Technical Data Sheet



Category III - Personal Protective Equipment (Regulation (EU) 2016/425)

EN ISO 374-1 (Type B), EN 374-2, EN 374-4, EN ISO 374-5

nitrylex® classic +

| DRUDI | ICT | DESCR | IDTION |
|-------|-----|-------|--------|

PHYSICAL PROPERTIES

| Type of the glove | Powder | free, examination and protective glove | Dimensions | Size | XS | S | М | L | XL |
|--------------------|--|--|--------------------|---------------|-------|-------|-------|--------|--------|
| | for singl | e use, non-sterile | | | (5-6) | (6-7) | (7-8) | (8-9) | (9-10) |
| Material | Nitrile | | Length [mm] | | 240 | 2.40 | 240 | 240 | 240 |
| Donning powder | - | | Minimum | | 240 | 240 | 240 | 240 | 240 |
| Colour | Blue | | | | | | | | |
| Shape | Ambidextrous, gloves fitting either hand | | Width [mm] | | ≤80 | 80±10 | 95±10 | 110±10 | 115±5 |
| Cuff | Beaded | | | | | | | | |
| External surface | Microtextured + fingertip textured | | Thickness | Middle finger | 0,08 | | | | |
| Internal surface | Chlorinated | | (single wall) [mm] | Palm | 0,06 | | | | |
| Packaging | 10 x 100 pcs | | Minimum | Cuff | 0,05 | | | | |
| PRODUCT REFERENCES | | Elongation at | Before ageing | 500 | | | | | |
| Size/ Reference | XS | RD30246001(0001) | break [%] | After ageing | | | 400 | | |
| number | S | RD30246002(0001) | Minimum | | | | | | |
| | М | RD30246003(0001) | Force at break [N] | Before ageing | | | 6,0 | | |
| | L | RD30246004(0001) | Minimum | After ageing | | | 6,0 | | |
| | XL | RD30246005(0001) | | | | | | | |

MANUFACTURING AND SAFETY STANDARDS

Manufacturing final release: G-I inspection level AQL 1.5 in accordance with ISO 2859-1 AQL

Powder content < 2mg/glove

CE classification Class I - Medical Device (Regulation (EU) 2017/745)

Compliances EN 455-1, EN 455-2, EN 455-3, EN 455-4

EN ISO 15223-1

EN 1041

EN ISO 13485

5 years

Viral test Test in accordance with ASTM F1671 & 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

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.

EN 16523-1

EN 420

Date: 10-06-2020, Rev. 2.0