

Technical Data Sheet



dermaGEL®

PRODUCT DESCRIPTION

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| Type of the glove | Examination, protective, powder free, non-sterile glove |
| Material | Natural rubber latex |
| Donning powder | - |
| Colour | Creamy |
| Shape | Ambidextrous |
| Cuff | Beaded |
| External surface | Textured |
| Internal surface | Non-latex polymer coating |
| Packaging | 10 x 100 pcs |

PRODUCT REFERENCES

| | | |
|-------------------------------|----|------------|
| Size/ reference number | XS | RD10006001 |
| | S | RD10006002 |
| | M | RD10006003 |
| | L | RD10006004 |
| | XL | RD10006005 |

PHYSICAL PROPERTIES

| Dimension | Size | XS (5-6) | S (6-7) | M (7-8) | L (8-9) | XL (9-10) |
|--|---------------|-------------|------------|------------|------------|--------------|
| Length [mm] Minimum | | 240 | 240 | 240 | 240 | 240 |
| Width [mm] | | ≤80 | 80± 10 | 95± 10 | 110± 10 | ≥110 |
| Thickness (single wall) [mm] Minimum | Middle finger | | | | 0,08 | |
| | Palm | | | | 0,08 | |
| | Cuff | | | | 0,075 | |
| Elongation at break [%] | Before ageing | | | | 700 | |
| | After ageing | | | | 500 | |
| Force at break [N] Minimum | Before ageing | | | | 6,0 | |
| | After ageing | | | | 6,0 | |

MANUFACTURING AND SAFETY STANDARDS

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| AQL (Pin-Holes) | Manufacturing final release; GL-I AQL ≤ 1,5 in accordance with test result according the procedure ISO 2859 | |
| Protein content | <50 µg/g glove (Modified Lowry's – EN 455-3) | |
| 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) | |
| Compliances | EN ISO 13485 EN ISO 14971 EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN 980 EN 1041 | EN 374-1 excluding point 5.3.2 EN 374-2 EN 420 |
| Viral test | Passes test in accordance with ASTM F 1671 | |
| Chemical substances permeation | Test in accordance with EN 374-3 | |
| Shelf life | 5 years | |

STORAGE

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| Storage instruction | Keep out of direct sunlight. Store in a cool, dry place in temperature 5-30° C. Keep away from sources of ozone and ignition. |
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