Kanam	INSTRUCTION FOR USE	SURGICARE

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

BRAND NAME:	dermagel® neopren
PRODUCT DESCRIPTION	Surgical and Protective Gloves, Non-latex, Synthetic Polychloroprene Powder-free, Sterile, for single use
Reference Number **depending on the manufactured LOT*	RC40011060-90 RC40011060-90_0016
Sterilization	Gamma (R)
Raw material	neoprene
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	3 Years (from the date of manufacturing)
MANUFACTURER	KANAM Latex Industries Pvt. Ltd. 12/67 C, Ananthanadarkudy Asaripallam (PO), Nagercoil - 629 201 Kanyakumari District Tamil Nadu, India
AUTHORIZED REPRESENTATIVE	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands
IMPORTER	Mercator Medical S.A. ul. H. Modrzejewskiej 30-376 Kraków, Poland 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: CE 0598 SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland.
MD CLASSIFICATION	Gloves classified as medical device – class IIa under Council Directive 93/42/EEC.
QUALISTY STANDARDS COMPLIANCE	EN ISO 13485:2016
PRODUCTS STANDARDS COMPLIANCE	EN ISO 14971:2019, EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN 556-1:2001|AC:2006, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 11137-1:2015/A2:2019, EN ISO 11137-2:2015
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: CE 2460 DNV Product Assurance AS, Veritasveien 3, N-1363 Høvik, Norway

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INTENDED USE	Sterile, surgical and protective gloves, made from neoprene, 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. 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 European Regulation 2017/745 on Medical Device and the European Regulation 2016/425 on Personal Protective Equipment. 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. Do not use package is damaged or wet. Dry hands thoroughly before donning. Risk of reuse: Do not reuse, reuse can cause cross infection and compromise safety. Gloves shall not be worn where there is a risk of entanglement by moving parts of machines is needed. Dexterity performance level is 5. 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. 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 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. Before usage, inspect the gloves for any defect or imperfections. For Single use only.
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. 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.
DECLARATION 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	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: Determination of resistance penetration

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

Test acc. to EN 16523-1 Permeation by Liquid chemical under conditions of continuous contact

Chemical	Status / Performance Level
40% Sodium Hydroxide (K)	Level 6
30% Hydrogen Peroxide (P)	Level 6
37% Formaldehyde (T)	Level 4

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 Resistance to Degradation by Chemicals

Chemical	Degradation [%]
40% Sodium Hydroxide (K)	-12.7
30% Hydrogen Peroxide (P)	-19.5
37% Formaldehyde (T)	-33.4

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

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.

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Tested acc. to ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Drugs and Concentration	Minimum Breakthrough Detection Time (Specimen 1/2/3) (Minutes)
Carmustine (BICNU) 3.3 mg/ml (3,300 ppm)	30.0 (30.0, 30.0, 30.0)
Cyclophosphamide (Cytoxan) 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240
Fluorouracil 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240
Cisplatin 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240
Thiotepa 10.0 mg/ml (10,000 ppm)	16.0 (75.7, 16.0, 75.7)
Mechlorethamine HCL 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240

SYMBOLS USED ON THE PACKAGINGS

MD	Medical device		Single sterile barrier system with protective packaging inside		Powder-free gloves
PPE	Personal Protective Equipment	NEOPRENE	Neoprene gloves	ISO 374-1/Type C	Designed to protect against to chemical risks acc. with EN ISO 374-1 (type C)
	Manufacturer		Keep dry	ISO 374-5:2016 VIRUS	Designed to protect against microorganisms risks acc. with EN ISO 374-5
EC REP	Authorized representative in the European Community/ European Union		Keep away from sunlight		Consult instruction for use
	Importer	35°C 5°C	Temperature limit 5-35^{0}C	1x para/pair/napa	1 pair of gloves in unit pouch
2	Do not re-use	O_3	Keep away from ozone	50 par / pairs / пары	50 pairs of gloves per unit dispenser

Last Rev. 10.2022, Date: 11.10.2022

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STERILE R	Sterilized using irradiation		Product quality is not ensured if the package is damaged	400 par / pairs / пари	400 pairs of gloves per carton
			Date of manufacture	20 PAP	Recyclable packaging
2 STERILIZE	Do not resterilize	REF	Catalogue number		Package is treated as municipal waste
LOT	LOT / batch number		Expiry date		indicates compliance with the requirements of Ukrainian market
#	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.