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CIN : U25199KL1974PTC002650  
GSTIN : 32AABCK0056E1Z8

**Admin. Office :**  
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CIN : U25199KL1974PTC002650  
GSTIN : 33AABCK0056E1Z6

**Factory : 1 ✓**  
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**Factory : 2**  
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**Factory : 3**  
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CIN : U25199KL1974PTC002650  
GSTIN : 33AABCK0056E1Z6

**Factory : 4**  
Plot Number:24, AMRL HI-TECH CITY LTD,  
SEZ, Rajakkalmangalam, Nanguneri,  
Tirunelveli Dist. - 627 108,  
Tamil Nadu, India.  
Ph :  
E-mail : officengn@kanamlatex.com  
CIN : U25199KL1974PTC002650  
GSTIN : 33AABCK0056E2Z5

## TECHNICAL DATA SHEET

### dermagel orthopedic



| PRODUCT DESCRIPTION |   | PHYSICAL PROPERTIES                     |  |                           |                          |      |     |     |     |     |     |
|---------------------|---|---|--|---------------------------|--------------------------|------|-----|-----|-----|-----|-----|
| Type of the glove   | Sterile, powder-free surgical and protective gloves for single use  | Size                                    | 5.5*                                     | 6.0                       | 6.5                      | 7.0  | 7.5 | 8.0 | 8.5 | 9.0 |     |
| Intended use        | Sterile, powder-free, natural rubber latex surgical gloves, made of natural rubber latex intended to be worn on hand of healthcare personnel, operating room personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment during surgical, especially orthopaedic procedures. Single use. | Length [mm]                             | EN 455-2 normative value                 | 250                       | 260                      | 260  | 270 | 270 | 270 | 280 | 280 |
|                     |   |   | Spec. [min]                              | 270                       | 280                      | 280  | 280 | 285 | 285 | 285 | 285 |
|                     |   | Width [mm]                              | EN 455-2 normative value                 | 72                        | 77                       | 83   | 89  | 95  | 102 | 108 | 114 |
|                     |   |   |  | ±4                        | ±5                       | ±5   | ±5  | ±5  | ±6  | ±6  | ±6  |
| Material            | Natural rubber latex  | Thickness single wall [mm]              | Middle finger [min]                      | 0,28                      |                          |      |     |     |     |     |     |
|                     |   |   | Palm [min]                               | 0,26                      |                          |      |     |     |     |     |     |
| Donning powder      | None  |   | Cuff [min]                               | 0,21                      |                          |      |     |     |     |     |     |
| Colour              | Brown   | Force at break [N] Minimum              | Before aging EN 455-2 normative value    | 9,0                       |                          |      |     |     |     |     |     |
| Shape               | Anatomic, curved fingers, hand specific   |   | After aging EN 455-2 normative value     | 9,0                       |                          |      |     |     |     |     |     |
| Cuff                | Beaded  | Tensile Strength [Mpa] Minimum          | Before aging ASTM D 3577 normative value | 24                        |                          |      |     |     |     |     |     |
| External surface    | Textured, chlorinated   |   | After aging ASTM D 3577 normative value  | 18                        |                          |      |     |     |     |     |     |
| Internal surface    | Polymerized   | Ultimate Elongation [%] Minimum         | Before aging ASTM D 3577 normative value | 750                       |                          |      |     |     |     |     |     |
| Packaging           | 1 pair per pouch, 50 pairs per dispenser, 200 pairs per carton  |   | After aging ASTM D 3577 normative value  | 560                       |                          |      |     |     |     |     |     |
|                     |   | Stress at 500% Elongation [Mpa] Maximum | Before aging ASTM D 3577 normative value | 5.5                       |                          |      |     |     |     |     |     |
|                     |   |   | After aging ASTM D 3577 normative value  | NA                        |                          |      |     |     |     |     |     |
|                     |   |   |  | Powder content [mg/glove] | EN 455-3 normative value | <2.0 |     |     |     |     |     |
|                     |   | Latex protein content [µg/g glove]      | EN 455-3 modified Lowry's assay          | <50                       |                          |      |     |     |     |     |     |

| MANUFACTURING AND SAFETY STANDARDS |   |
|------------------------------------|---|
| Manufacturer                       | Kanam Latex Industries (P) Ltd.<br>12/67 Ananthanadarkudy,<br>Asaripallam P.O, Nagercoil 629 201,<br>Kanyakumari District,Tamil Nadu, India |
| EC Representative                  | AMSTERMED B.V.<br>Saturnusstraat 46-62<br>Unit 032, 2132 HB Hoofddorp<br>The Netherlands  |

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|   |  |                 |                                |                 |  |                 |                 |                 |
|---|--|-----------------|--------------------------------|-----------------|--|-----------------|-----------------|-----------------|
| Importer                                | Mercator Medical S.A.<br>H. Modrzejewskiej 30 street<br>31-327 Cracow, Poland  |                 |                                |                 |  |                 |                 |                 |
| AQL                                     | Manufacturing final release: G-I inspection level AQL 0.65 in accordance with ISO 2859-1.  |                 |                                |                 |  |                 |                 |                 |
| Sterilization                           | Gamma (R)  |                 |                                |                 |  |                 |                 |                 |
| Classification                          | Medical Device: class IIa<br>Rule classification acc. to declaration of conformity   |                 |                                |                 | Personal Protective Equipment: Category III<br>(Regulation (EU) 2016/425)<br>Type B (EN ISO 374-1) |                 |                 |                 |
| Conformity assessment body              | DNV Product Assurance AS, Notified Body No 2460<br>Veritasveien 3, 1363 Høvik, Norway  |                 |                                |                 | SGS FIMKO OY, Notified Body No 0598<br>Takomotie 8, 00380, Helsinki, Finland                       |                 |                 |                 |
| Product compliances                     | EN 455-1, EN 455-2, EN 455-3, EN 455-4,<br>EN ISO 15223-1, EN ISO 20417,<br>EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10,<br>EN ISO 11737-1, EN ISO 11737-2,<br>EN ISO 11607-1, EN ISO 11607-2,<br>EN ISO 14971, EN 556-1   |                 |                                |                 | EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN ISO 374-5,<br>EN 16523-1, EN ISO 21420                |                 |                 |                 |
|   | R sterilization  |                 | EN ISO 11137-1, EN ISO 11137-2 |                 |  |                 |                 |                 |
| Quality management standards            | EN ISO 13485, ISO 9001, ISO 14001  |                 |                                |                 |  |                 |                 |                 |
| Viral test penetration                  | Test in accordance with ASTM F1671.<br>Product complies with the requirements of EN ISO 374-5 (ISO 16604).   |                 |                                |                 |  |                 |                 |                 |
| Bacteria and fungi penetration          | Test in accordance with EN ISO 374-5 (EN ISO 374-2).   |                 |                                |                 |  |                 |                 |                 |
| Chemical substances permeation test     | Test in accordance with EN 16523-1.  |                 |                                |                 |  |                 |                 |                 |
| Biocompatibility/ biological evaluation | Test in accordance with EN ISO 10993-5. No cytotoxic evidence observed.<br>Test in accordance with EN ISO 10993-10. No skin irritation and sensitization evidence observed.  |                 |                                |                 |  |                 |                 |                 |
| REACH                                   | The product does not contain substances listed in candidate list according to Regulation (EC) 1907/2006.   |                 |                                |                 |  |                 |                 |                 |
| STORAGE AND DISPOSAL                    |  |                 |                                |                 |  |                 |                 |                 |
| Long-term storage instructions          | It is recommended to store the gloves in dry place, in the temperature of 5-38°C and to protect them against direct sunlight. Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone. Do not keep in direct vicinity of solvents, oils, fuels and lubricants.   |                 |                                |                 |  |                 |                 |                 |
| Transport instructions                  | Transport in conditions ensuring an appropriate hygienic standard, protecting the product against dirt. The product is not thermolabile - changing conditions regarding temperature or humidity in the short-term transport period do not affect the usability of the product or its properties or safety of use in any way. The product does not require transport in controlled conditions in terms of temperature and humidity (confirmed on the basis of accelerated aging tests and risk analysis). |                 |                                |                 |  |                 |                 |                 |
| Shelf life                              | 3 years from manufacturing date  |                 |                                |                 |  |                 |                 |                 |
| Product disposal                        | Used product should be treated as contaminated material, therefore local regulations regarding the disposal of such materials should be applied.   |                 |                                |                 |  |                 |                 |                 |
| Packaging disposal                      | Master packaging (carton, dispenser) is made of homogeneous material, does not contain any foil elements, does not contain any different type of materials, does not need to be separated into fractions. Packaging is 100% recyclable, in accordance with local regulations.<br>Unit packaging (outer envelope and inner envelope) is to be regarded as contaminated medical material and local regulations for the handling of such materials must be followed.  |                 |                                |                 |  |                 |                 |                 |
| PRODUCT REFERENCES                      |  |                 |                                |                 |  |                 |                 |                 |
| Size / REF number                       |  |                 |                                |                 |  |                 |                 |                 |
| Sterilization                           | 5.5*   | 6.0             | 6.5                            | 7.0             | 7.5  | 8.0             | 8.5             | 9.0             |
| Gamma (R)                               | N/A  | RC10009060_0016 | RC10009065_0016                | RC10009070_0016 | RC10009075_0016  | RC10009080_0016 | RC10009085_0016 | RC10009090_0016 |
|   | RC10077055_0016  | RC10077060_0016 | RC10077065_0016                | RC10077070_0016 | RC10077075_0016  | RC10077080_0016 | RC10077085_0016 | RC10077090_0016 |

\* size available on request