

# Technical Data Sheet



## nitrylex® black

### PRODUCT DESCRIPTION

|                   |                                                                           |
|-------------------|---------------------------------------------------------------------------|
| Type of the glove | Non-sterile, powder free, examination and protective glove for single use |
| Material          | Nitrile                                                                   |
| Donning powder    | -                                                                         |
| Colour            | Black                                                                     |
| Shape             | Ambidextrous, gloves fitting either hand                                  |
| Cuff              | Beaded                                                                    |
| External surface  | Microtextured + fingertip textured + polymerized                          |
| Internal surface  | Polymerized + chlorinated                                                 |
| Packaging         | 10 x 100 pcs                                                              |

### PRODUCT REFERENCES

|                         |    |            |
|-------------------------|----|------------|
| SIZE / REFERENCE NUMBER | XS | RD30104001 |
|                         | S  | RD30104002 |
|                         | M  | RD30104003 |
|                         | L  | RD30104004 |
|                         | XL | RD30104005 |

### PHYSICAL PROPERTIES

| Dimensions                   | Size          | XS<br>(5-6) | S<br>(6-7) | M<br>(7-8) | L<br>(8-9) | XL<br>(9-10) |
|------------------------------|---------------|-------------|------------|------------|------------|--------------|
| Length [mm]                  |               |             |            |            |            |              |
| Minimum                      |               | 240         | 240        | 240        | 240        | 240          |
| Width [mm]                   |               | ≤80         | 80<br>±10  | 95<br>±10  | 110<br>±10 | ≥110         |
| Thickness (single wall) [mm] |               |             |            |            |            |              |
| Minimum                      | Middle finger |             |            | 0,09       |            |              |
|                              | Palm          |             |            | 0,06       |            |              |
|                              | Cuff          |             |            | 0,05       |            |              |
| Elongation at break [%]      |               |             |            |            |            |              |
| Minimum                      | Before ageing |             |            | 500        |            |              |
|                              | After ageing  |             |            | 400        |            |              |
| Force at break [N]           |               |             |            |            |            |              |
| Minimum                      | Before ageing |             |            | 6,0        |            |              |
|                              | After ageing  |             |            | 6,0        |            |              |

### MANUFACTURING AND SAFETY STANDARDS

|                                |                                                                                                                                                                                                                               |                                                                                 |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| AQL                            | Manufacturing final release: G-I inspection level AQL 1.0 in accordance with ISO 2859-1                                                                                                                                       |                                                                                 |
| Protein content                | N/A                                                                                                                                                                                                                           |                                                                                 |
| CE classification              | Class I – Medical Device (Regulation (EU) 2017/745)                                                                                                                                                                           | Category III – Personal Protective Equipment (Regulation (EU) 2016/425)         |
| Compliances                    | 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 |
| Viral test                     | Test in accordance with ISO 16604                                                                                                                                                                                             |                                                                                 |
| Cytostatics permeation         | Test in accordance with ASTM D6978                                                                                                                                                                                            |                                                                                 |
| Chemical substances permeation | Test in accordance with EN 16523-1                                                                                                                                                                                            |                                                                                 |
| Food contact                   | 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 |                                                                                 |
| Shelf life                     | 3 years                                                                                                                                                                                                                       |                                                                                 |

### STORAGE

|                     |                                                                                                                               |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------|
| Storage instruction | Keep out of direct sunlight. Store in a cool, dry place in temperature 5-35° C. Keep away from sources of ozone and ignition. |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------|