

## Technical Data Sheet

### nitrylex® black



| PRODUCT DESCRIPTION                       |   | PHYSICAL PROPERTIES                 |                          |   |         |         |           |  |
|---|---|-------------------------------------|--------------------------|---|---------|---------|-----------|--|
| <b>Type of the glove</b>                  | Non-sterile, powder free, examination and protective glove, for single use  | <b>Dimensions</b>                   | Size                     |   |         |         |           |  |
| <b>Material</b>                           | Nitrile   |                                     | XS (5-6)                 | S (6-7)   | M (7-8) | L (8-9) | XL (9-10) |  |
| <b>Donning powder</b>                     | -   | <b>Length [mm]</b>                  | 240                      |   |         |         |           |  |
| <b>Colour</b>                             | Black   | Minimum                             |                          |   |         |         |           |  |
| <b>Shape</b>                              | Ambidextrous, gloves fitting either hand  | <b>Width [mm]</b>                   | ≤80                      | 80 ±10  | 95 ±10  | 110 ±10 | ≥110      |  |
| <b>Cuff</b>                               | Beaded  | <b>Thickness (single wall) [mm]</b> | Middle finger            |   | 0,09    |         |           |  |
| <b>External surface</b>                   | Microtextured + fingertip textured + polymerized  |                                     | Palm                     |   | 0,06    |         |           |  |
| <b>Internal surface</b>                   | Polymerized + chlorinated   |                                     | Cuff                     |   | 0,05    |         |           |  |
| <b>Packaging</b>                          | 10 x 100 pcs  | <b>Elongation at break [%]</b>      | Before ageing            |   | 500     |         |           |  |
| <b>PRODUCT REFERENCES</b>                 |   |                                     | After ageing             |   | 400     |         |           |  |
| <b>SIZE / REFERENCE NUMBER</b>            | XS  | RD30104001                          | <b>Force at break[N]</b> | Before ageing   |         | 6,0     |           |  |
|   | S   | RD30104002                          |                          | After ageing  |         | 6,0     |           |  |
|   | M   | RD30104003                          |                          | Minimum   |         |         |           |  |
|   | L   | RD30104004                          |                          |   |         |         |           |  |
|   | XL  | RD30104005                          |                          |   |         |         |           |  |
| <b>MANUFACTURING AND SAFETY STANDARDS</b> |   |                                     |                          |   |         |         |           |  |
| <b>AQL</b>                                | Manufacturing final release: G-I inspection level AQL 1.0 in accordance with ISO 2859-1   |                                     |                          |   |         |         |           |  |
| <b>Powder content</b>                     | < 2 mg/glove (according to EN 455-3)  |                                     |                          |   |         |         |           |  |
| <b>Protein content</b>                    | N/A   |                                     |                          |   |         |         |           |  |
| <b>CE classification</b>                  | Class I – Medical Device (Regulation (EU) 2017/745)   |                                     |                          | Category III – Personal Protective Equipment (Regulation (EU) 2016/425)         |         |         |           |  |
| <b>Compliances</b>                        | EN 455-1, EN 455-2, EN 455-3, EN 455-4<br>EN ISO 15223-1<br>EN 1041<br>EN ISO 13485   |                                     |                          | EN ISO 374-1 (Type B), EN 374-2, EN 374-4, EN ISO 374-5<br>EN 16523-1<br>EN 420 |         |         |           |  |
| <b>Viral test</b>                         | Test in accordance with ISO 16604   |                                     |                          |   |         |         |           |  |
| <b>Cytostatics permeation</b>             | Test in accordance with ASTM D6978  |                                     |                          |   |         |         |           |  |
| <b>Chemical substances permeation</b>     | Test in accordance with EN 16523-1  |                                     |                          |   |         |         |           |  |
| <b>Food contact</b>                       | Declaration of conformity for food contact in accordance with Regulation (EC) No 1935/2004 and with Commission Regulation (EU) No 10/2011 and Overall Migration Test in accordance with Commission Regulation (EU) No 10/2011 |                                     |                          |   |         |         |           |  |
| <b>Shelf life</b>                         | 3 or 5 years depends on LOT number (check the packaging)  |                                     |                          |   |         |         |           |  |
| <b>STORAGE</b>                            |   |                                     |                          |   |         |         |           |  |
| <b>Storage instruction</b>                | Keep out of direct sunlight. Store in a cool, dry place in temperature 5-35° C. Keep away from sources of ozone and ignition.   |                                     |                          |   |         |         |           |  |