. 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.

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