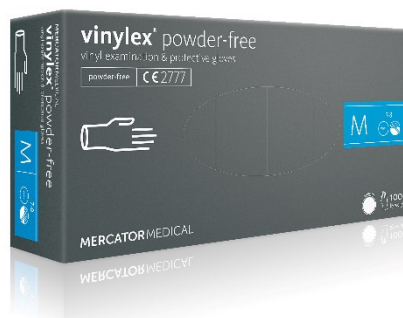


Technical Data Sheet



vinylex® powder-free

PRODUCT DESCRIPTION

| | |
|--------------------------|---|
| Type of the glove | Non-sterile, powder free, examination and protective glove for single use |
| Material | Polyvinyl chloride (vinyl) |
| Donning powder | - |
| Colour | Transparent |
| Shape | Ambidextrous, gloves fitting either hand |
| Cuff | Beaded |
| External surface | Smooth |
| Internal surface | Polyurethane coated |
| Packaging | 10 x 100 pcs |

PRODUCT REFERENCES

| SIZE / REFERENCE NUMBER | XS | RD20018001 |
|-------------------------|----|------------|
| | S | RD20018002 |
| | M | RD20018003 |
| | L | RD20018004 |
| | XL | RD20018005 |

PHYSICAL PROPERTIES

| Dimensions | Size | XS | S | M | L | XL |
|-------------------------------------|---------------|-------|-------|-------|-------|--------|
| | | (5-6) | (6-7) | (7-8) | (8-9) | (9-10) |
| Length [mm] | | 240 | 240 | 240 | 240 | 240 |
| Minimum | | | | | | |
| Width [mm] | | ≤80 | 80 | 95 | 110 | ≥110 |
| | | | ±10 | ±10 | ±10 | |
| Thickness (single wall) [mm] | | | | | | |
| Minimum | Middle finger | | | 0,08 | | |
| | Palm | | | 0,07 | | |
| | Cuff | | | 0,05 | | |
| Elongation at break [%] | | | | | | |
| Minimum | Before ageing | | | 300 | | |
| | After ageing | | | 300 | | |
| Force at break [N] | | | | | | |
| Minimum | Before ageing | | | 3,6 | | |
| | After ageing | | | 3,6 | | |

MANUFACTURING AND SAFETY STANDARDS

| | | |
|---------------------------------------|---|---|
| AQL | Manufacturing final release: G-I inspection level AQL 1.5 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 EN ISO 15223-1 EN 1041 EN ISO 13485 | EN ISO 374-1 (Type C), EN 374-2, EN 374-4, EN ISO 374-5 EN 16523-1 EN 420 |
| Viral test | Passes test in accordance with ASTM F1671 & ISO 16604 | |
| Cytostatics permeation | N/A | |
| 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. |
|----------------------------|---|