



# nitrylex® pink

The instruction below should be used in conjunction with detailed information on the packaging.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Short description of the product</b></p> <p>examination and protective gloves, nitrile, powder-free, non-sterile for disposable use</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p><b>Properties / Application</b></p> <p>These are non-sterile examination and protective gloves for single use, intended for use in medical field to: protect patient and user from cross-contamination, conducting medical examinations, diagnostic and therapeutic procedures and for handling medical contaminated material. Gloves are classified as Medical Devices Class I and as a Personal Protective Equipment category III complex design – providing limited protection against chemicals hazards. Their design and labelling corresponds to the requirements of the European Medical Device Directive 93/42/EEC and the European Directive on Personal Protective Equipment 89/686/EEC, both as amended. It should be noted, that confirmed protection level does not reflect real working conditions, where other factors may influence to the protection level. Gloves should be used solely according to their intended application.</p> |
| <p><b>Full description of the product</b></p> <p>raw material: nitrile<br/>                 external surface: microtextured + fingertip textured, polymerized<br/>                 internal surface: polymerized + chlorinated<br/>                 cuff: beaded<br/>                 colour: pink<br/>                 shape: ambidextrous, fitting to the right and left hand<br/>                 size range XS (5-6), S (6-7), M (7-8), L (8-9), XL (9-10)<br/>                 AQL: 1.5<br/>                 Quantity in an individual packaging: 100 pcs. by weight<br/>                 Shelf life: 3 years (from the date of manufacturing)<br/>                 Minimum glove length is 240 mm – gloves are suitable for special purposes, there are examination gloves</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p><b>Contact with food</b></p> <p> Gloves marked with the symbol indicating contact with food comply with the requirements of Regulation (EU) No 10/2011, European Regulation (EC) No 1935/2004 and with Regulation (EC) No 2023/2006 on Good Manufacturing Practice.<br/>                 Not all gloves can be used in contact with every type of food, because some of them can release harmful substances penetrating directly into the food. For more detailed information concerning intended use to particular food category, please contact the company Mercator Medical.</p>                                                                                                                                                                                                                                                                                 |
| <p><b>Storage instructions</b></p> <p>It is recommended to store the gloves in a dry place, in the temperature of 5-35°C and to protect them against sunlight and fluorescent light. Recommended relative humidity in the room where the gloves are stored is 60 ±20%.<br/>                 Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone.<br/>                 Do not keep in direct vicinity of solvents, oils, fuels and lubricants.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p><b>Components / hazardous components</b></p> <p>Some gloves may contain components known to be a possible cause of allergy for person allergic to them, who may develop contact irritation and/or allergic reaction. Gloves made from natural rubber latex may cause allergic reactions, including anaphylactic responses. In the case of an allergic reaction, seek medical assistance immediately.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><b>Precautions and indications for use</b></p> <p>Dry the hands well before putting the gloves on. Check the gloves before wearing them if they do not have any faults (holes, contaminations). After taking the gloves off, wash the hands thoroughly, dry them and apply a nourishing cream. Use at least 1 pair of gloves for one patient and one procedure, these are disposable gloves. The gloves soiled with blood or body fluids should be disposed as medical waste. Take care not to let chemical substances get under the gloves through the cuff. If a chemical substance reaches the skin, wash it away immediately with plenty of water with soap. If the gloves get punctured, torn or broken during their use, take them off and put on the new ones. Avoid using gloves dirty in the inside as they may cause irritation leading to skin inflammation or more serious damages. The gloves should not be used in contact with open fire and to protect against any sharp tools. The gloves are not intended for welding, electric shock protection, ionizing radiation or from the effect of hot or cold objects. Protection is limited only to palm, results relate to palm and were examined in laboratory conditions.</p> | <p><b>Disposal</b></p> <p>Used gloves can be contaminated with contagious or other hazardous substances. They should be disposed of in accordance with local regulation. Gloves should be buried or burned under controlled conditions.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p><b>Manufacturer</b></p> <p>MERCATOR MEDICAL S.A.<br/>                 ul. H. Modrzejewskiej 30<br/>                 31-327 Cracow, Poland<br/> <a href="http://www.mercatormedical.eu">www.mercatormedical.eu</a></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <p><b>CE classification - Product Standards Compliance</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <p>Gloves are classified as Medical Device – class I according to Council Directive 93/42/EEC.<br/>                 Compliance with standards: EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN 980:2008, EN 1041:2008.</p> <p>Gloves are classified as Personal Protective Equipment – category III according to Regulation EU 2016/425.<br/>                 Compliance with standards: EN 420:2003+A1:2009, EN 388:2003, EN 374-1:2003 (excluding clause 5.3.2), EN 374-2:2003, EN 374-3:2003.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>EC Type Examination Certificate (Article 10 of the Directive 89/686/EEC) issued by:<br/> <b>SATRA (Notified Body No. 0321)</b></p> <p>Checking of PPE manufactured (Article 11A of the Directive 89/686/EEC):<br/> <b>CE 0321</b><br/> <b>SATRA Technology Centre</b><br/>                 Wyndham Way, Telford Way<br/>                 Kettering, Northamptonshire<br/>                 NN16 8SD, United Kingdom</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |





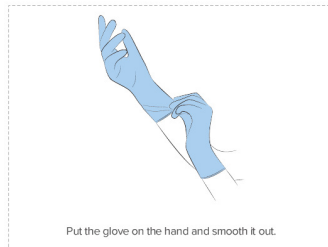
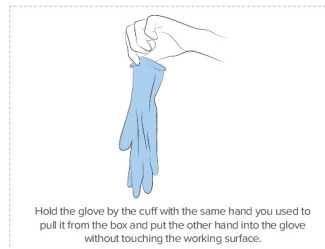
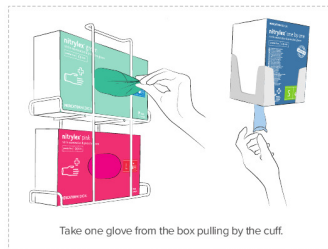
| Permeation performance levels as per EN 374-1:2003          |         | Test according to EN 374-2:2003 – Level 2 (ISO 2859)                                      |         |         |         |         |         |
|-------------------------------------------------------------|---------|-------------------------------------------------------------------------------------------|---------|---------|---------|---------|---------|
| • Level 1 > 10 min • Level 2 > 30 min • Level 3 > 60 min    |         | Performance level                                                                         |         | AQL     |         |         |         |
| • Level 4 > 120 min • Level 5 > 240 min • Level 6 > 480 min |         | Level 3                                                                                   |         | < 0.65  |         |         |         |
| Test results acc. to EN 374-3:2003                          |         | Level 2                                                                                   |         | < 1.5   |         |         |         |
| 1.5% Methanol in water                                      | Level 6 | Level 1                                                                                   |         | < 4.0   |         |         |         |
| 40% Sodium hydroxide                                        | Level 6 | Test according to EN 388:2003                                                             |         |         |         |         |         |
| 50% Sulphuric acid                                          | Level 6 | Abrasion Resistance                                                                       |         | Level 0 |         |         |         |
| 13% Sodium hypochlorite                                     | Level 6 | Blade Cut Resistance                                                                      |         | Level 0 |         |         |         |
| 37% Formaldehyde                                            | Level 4 | Tear Resistance                                                                           |         | Level 0 |         |         |         |
| 50% Glutaraldehyde                                          | Level 6 | Puncture Resistance                                                                       |         | Level 0 |         |         |         |
| 0.15 Phenol                                                 | Level 6 | Levels of effectiveness of protection against mechanical dangers according to EN 388:2003 |         |         |         |         |         |
|                                                             |         | Test                                                                                      | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|                                                             |         | Abrasion resistance (number of cycles)                                                    | 100     | 500     | 2000    | 8000    | -       |
|                                                             |         | Blade cut resistance (index)                                                              | 1.2     | 2.5     | 5.0     | 10.0    | 20.0    |
|                                                             |         | Tear resistance (N)                                                                       | 10      | 25      | 50      | 75      | -       |
|                                                             |         | Puncture resistance (N)                                                                   | 20      | 60      | 100     | 150     | -       |

**Symbols used on the packaging**

|  |                                                                                                                   |  |                                                                                                                     |  |                                                               |
|--|-------------------------------------------------------------------------------------------------------------------|--|---------------------------------------------------------------------------------------------------------------------|--|---------------------------------------------------------------|
|  | Do not re-use / gloves are intended for single use                                                                |  | Non-sterile gloves                                                                                                  |  | Powdered gloves                                               |
|  | Do not use, if package is damaged                                                                                 |  | Keep away from solar and fluorescent light                                                                          |  | Powder free gloves                                            |
|  | Keep away from moisture, store in a dry place                                                                     |  | Temperature limitation / gloves store in temperature 5-35°C                                                         |  | Presence of polymer coating on the inner surface of the glove |
|  | Raw material – natural rubber latex                                                                               |  | Keep away from ozone                                                                                                |  | Presence of cosmetic coating on the inner surface of glove    |
|  | Catalogue number                                                                                                  |  | Lot / batch number                                                                                                  |  | Presence of silk coating on the inner surface of glove        |
|  | European Authorised Representative, symbol should be accompanied by name and address of Authorised Representative |  | Gloves protecting against chemical dangers with triple digit literal code                                           |  | Presence of external texture on the glove                     |
|  | Waterproof gloves and low chemical protection                                                                     |  | Antistatic gloves                                                                                                   |  | Gloves made from nitrile                                      |
|  | Protection against micro-organisms                                                                                |  | Date of manufacture                                                                                                 |  | Gloves made from vinyl                                        |
|  | Manufacturer, symbol should be accompanied by name and address of Manufacturer                                    |  | Protective glove against mechanical risk (if applicable accompanied by 4 digit code of relevant performance levels) |  | Gloves made from neoprene                                     |
|  | Expiry date                                                                                                       |  | Consult instructions for use                                                                                        |  | Gloves made from polyisoprene                                 |
|  | Food contact materials (article is suitable for food contact)                                                     |  | Package made from paper, qualify for recycling                                                                      |  | 50 gloves by weight                                           |
|  | Package is treated as municipal waste                                                                             |  | Indicates compliance with the requirements of Ukrainian market                                                      |  | 100 gloves by weight                                          |
|  | Indicates compliance with the requirements of Russian market                                                      |  | Indicates compliance with the requirements of Ukrainian market                                                      |  | 200 gloves by weight                                          |
|  |                                                                                                                   |  |                                                                                                                     |  | Additional information on inner side of package               |



## ■ HOW TO PUT THE GLOVES ON?



## ■ HOW TO TAKE THE GLOVES OFF?

