**MERCATOR** MEDICAL Protecting.

# **Technical Data Sheet**



# nitrylex<sup>®</sup> PF PROTECT a'200 violet

## **PRODUCT DESCRIPTION**

| PRODUCT DESCRIPTION |   |                          | PHYSICAL PROPERTIES          |                |       |       |       |       |        |
|---------------------|---|--------------------------|------------------------------|----------------|-------|-------|-------|-------|--------|
| Type of the glove   | Examination, protective, powder free, non-sterile |                          | Dimension                    | Size           | XS    | S     | М     | L     | XL     |
| Material            | Nitrile   |                          |                              |                | (5-6) | (6-7) | (7-8) | (8-9) | (9-10) |
| Donning powder      | -   |                          | Length [mm]                  |                | 240   | 240   | 240   | 240   | 240    |
| Colour              | Violet  |                          | Minimum                      |                | 240   | 240   | 240   | 240   | 240    |
| Shape               | Ambide  | xtrous                   | Width [mm]                   |                | ≤80   | 80±   | 95±   | 110±  | ≥110   |
| Cuff                | Beaded  |                          |                              |                |       | 10    | 10    | 10    |        |
| External surface    | Texture   | d on finger tips         | Thickness                    | Middle finger  |       | 0,05  |       |       |        |
| Packaging           | 10 x 200  | ) pcs                    | (single wall)                | Palm           |       | 0,05  |       |       |        |
| PRODUCT REFERENCES  |   |                          | [mm]                         | [mm] Cuff 0,05 |       |       |       | 05    |        |
| Size/ reference     | XS RD30098001                                     |                          | Minimum                      |                |       |       |       |       |        |
| number              | S   | RD30098002               |                              |                |       |       |       |       |        |
|                     | Μ   | RD30098003<br>RD30098004 | Elongation at Before agein   |                | 5     | 500   |       |       |        |
|                     | L   |                          | break [%]                    | After ageing   |       | 400   |       |       |        |
|                     | XL  | RD30098005               | Fores at break               | Defere estine  |       |       | c     | 0     |        |
|                     |   |                          | Force at break Before ageing |                |       | 6,0   |       |       |        |
|                     |   |                          | <b>[N]</b> Minimum           | After ageing   |       |       | 6     | ,0    |        |
|                     |   |                          |                              |                |       |       |       |       |        |

#### MANUFACTURING AND SAFETY STANDARDS Manufacturing final release; GL-I AQL ≤ 1,5 in accordance with test result according the procedure ISO 2859 AQL (Pin-Holes) **Protein content** Not applicable **CE** classification Class I – Medical Device (Council Directive 93/42/EEC and Directive 2007/47/EC) Category I, for minimal risk – Personal Protective Equipment (Council Directive 89/686/EEC) EN ISO 13485 EN 374-1 excluding point 5.3.2 Compliances EN ISO 14971 EN 374-2 EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN 420 EN 980 EN 1041 Shelf life 3 years STORAGE Storage Keep out of direct sunlight. Store in a cool, dry place in temperature 5-30° C. Keep away from sources of ozone and ignition. instruction Issue date: 06.05.2014 Prepared by: Justyna Wiśniowska-Woźny – Technical Documentation Specialist

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