



INSTRUCTIONS FOR USE

STERILE, SINGLE USE LATEX SURGICAL GLOVES, POWDERED

PRODUCT: STERILE SINGLE USE LATEX SURGICAL GLOVES, POWDERED

BRAND: MEDICMILE, MEDICMILE PLUS, MYTOUCH, and SWEAR

BASIC UDI- 89043733LSG4H

TYPE OF GLOVES – TYPE-I

Intended Use:

These are sterile surgical gloves for single use, intended for use in medical field to protect patient and user from cross- contamination, conducting medical surgical & examinations, diagnostic and therapeutic procedures and for handling medical contaminated material. Gloves are classified as Medical Devices Class IIa and as a Personal Protective Equipment Category III, type C. 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 374-1:2016+A1:2018 and microorganism (viruses, bacteria and fungi) risks according with EN ISO 374-5:2016. 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 application.

Device Description:

Sterile, surgical gloves are single use disposable devices made of natural rubber latex that comes in creamy white colour. These gloves may or may not bear powder to facilitate donning. Hand Specific, Beaded Cuff, Micro rough textured. Surgical Gloves are designed to be perfectly anatomical for comfortable wrinkle-free fitting. The extremely soft rubber reduces finger fatigue and increases efficiency. Low powder content that minimizes skin irritation.

Caution:

Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions. Failure to do so may result in complications. To be used by an expert qualified medical professional. This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged. The device is for Single Use Only.

Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions.

Target Patient Population:

All age group Patients (including-Pre-term infants, Neonates, Children, Adolescents, Adults and Old Age).

Target User Groups:

Qualified medical professionals for performing surgical and other invasive procedures (Do not require high level of tactile sensibility) such as: Surgeons & Co-surgeons - General Surgery, Urology, Cardio, Vascular, Neuro, Oncology, Plastic, Paediatric, Endocrinology, Gastro, Anaesthesiologists, OT Staff, Nursing Staff, Technicians, Emergency medical technicians (EMTs), Paramedics, House Keeping staff from hospital & Caregivers, etc.

Target Environment:

The sterile single use latex surgical gloves are recommended to be used in sterile fields in the healthcare facilities such as operation room and other clinical settings that could introduce microbes into a patient.

These gloves can be used in healthcare facilities by the healthcare workers when they come in contact with a patient's bodily fluids, such as blood, vomit or urine, or any other possible contaminants, etc.



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Device Packaging :

Sterile, One Pair of Paper Wrapped Gloves packed in tear-able paper pouch pack.

Size :

6.0, 6.5, 7.0, 7.5, 8.0, 8.5.

Material of Construction :

Natural Rubber Latex.

Device Shelf Life:

3 years from the date of manufacture printed on the Product Label.

Method of Sterilization :

ETO Sterilization Process.

Duration of Use :

Duration of Use is transient use (<60 min).

Application of the Body :

Surface contacting device & Contact with mucosal membranes.

Mode of action/Principle of operation:

The Sterile Single Use Latex Surgical Gloves creates a protective barrier between user hands and bodily fluids, bodily tissues, mucous membranes, broken skin, potentially infectious materials and other contaminants to prevent transmission of harmful diseases & viruses during invasive surgical procedures and hence protect both the patients and users from infection.

Medical Benefits:

- NRL gloves are competent barrier to protect against infections for both healthcare professionals and the patients.
- NRL gloves provide lower rates of perforation and lower viral leakage rates.
- NRL gloves are easy to put on comfortable to wear and provide adequate, durable protection.
- NRL gloves have good barrier integrity.
- NRL gloves have less after-use defects.
- NRL gloves have significant greater satisfaction with regard to factors such as quality, safety and durability.
- NRL gloves have high tear propagation strength.
- NRL gloves have high tensile strength.
- NRL gloves have good fit and comfort.

Care Instructions:

Storage:

It is recommended to store the gloves in dry place, in the temperature of 5-40°C and to protect them against direct sunlight and fluorescent light. If gloves are properly stored, as indicated above, they won't lose their performances and won't change the glove characteristics significantly. If gloves could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.

It is recommended to protect the gloves against humidity. Keep the gloves in a distance of not less than 1m from



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heating devices, sources of fire and ozone.

Cleaning: The gloves are not designed to be laundered.

Indications :

Wearing gloves helps protect both patients and health care workers from infection. When there is a likelihood of coming into direct contact with a patient or patient's blood or other potentially infectious materials (e.g. body fluid, moist body, substances and saliva [in dental procedures]). Defined pathogen barrier as protection from biological agents.

Contra-indications :

- Allergic to the patients or users those sensitive to natural rubber latex.
- Latex Gloves should not be used in protection from chemicals, radiations protection.
- These gloves are not to be used for Microsurgery procedures and chemotherapy procedures.

Potential Complications / Risks:

Dermatological response- Rash, Itch, Hives, Edema, Irritation, Erythema. Non-dermatological response – Dyspnea, Eye Irritation, Nasal Irritation, Wheezing. Diagnostic terms – Allergy (Type-I & IV), Anaphylaxis, Asthma, Contact dermatitis, Rhinitis, Irritant Dermatitis, Urticaria, Tissue Injury.

Powder-associated complications including inflammation, allergic reactions and increased risk of infection, contamination and irritation. Pinholes, Thin Spots, Tears, Ripped, Punctured, Exposure to body fluid, Swelling, Microbial penetration of Gloves, Gloves Perforation.

Warnings against Components / hazardous components:

- 1) This device is intended for Single use only. Do Not re-sterilize and /or reuse of the device this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.
- 2) Re-use of single use device creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability.
- 3) Product contains natural rubber latex which may cause allergic reactions including anaphylactic responses. Components used in making gloves 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.
- 4) Gloves that are discoloured or stiff may also indicate excessive use or degradation from chemicals. Dispose of gloves when they show any sign of deterioration. Discard the device after single use.

Precautions :

- 1) Check the integrity of the individual sterilized pack of device, before use. Do not use if pack is damaged.
- 2) This product contains natural rubber latex.
- 3) Destroy / Dispose the device & its accessories after single use as bio-medical waste as per applicable laws.
- 4) Do not Re-sterilize. Do not Re-use. Discard after single use.
- 5) Before usage, inspect the gloves for any defects or imperfections such as holes, pinholes and tears. If the gloves are ripped or punctured during use, dispose of them immediately. If in doubt, do not use the gloves, get a new pair.



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- 6) Contaminated gloves should be cleaned or washed before removal.
- 7) Ensure the body fluids, blood, chemicals and other infectious materials cannot enter via the cuff.
- 8) The gloves should not come in contact with a naked flame.
- 9) Gloves shall not be used for protection against ionising radiation or for use in containment enclosures.
- 10) Do not let chemical substances get under the gloves through the cuff. If a chemical substance reaches the skin, wash it away immediately with plenty of water. If the gloves get punctured, torn or broken during their use, take them off and put on the new ones. Avoid using gloves dirty in the inside as they may cause irritation leading to skin inflammation or more serious damages.
- 11) 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 the temperature, abrasion and degradation. The gloves should not be used in contact with open fire and to protect against any sharp tools. The gloves are not intended for welding, electric shock protection, ionizing radiation or from the effect of hot or cold objects.
- 12) The chemical resistance has been assessed under laboratory conditions.
- 13) Gloves are suitable for special purposes as they are surgical gloves where risk of wrist injury caused by chemicals is considered to be minimal. Length suitable for tasks that require hand protection. Gloves shorter than minimum lengths required by EN 420 standard. Glove minimum length in accordance to EN 455-2 standard.

Adverse Events :

Dermatological response- Rash, Itch, Hives, Edema, Irritation, Erythema. Non-dermatological response –Eye Irritation, Nasal Irritation, Wheezing. Diagnostic terms – Allergy (Type-I & IV), Anaphylaxis, Asthma, Contact dermatitis, Rhinitis, Irritant Dermatitis, Urticaria, Tissue Injury.

Powder-associated complications including inflammation, allergic reactions and increased risk of infection, contamination and irritation. Exposure to body fluid, Swelling, Microbial penetration of Gloves, Gloves Perforation.

Allergic manifestations due to natural rubber latex, Surgical Site Infections due to powder content.

Instructions / Measures to be taken in the event of device malfunction or any adverse event:

- (1) To be used by a qualified medical professional. Use maximal sterile barrier precautions during use of the gloves.
- (2) Wear sterile gloves ONLY for procedures where an aseptic technique is required.
- (3) If hands come into contact with a patient's blood or body fluids due to a hole/puncture in gloves during surgery, remove the gloves immediately and wash your hands with soap. To continue the procedures please wear new pair of gloves on your hands.

Use Instructions :

- (1) Wash up and scrub hands and preferably use pre sterile protective gloves.
- (2) Tear open the tear-able pack and remove the device safely.
- (3) Take out the inner wrap. Open the inner wrapper so that you can see both gloves.
- (4) Before use, inspect gloves for physical damage such as tears or pinholes.
- (5) Put the wrapped sterile gloves on your clean, dry work surface.
- (6) **Step 1. Put on the first glove**
 - (i) Take the hand you write with and grasp the glove for your other hand at the folded edge of the cuff.



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- (ii) Pick up the glove by the folded edge.
- (iii) Put your hand inside the glove. Keep your hand flat and your thumb tucked in.
- (iv) Pull the glove on.
- (v) Be careful not to touch the outside of the glove. Touch only the part of the glove that will be next to your skin.

- (vi) Leave the cuff on the glove folded.

Step 2. Put on the second glove

- (i) Now, slip the fingers of your gloved hand into the folded cuff of the other glove.
- (ii) Lift up the second glove.
- (iii) Put the glove over your fingers. The hand that you are putting the glove on should stay flat. Keep the gloved thumb up and back to keep from touching your bare palm or wrist.
- (iv) Pull the glove over your hand.
- (v) Adjust each glove to get a snug fit.
- (vi) Reach under the cuffed part to pull up or adjust.

Step 3. After the gloves are on

- (i) Keep your hands in front of you and above your waist. Don't touch anything outside the sterile field.
 - (ii) If you break sterile procedure, remove the gloves, get a new package, and start again.
- (7) Always wash hands with soap and water after removing gloves.

Disposal:

Used Gloves can be contaminated with contagious or other hazardous substances. They should be disposed as bio-medical waste as per local regulations.

Adverse Event Reporting:

In any device malfunction or in case of an adverse event that happened to the user or patient during surgical or examination procedure, please report this adverse event to the manufacturer (Swear Healthcare) or authorized representative and competent authority of the member state where user/ patient is established without any delay or within 24 hrs, as per applicable adverse event reporting regulations.

MD classification & compliance:

Gloves are classified as class IIa according to Annex VIII of the Regulation (EU) 2017/745 and comply to standards:

EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN ISO 20417:2021.



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PERSONAL PROTECTIVE EQUIPMENT:

PPE classification & compliance:

Gloves are classified In Compliance with the Harmonized Standards Personal Protective Equipment, risk category III under Regulation (EU)2016/425 and comply to standards:

EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN ISO 20417:2021.
EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016.

Notified Body responsible for EU Type Examination (Module B) and on-going conformity (Module C2):

SGS Fimko Oy,
Takomotie 8, FI-00380 Helsinki, Finland
Notified Body No. 0598

1.	EN ISO 374-1:2016/Type B  KTP	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance penetration <table><tr><td>a)</td><td>Air leak test</td><td>Pass</td></tr><tr><td>b)</td><td>Water leak test</td><td>Pass</td></tr></table>	a)	Air leak test	Pass	b)	Water leak test	Pass																										
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2.	EN 16523-1 : 2015+A1:2018	Low chemical resistance pictogram for gloves <table><tr><th>Resistance to Permeation by Chemicals</th><th>Status / Performance level</th></tr><tr><td>Methanol</td><td>Level 0</td></tr><tr><td>Acetone</td><td>Level 0</td></tr><tr><td>Acetonitrile</td><td>Level 0</td></tr><tr><td>Dichloromethane</td><td>Level 0</td></tr><tr><td>Carbon disulphide</td><td>Level 0</td></tr><tr><td>Toluene</td><td>Level 0</td></tr><tr><td>Diethylamine</td><td>Level 0</td></tr><tr><td>Ethyl acetate</td><td>Level 0</td></tr><tr><td>n-Heptane</td><td>Level 0</td></tr><tr><td>Sodium hydroxide 40%</td><td>Level 6</td></tr><tr><td>Nitric acid 65%</td><td>Level 1</td></tr><tr><td>Acetic acid 99%</td><td>Level 0</td></tr><tr><td>Ammonium hydroxide 25%</td><td>Level 0</td></tr><tr><td>Formaldehyde 37%</td><td>Level 2</td></tr><tr><td>Hydrogen peroxide 30%</td><td>Level 3</td></tr></table>	Resistance to Permeation by Chemicals	Status / Performance level	Methanol	Level 0	Acetone	Level 0	Acetonitrile	Level 0	Dichloromethane	Level 0	Carbon disulphide	Level 0	Toluene	Level 0	Diethylamine	Level 0	Ethyl acetate	Level 0	n-Heptane	Level 0	Sodium hydroxide 40%	Level 6	Nitric acid 65%	Level 1	Acetic acid 99%	Level 0	Ammonium hydroxide 25%	Level 0	Formaldehyde 37%	Level 2	Hydrogen peroxide 30%	Level 3
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3.

EN ISO 374-1:2016/Type B


KTP



It refers to the Instruction for use as per EN ISO 21420:2020

Protective gloves – General Requirements	Status / Performance level
Sizing	6.0, 6.5, 7.0, 7.5, 8.0, 8.5
Dexterity	Performance Level 5
pH Value	Pass

Tested for protection against liquid penetration and Micro organism

Resistance to Penetration	Status / Performance Result	level
Air Leakage	Performance Level 2	Pass
Water Leakage	Performance Level 2	Pass

Low chemical resistance pictogram for gloves

Resistance to Permeation by Chemicals	Status / Performance level
Sodium Hydroxide 40%	Class 6
Ammonia 25%	Class 6
Iso Propanol 99%	Class 0
Hydrogen Peroxide 30%	Class 5
Formaldehyde 37%	Class 2

4.

EN ISO 374-4 : 2019

Resistance to degradation by Chemicals.

Resistance to Degradation by chemicals	Observation	Result in %
Methanol (67-56-1)	Moderate swelling	14.4
Acetone (67-64-1)	Moderate swelling	48.0
Acetonitrile (75-05-8)	Moderate swelling	36.1
Dichloromethane (75-09-2)	Complete degradation	100.0
Carbon disulphide (75-15-0)	Severe swelling	96.3
Toluene (108-88-3)	Severe swelling	96.6
Diethylamine (109-89-7)	Severe swelling	92.8



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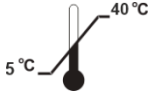
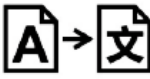
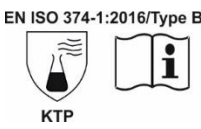
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5.	EN ISO 21420:2020+A1:2024	<table><tr><td colspan="2">Protective gloves - General requirements and test methods</td></tr><tr><td>Sizing</td><td>8,9,10</td></tr><tr><td>Dexterity</td><td>Level 5</td></tr></table>	Protective gloves - General requirements and test methods		Sizing	8,9,10	Dexterity	Level 5																		
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6.	ISO 3071: 2020	<table><tr><td>pH Value</td><td>Pass</td></tr></table>	pH Value	Pass																						
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7.	ISO 16190:2021	<table><tr><td>Polyaromatic hydrocarbons Content (PAH)</td><td>Pass</td></tr></table>	Polyaromatic hydrocarbons Content (PAH)	Pass																						
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8.	EN ISO 374-5:2016  VIRUS	The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.																								



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SYMBOLS USED IN MEDICAL DEVICE PACKAGING

	Manufacturer		Date of Manufacture		Keep away from Sunlight
	Use by Date/ Expiry Date		Keep Dry		Contains presence of Natural Rubber Latex
	Batch Code		Do not Re-use		Country of Manufacture
	Sterilized using Ethylene Oxide		Do not use if package is damaged and consult instructions for use		Do not resterilize
	Consult Instructions for Use		Storage Temperature		Caution
	Unique Device Identifier		Authorized Representative in the European Community/ Authorized representative European Union		Medical Device
	Single sterile barrier system with protective packaging inside		Translation		Intertek Medical Notified Body AB Torshamnsgatan 43, Box 1103 SE-164 22 Kista Sweden
	Personal Protective Equipment		Designed to protect against chemical risks acc. with EN ISO 374-1:2016		Designed to protect against microorganisms risks acc. with EN ISO 374-5
	SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland Notified Body No. 0598		Consult "e-IFU" for use		



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[Mfg. Lic. No.: MFG/MD/2023/000474]



Manufactured by :

SWEAR HEALTHCARE PVT. LTD.

Factory Address:

F-373 & 374, RIICO Growth Center Extension,

Dholpur-328001 (Rajasthan) (INDIA)

Customer Care Officer: Mr. Y. Gaur

Phone No.: +91-124-425-5279

Website: www.swearhealthcare.com

E-mail: customercare@swearhealthcare.com

Contact Our Customer Care Executive at Above contacts

Consult "e-IFU" for use: <https://www.swearhealthcare/ifu/>



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Swatar, BKR 4013 Malta

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Declaration of Conformity and this instruction for use can be found under below web address:
<https://www.swearhealthcare.com/>

REVISION HISTORY

Revision No.	Revision Date	Description of change	Change Initiated by	Approval Authority
00	01.10.2025	Initial Issue –Fresh Issue of PPE IFU	--	Managing Director / MR
01	28.04.2026	Notified body Tech. file review query	Gagandeep Singh	Managing Director / MR
02	02.07.2026	Notified body Tech. file review query	Gagandeep Singh	Managing Director / MR