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| Kanam | INSTRUCTION FOR USE | SURGICARE |

The instruction below should be used in conjunction with detailed information on the packaging.

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| **BRAND NAME** | **comfort® powdered** | |
| **PRODUCT DESCRIPTION** | Surgical and Protective Gloves, Natural rubber latex, Powdered, Sterile, for single use | |
| **Reference Number** **depending on the manufactured LOT* | RC11001060-90<br>RC11001060-90_0016 | RC11002060-90<br>RC11002060-90_0016 |
| **Sterilization** | Ethylene oxide (EO) | Gamma (R) |
| **Raw material** | natural rubber latex | |
| **Size range** | 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0 | |
| **AQL** | 0.65 | |
| **Packaging** | 1 pair per pouch, 50 pairs per dispenser, 400 pairs per carton | |
| **Shelf life** | 5 years (from the date of manufacturing) | |
| **MANUFACTURER** | KANAM LATEX INDUSTRIES PVT. LTD.<br>12/67 C, Ananthanadarkudy<br>Asaripallam (PO), Nagercoil - 629 201<br>Kanyakumari District<br>Tamil Nadu, India | |
| **AUTHORIZED REPRESENTATIVE** | EMERGO EUROPE<br>Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands | |
| **IMPORTER** | Mercator Medical S.A.<br>ul. H. Modrzejewskiej 30<br>31-327 Kraków, Poland<br>www.mercatormedical.eu | |
| **PPE CLASSIFICATION** | Gloves are category III Personal Protective Equipment as per Annex I of the Regulation 2016/425. | |
| **PRODUCT STANDARDS COMPLIANCE** | EN ISO 21420:2020, EN ISO 374-1:2016 +A1:2018 (type C), EN 374-2:2014, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016. | |
| **NOTIFIED BODY** | EU Type Examination (Module B) and conformity to type based on quality assurance of the production process (module D) under surveillance of the Notified Body SGS FIMKO OY, No 0598:<br>CE 0598<br>SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland. | |
| **MD CLASSIFICATION** | Gloves classified as medical device – class IIa under Council Directive 93/42/EEC. | |
| **QUALITY SYSTEM STANDARDS** | EN ISO 13485:2016 | |
| **PRODUCT STANDARDS COMPLIANCE** | EN ISO 14971:2019, EN ISO 15223-1:2016, EN 1041:2008+A1:2013,<br>EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009,<br>EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-7:2008 (for EO sterilized gloves), EN ISO 10993-10:2013,<br>EN 556-1:2001\|AC:2006, EN ISO 11737-1:2018, EN ISO 11737-2:2020,<br>EN ISO 11135:2014/A1:2019 (for EO sterilized gloves),<br>EN ISO 11138-2:2017 (for EO sterilized gloves)<br>EN ISO 11137-1:2015/A2:2019 (for gloves sterilized by irradiation),<br>EN ISO 11137-2:2015 (for gloves sterilized by irradiation). | |

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| NOTIFIED BODY | Conformity assessment procedure according to Annex II (excluding section 4) and surveillance carried out by Notified Body DNV Product Assurance AS, no 2460:<br>CE 2460<br>DNV Product Assurance AS, Veritasveien 3, N-1363 Høvik, Norway |
| INTENDED USE | Sterile, surgical and protective gloves, made from natural rubber latex, anatomical shape, with thumb positioned towards the palm side of the index finger which reduces the fatigue on the hands, intended to be worn on the hands usually in surgical settings to provide barrier against potentially infectious fluids or other contaminants and to protect the patient by ensuring sterility of the wound environment. These gloves are intended for single use only.<br>Gloves are classified as Medical Devices Class IIa and as a Personal Protective Equipment Category III. Gloves designed to protect against substances and mixtures which are hazardous to health and against harmful biological agents. Gloves designed to protect against to chemical risk according with EN ISO 374-1 and microorganism (viruses, bacteria and fungi) risks according with EN ISO 374-5. Their design and labelling corresponds to the requirements of the Council Directive 93/42/EEC on Medical Device and the European Regulation 2016/425 on Personal Protective Equipment.<br>Gloves should be used solely according to their intended use. |
| PRECAUTIONS | The results do not reflect the actual duration of protection in the workplace due to other factors influencing the performance, such as temperature, abrasion, degradation etc.<br>Do not use if package is damaged or wet.<br>Dry hands thoroughly before donning.<br>Risk of reuse: Do not reuse, reuse can cause cross infection and compromise safety.<br>Gloves shall not be worn where there is a risk of entanglement by moving parts of machines is needed.<br>Dexterity performance level is 5.<br>Do not resterilize. |
| WARNINGS | The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400mm – where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture. This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.<br>It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperatures, abrasion and degradation.<br>When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc., may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.<br>Before usage, inspect the gloves for any defect or imperfections.<br>For single use only. |

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| COMPONENTS / HAZARDOUS COMPONENTS | Some gloves may contain components known to be a possible cause of allergy for person allergic to them, who may develop contact irritation and/or allergic reaction. Natural rubber latex gloves may cause allergic reactions including anaphylactic reactions. In case of an allergic reaction, seek medical assistance immediately. |
| STORAGE INSTRUCTION | Do not expose to direct sunlight, ozone sources or sources of fire. Store in a dry and cool place, at a temperature of 5-35°C. Do not keep in direct vicinity of solvents, oils, fuels and lubricants. |
| DISPOSAL | Used gloves should be treated as a contaminated material, therefore local regulations regarding the disposal of such materials should be applied. |
| DECLARTION OF CONFORMITY | Declaration of Conformity and this instruction for use available under below web address: https://mercatormedical.eu |

SUMMARY OF THE TESTS PERFORMED

Test acc. to EN ISO 21420 Protective gloves -- General requirements and test methods.

| Protective gloves – General Requirements | Status / Performance Level |
|---|---|
| Sizing | 6.0; 6.5; 7.0; 7.5; 8.0; 8.5, 9.0 |
| Dexterity | Performance Level 5 |
| pH value | Pass |
| Polyaromatic hydrocarbons Content (PAH) | Pass |

Test acc. to EN 374-2 Protective gloves against chemicals and micro-organisms – Part 2: Determination of resistance penetration

| Test name | Status / Performance Level |
|---|---|
| Air leak test | Pass |
| Water leak test | Pass |

Test acc. to EN 16523-1 Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

| Chemical | Status / Performance Level |
|---|---|
| 40% Sodium Hydroxide (K) | Level 5 |
| 30% Hydrogen Peroxide (P) | Level 6 |
| 37% Formaldehyde (T) | Level 1 |

Level 1 >10 min, Level 2 > 30 min, Level 3> 60 min, Level 4 > 120 min, Level 5 > 240 min, Level 6 > 480 min.

Test acc. to EN ISO 374-4 Protective gloves against dangerous chemicals and micro-organisms — Part 4: Determination of resistance to degradation by chemicals

| Chemical | Degradation [%] |
|---|---|
| 40% Sodium Hydroxide (K) | 22.9 |
| 30% Hydrogen Peroxide (P) | 20.5 |
| 37% Formaldehyde (T) | 10.6 |

EN ISO 374-4: 2019 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

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Tested acc. to ASTM F1671 for viral penetration
Product meet the requirements of **EN ISO 374-5 (ISO 16604)**

| Test name | Status / Performance Level |
|---|---|
| Protection against bacteria & fungi | Pass |
| Protection against viruses | Pass |

EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

## SYMBOLS USED ON THE PACKAGINGS

| | | | |
|---|---|---|---|
| MD | Medical device | | Single sterile barrier system with protective packaging inside |
| PPE | Personal Protective Equipment | LATEX | Latex gloves |
| | Manufacturer | | Keep dry |
| EC REP | Authorized representative in the European Community/ European Union | | Keep away from sunlight |
| | Importer | 5°C 35°C | Temperature limit 5-35$^0$C |
| | Do not re-use | $O_3$ | Keep away from ozone |
| STERILE EO | Sterilized using ethylene oxide | | Product quality is not ensured if the package is damaged |
| STERILE R | Sterilized using irradiation | | Date of manufacture |
| | Do not resterilize | REF | Catalogue number |
| LOT | LOT / batch number | | Expiry date |

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| ISO 374-1/Type C | designed to protect against to chemical risks acc. with EN ISO 374-1 (type C) |
| ISO 374-5:2016 VIRUS | Designed to protect against microorganisms risks acc. with EN ISO 374-5 |
| | Consult instruction for use |
| 1x para/pair/napa | 1 pair of gloves in unit pouch |
| 50 par / pairs / пары | 50 pairs of gloves per unit dispenser |
| 400 par / pairs / пары | 400 pairs of gloves per carton |
| 20 PAP | Recyclable packaging |
| | Package is treated as municipal waste |
| | indicates compliance with the requirements of Ukrainian market |

*Last Rev. 10.2022, date: 11.10.2022*

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| # | Model number | UDI | Unique device identifier | IN | Country of manufacture (2 letters refer to country code) |

## GLOVE DONNING PROCEDURE

a) Remove the walleted gloves (inner wrapper) from the Pouch (outer wrapper).
b) Open the walleted glove to see “Left” and “Right” compartment.
c) Pinch back upper and lower flaps of the inner wrapper.
d) Using the middle flaps, open the wrapper touching only the 1 inch margin for safety.
e) Be sure wrapper does not close over gloves after opening to avoid contamination.
f) Using the thumb and the first two fingers of the non-dominant hand, pinch the cuff of the folded edge of the glove cuff for the dominant hand, touching only the inside surface of the glove.
g) Slide dominant hand in to the gloves keeping hand point downwards and pull up to wrist.
h) Using the glove hand insert the 4 fingers under the cuff of the other glove and pull the glove up to the arm.
i) Adjust the gloves as necessary

## GLOVE REMOVING PROCEDURE

a) Take hold of the first glove at the wrist.
b) Fold it over and peel it back, turning it inside out as it goes. Once the glove is off, hold it with your gloved hand.
c) To remove the other glove, place your bare fingers inside the cuff without touching the glove exterior. Peel the glove off from the inside, turning it inside out as it goes. Use it to envelope the other glove.