Instruction for use

The instruction below should be used in conjunction with detailed information on the packaging.
This instructions is not the instructions for use of medical device and must not be used for that purpose.

BRAND NAME	**dermagel basic**
PRODUCT DESCRIPTION	surgical and protective, latex, powder-free gloves, sterile, for single use
Reference Number	RC100820 55-90_2937
Sterilization	Radiation / E- beam (R)
Raw material	Natural Rubber Latex
Size	5.5, 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 manufacturing date
MANUFACTURER	Guilin HBM Health Protections Inc. No. 1-2, Shuijing East Road Economic & Technological Development Area 541805 Guilin, Guangxi, China
AUTHORIZED REPRESENTATIVE	HBM Medical Coliemore House, Coliemore Road Dalkey, Co Dublin A96 A8D5 Ireland
IMPORTER	Mercator Medical S.A. H. Modrzejewskiej 30 Street 31-327 Cracow, Poland
PPE CLASSIFICATION	Personal Protective Equipment category III - Regulation (EU) 2016/425
PRODUCT STANDARDS COMPLIANCE	EN ISO 21420:2020, EN ISO 374-1:2016/A1:2018 (Type B), EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016
NOTIFIED BODY	EU Type Examination (Module B) issued by Notified Body: ANCCP Certification Agency Srl, Notified Body No 0302, Via Dello Struggino, 6, 57121 – Livorno, Italy The conformity to type based on quality assurance of the production process (Module D) under surveillance of the Notified Body: Satra Technology Europe Ltd, No 2777 CE 2777 Bracetown Business Park, Clonee, Dublin 15 Dublin, Ireland
MD CLASSIFICATION	Medical device class IIa - rule classification acc. to declaration of conformity
PRODUCT STANDARDS COMPLIANCE	EN ISO 14971:2019+A11:2021, EN ISO 15223-1:2021, EN ISO 20417:2021, EN 455-1:2020+A1:2024, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, ISO 2859-1:1999+A1:2011, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023; EN ISO 10993-11:2018, EN ISO 10993-23:2021, EN 556-1:2024, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, EN ISO 11137-1:2015/A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A1:2023, EN ISO 11607-2:2020/A1:2023
NOTIFIED BODY	Conformity assessment procedure according to Annex IX, Chapter I and III and surveillance carried out by BSI Group The Netherlands B.V., No 2797 CE 2797 Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands
QUALITY SYSTEM STANDARDS	ISO 13485:2016 / EN ISO 13485:2016

	ISO 9001: 2015 ISO 14001:2015
INTENDED USE	Sterile surgical and protective gloves 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 procedure. 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 Medical Device regulations and the European Regulation 2016/425 on Personal Protective Equipment. Chemo-risk gloves designed for protection while working with the administration of chemotherapy drugs. Gloves should be used solely according to their intended use.
	This product is classified as medical device class IIa in accordance with Regulation (EU) 2017/745 (Annex VIII), but this document is not the instructions for use of medical device. As medical device class IIa, this product can be safely used without any such instructions for use and in accordance with the provisions of Annex I p. 23.1(d) of Regulation (EU) 2017/745, instructions for use of medical device is not required. At the same time, this instruction is not instructions for use of medical device and must not be used for that purpose.
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 if 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 re-sterilize.
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.
WARNINGS ABOUT POTENTIAL ALLERGIC REACTIONS	The product contains natural rubber latex which may cause allergic reactions including anaphylactic responses. Components used in gloves production process may cause allergic reactions in some people. 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 consult a doctor. During the production process, the following chemical accelerators and antioxidants may be used, which may cause potential allergic reactions type IV: I. Zinc diethyldithiocarbamate (ZDEC) II. 4,4 '- bis (phenyl isopropyl Diphenylamine) This information is included in this manual based on requirements of EN 455-3:2023 standard - Disposable medical gloves - Requirements and tests in biological evaluation. The product has been tested in accordance with EN ISO 10993-5,10, and has not shown any cytotoxic, irritating or skin sensitizing effects.
REACH INFORMATION	The products covered by this instruction do not contain substances listed in the latest version of the candidate list according to Regulation (EC) 1907/2006; These products also do not contain substances with carcinogenic, mutagenic or reproductive toxic effects (substances defined in Regulation (EU) 2017/745, Annex 1, Section 10.4.1) They do not contain polycyclic aromatic hydrocarbons (PAH) (substances defined in EN ISO 21420, p. 4.2. f); and phthalates, plasticizers containing phthalates, thiurams.
LONG-TERM STORAGE INSTRUCTIONS	It is recommended to store the gloves in dry place, in the temperature of 5-40°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).
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. Packaging for disposal - dispose of in the blue container. 
	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.
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 and test methods.

Protective gloves – General Requirements	Status / Performance Level
Sizing	5.5; 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 ISO 374-1 Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks, **EN 16523-1** Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact and **EN ISO 374-4** Protective gloves against dangerous chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals

Chemical	Status / Performance Level	Degradation [%]
40% Sodium Hydroxide (K)	6	-1.99
30% Hydrogen Peroxide (P)	6	-1.68
37% Formaldehyde (T)	6	-0.61
n-heptane (J)	0	59.52
25% Ammonium Hydroxide (O)	0	-3.48

Level 1 >10 min, Level 2 > 30 min, Level 3> 60 min, Level 4 > 120 min, Level 5 > 240 min, Level 6 > 480 min
EN ISO 374-4: 2019 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

Test acc. to ASTM F1671 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System
Test acc. to EN ISO 374-5 (ISO 16604) Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

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.

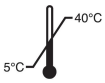
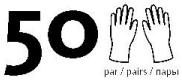
Test acc. to ASTM F1670 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood

Test name	Status / Performance Level
Synthetic blood permeation	Pass

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

Drug and Concentration	Minimum breakthrough detection time (Specimen 1/2/3) [minutes]
Carmustine 3,3 mg/ml (3,300 ppm)	11.1 (14.2; 11.1; 15.3)
Cyclophosphamide 20 mg/ml (20,000 ppm)	>240
Doxorubicin HCl (Adriamycin) 2 mg/ml (2,000 ppm)	>240
Etoposide 20 mg/ml (20,000 ppm)	>240
Fluorouracil 50 mg/ml (50,000 ppm)	>240
Melphalan 5 mg/ml (5,000 ppm)	>240
Methotrexate 25 mg/ml (25,000 ppm)	>240
Mitomycin C 0,5 mg/ml (500 ppm)	>240
Mitoxantrone HCl 2 mg/ml (2,000 ppm)	>240

SYMBOLS USED ON THE PACKAGINGS

	Manufacturer		Authorized representative in the European Community / European Union		Importer
	Medical device		Latex gloves		Do not re-use
	Do not resterilize		Single sterile barrier system with protective packaging inside		Sterilized using irradiation
	Product quality is not ensured if the package is damaged		Keep away from sunlight		Keep dry
	Temperature limit		Date of manufacture		Country of manufacture (2 letters refer to country code)
	Unique device identifier		Catalogue number		LOT / batch number
	Expiry date		Model number		Consult instruction for use
	1 pair of gloves in unit pouch		50 pairs of gloves per unit dispenser		400 pairs of gloves per carton
	Package is treated as municipal waste		Recyclable packaging	SIZE	Marking of glove size
	Designed to protect against to chemical risks acc. to EN ISO 374-1 (type B)		Designed to protect against microorganisms risks acc. to EN ISO 374-5		

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.

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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.

Rev. 1.0, 02.06.2025