## 01 Product Description

| | | |
|---|---|---|
| Product Name | : | Powder Free Sterile Latex Surgical Gloves |
| Material | : | Natural Rubber Latex |
| Colour | : | White to Pale Yellow |
| Shape | : | Anatomic |
| Cuff | : | Beaded |
| External Surface: | | Textured |
| Internal Surface : | | Chlorinated |
| Size | : | 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 and 9.0 |
| Sterilization | : | Ethylene Oxide (EO) / GAMMA (R) |
| Shelf Life | : | 3 years |
| Basic UDI-DI | : | 806363LSGFM4 |

## 02 Intended Use

This disposal medical device is made up of natural rubber latex which is anatomically shaped with thumb position 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 and other contaminants.

## 03 Product Classification & Standard compliance

| | |
|---|---|
| Medical Device Classification | : Class IIa, Rule#06 |
| Conformity assessment route | : Annex II section 4 of council directive (EU) 2017/745 |
| Regulatory Authority | : DNV Product Assurance As |
| Notified Body Number | : 2460 |
| Standard Compliance | : |

EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2013, EN 566-1:2024, EN ISO 11135: 2014/A1:2019, EN ISO 11137-1:2015/A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, ISO 11607-1:2020/A1:2023, ISO 11607-2:2020/A1:2023, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-7:2008, EN ISO 10993-10:2021, EN ISO 10993-11:2017, EN ISO 10993-23:2021, ISO 10282:2023, ASTM D 3577-19(2023), ISO 13485:2016, ISO 14001:2015, ISO 9001 : 2015, IS 13422 : 2024.

## 04 Storage Instruction

Gloves must be stored in cool dry environment which is dust free. Cartons and Boxes must be stored unopened until required. Recommended storage temperature is 5°C-35°C. Avoid exposure to direct light, heat and excessive humidity.
As ozone is deleterious, storage area should not contain any equipment capable of generating ozone such as ultraviolet light, fluorescent lights, mercury vapour lamps, photocopier, high voltage equipment, x-ray units, electric motors and electro surgical equipments.

## 05 Indication For Use

- Dry hands thoroughly before donning.
- Protective gloves should only be used for the intended application and in the correct size.
- These are sterile gloves for single use only.
- Users should take care when using the gloves. Using them solely according to their intended application.
- Before usage, inspect the gloves for any defect or imperfection.

## 06 Contraindication

- Latex gloves are made of Natural rubber latex, which may cause allergic reactions including anaphylaxis response if the user is allergic to latex.
- Gloves contain Natural Latex; persons who are sensitive to Latex should consult a physician before using.

## 07 Precautions

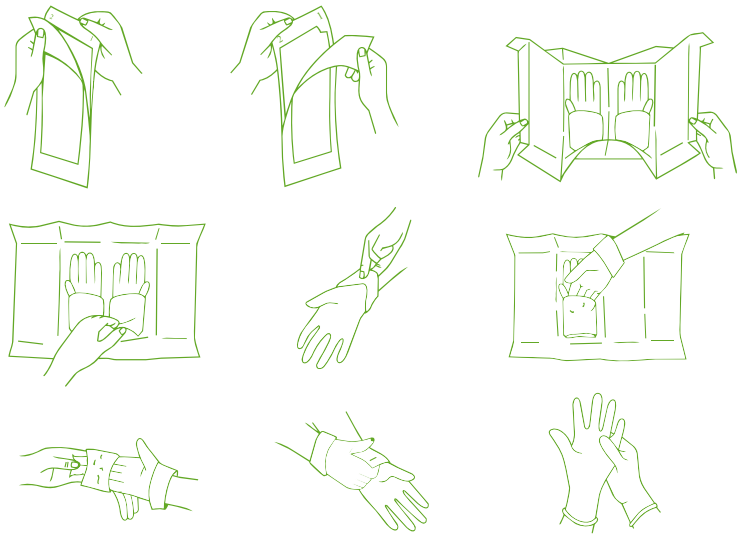
- Do not use if package is damaged or wet.
- Risk of reuse: May cause infection, allergic reaction and poor barrier protection.
- Gloves shall not be worn where there is a risk of entanglement by moving parts of machines is needed.
- The results do not reflect the actual duration of protection in the workplace due to other factors influencing the performance, such as temperature, abrasion, degradation etc.

## 08 Warnings

- Dispose off the devices and packaging after use as per Bio-Medical waste laws.
- Do not re-sterilize.
- The product contains Natural Rubber Latex which may cause allergic reactions including anaphylactic responses to some individuals.
- The gloves not intend to prevent Electrical shock care should be taken to have proper earthing in Medical Device Electrical appliances user.
- Necessary caution to be practiced against probable Electrical Hazards.

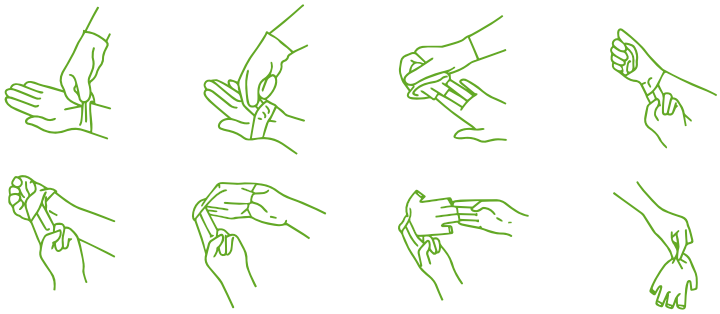
## 09 Directions for use

### Glove Opening and Donning Procedure :



- Remove the walleted gloves (inner wrapper) from the Pouch (outer wrapper) by Peel open from the corner for Paper Pouch (Peel down to open pouch).
- Open the walleted glove to see “Left” and “Right” compartment.
- Pinch back upper and lower flaps of the inner wrapper.
- Using the middle flaps, open the wrapper touching only the 1 inch margin for safety.
- Be sure wrapper does not close over gloves after opening to avoid contamination.
- 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.
- Slide dominant hand in to the gloves keeping hand point downwards and pull up to wrist.
- Using the glove hand insert the 4 fingers under the cuff of the other glove and pull the glove up to the arm.
- Adjust the gloves as necessary.

### Glove Removal Procedure :



- Take hold of the first glove at the wrist.
- 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.
- 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.

## 10 Explanation of Symbols

| | |
|---|---|
| | Manufacturer |
| EU REP | Authorized representative in the European Community<br>AMSTERMED B.V.,<br>Saturnusstraat 46-62,<br>Unit 032, 2132 HB Hoofddorp,<br>The Netherlands |
| IND | Date of Manufacture / Country of Manufacture |
| | Use by date |
| LOT | Lot No |
| REF | Reference Number / Catalogue Number |
| SN | Serial Number |
| CE 2460 | CE Logo |
| STERILE EO | Sterilization using Ethylene oxide |
| STERILE R | Sterilization using Irradiation |
| | Single Sterile Barrier System |
| 2 STERILIZE | Do not re-sterilize |
| | Do not use package is damaged or wet |
| | Keep away from sunlight |
| | Keep dry |
| 5°C 35°C | Temperature limit |
| | This way up or end up |
| $O_3$ | Keep away from Ozone |
| | Single Use |
| | Instruction for Use |
| | Caution |
| LATEX | Latex Caution |
| Allergen IV | Presence of Type IV allergen |
| MD | Medical Device |
| UDI | Unique Device Identifier |

## 11 Personal Protective Equipment

EN ISO 374-1/Type A | EN ISO 374-1/Type B | EN ISO 374-1/Type C


UVWXYZ


XYZ





TYPE A Permeation min. 6 chemicals, level 2 (table 1)
TYPE B Permeation min. 3 chemicals, level 2 (table 1)
TYPE C Permeation min. 1 chemical, level 1 (table 1)

EN ISO 374-5:2016


VIRUS

Protective gloves protecting from viruses, bacteria and fungus

EN ISO 374-5:2016



Protective gloves protecting from bacteria and fungus

### Table 1

| Chemicals | |
|---|---|
| A | Methanol |
| B | Acetone |
| C | Acetonitrile |
| D | Dichloromethane |
| E | Carbon disulphide |
| F | Toluene |
| G | Dimethylamine |
| H | Tetrahydrofuran |
| I | Ethyl acetate |
| J | n-Heptane |
| K | Sodium hydroxide 40% |
| L | Sulphuric acid 96% |
| M | Nitric acid 65% |
| N | Acetic acid 99% |
| O | Ammonium hydroxide 25% |
| P | Hydrogen peroxide 30% |
| S | Hydrofluoric acid 40% |
| T | Formaldehyde 37% |

### Performance Level

| Time | Protection index |
|---|---|
| >10 min | 1 |
| >30 min | 2 |
| >60 min | 3 |
| >120 min | 4 |
| >240 min | 5 |
| >480 min | 6 |

EN ISO 374-1/Type B


KMPT

EN ISO 374-5:2016


VIRUS

CE 0598

In Compliance with the Harmonized Standards
Personal Protective Equipment, risk category III under
Regulation (EU)2016/425
EN ISO 21420 : 2020
EN ISO 374-1 : 2016
EN ISO 374-2 : 2019
EN 16523-1 : 2015+A1:2018
EN ISO 374-4 : 2019
EN ISO 374-5 : 2016
Regulatory Authority : SGS Fimko Oy,
Takomotie 8, FI-00380, Helsinki, Finland.
Notified Body Number : 0598

## 12 Warnings as per EN 374-1 & 5

- This information does not reflect the actual duration of protection in the work place and the differentiation between mixtures and pure chemicals.
- 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.
- It is recommended to check that the gloves are suitable for the intended use because the conditions at the work place 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.
- The Penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

## 13 Test Results as per EN ISO 374-1 & 5

### 1. EN ISO 21420 : 2020

Protective Gloves - General Requirement and test methods

| Type | Declared Size | 5.5 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 |
|---|---|---|---|---|---|---|---|---|---|
| Glove | Length (mm) | 272 | 281 | 279 | 279 | 287 | 284.7 | 284.3 | 288.3 |
| | Circumference (mm) | 149 | 159 | 167.7 | 184 | 195 | 204.7 | 218.7 | 224.3 |
| | Dexterity | Performance Level 5 | | | | | | | |
| | pH value | 6.5 | | | | | | | |

Polyaromatic Hydrocarbons content

| | Results |
|---|---|
| Benz (a) anthracene | Not Detected |
| Chrysene | Not Detected |
| Benzo (b) Fluoranthene | Not Detected |
| Benzo (k) Fluoranthene | Not Detected |
| Benzo (a) pyrene | Not Detected |
| Dibenz (a,h) anthracene | Not Detected |
| Benzo (e) pyrene | Not Detected |
| Benzo (j) Fluoranthene | Not Detected |

## 2. EN ISO 374-2 : 2019

Protective gloves against dangerous chemicals and micro-organisms - Part 2 : Determination of resistance to penetration

| Resistance to Penetration | Status |
|---|---|
| Air Leakage | Pass |
| Water Leakage | Pass |

| Clause | Test Name | Test Results | | Performance level |
|---|---|---|---|---|
| 7.2 | Air leak test (Air Pressure Used: 0.5 kPa) | Sample size | Leakage | Pass |
| | | 5.5 | No Leakage | |
| | | 6.0 | No Leakage | |
| | | 6.5 | No Leakage | |
| | | 7.0 | No Leakage | |
| | | 7.5 | No Leakage | |
| | | 8.0 | No Leakage | |
| | | 8.5 | No Leakage | |
| | | 9.0 | No Leakage | |
| 7.3 | Water leak test | Sample size | Leakage | Pass |
| | | 5.5 | No Leakage | |
| | | 6.0 | No Leakage | |
| | | 6.5 | No Leakage | |
| | | 7.0 | No Leakage | |
| | | 7.5 | No Leakage | |
| | | 8.0 | No Leakage | |
| | | 8.5 | No Leakage | |
| | | 9.0 | No Leakage | |

## 3. EN ISO 374-4 : 2019

Protective gloves against dangerous chemicals and micro-organisms - Part 4 : Determination of resistance to degradation by chemicals

| Chemical / CAS No | Exposure Duration | Test Results (Percentage change in puncture resistance | | Observation |
|---|---|---|---|---|
| Sodium hydroxide 40% 1310-73-2 | 60±5 minutes | Glove sample | Result (%) | No change |
| | | 1 | 9.4 | |
| | | 2 | 8.6 | |
| | | 3 | 9.1 | |
| | | Mean | 9.0 | |
| | | Standard Deviation | 0.395 | |
| Sulphuric acid 96% 7664-93-9 | 60±5 minutes | Glove sample | Result (%) | Severe Swelling & Colour change |
| | | 1 | 91.1 | |
| | | 2 | 90.4 | |
| | | 3 | 90.3 | |
| | | Mean | 90.6 | |
| | | Standard Deviation | 0.409 | |
| Nitric acid 65% 7697-37-2 | 60±5 minutes | Glove sample | Result (%) | Severe Swelling & Colour change |
| | | 1 | 77.4 | |
| | | 2 | 77.4 | |
| | | 3 | 77.5 | |
| | | Mean | 77.4 | |
| | | Standard Deviation | 0.076 | |
| Acetic acid 99% 64-19-7 | 60±5 minutes | Glove sample | Result (%) | Slight swelling |
| | | 1 | 12.6 | |
| | | 2 | 11.8 | |
| | | 3 | 12.5 | |
| | | Mean | 12.3 | |
| | | Standard Deviation | 0.468 | |
| Hydrogen peroxide 30% 7722-84-1 | 60±5 minutes | Glove sample | Result (%) | No change |
| | | 1 | -10.9 | |
| | | 2 | -9.4 | |
| | | 3 | -8.1 | |
| | | Mean | -9.5 | |
| | | Standard Deviation | 1.373 | |
| Formaldehyde 37% 50-00-0 | 60±5 minutes | Glove sample | Result (%) | Slight swelling |
| | | 1 | 5.2 | |
| | | 2 | 7.1 | |
| | | 3 | 4.0 | |
| | | Mean | 5.4 | |
| | | Standard Deviation | 1.566 | |

## 4. EN 16523-1 : 2015+A1:2018

Determination of material resistance to permeation by chemicals - Part 1 : Permeation by Liquid chemical under conditions of continuous contact.

| Chemical CAS No | Loop System /collection medium | Analytical Technique used | Mean thickness (mm) | NBT at NPR 1.0 µg $cm^{-2}$ $min^{-1}$ (minutes) | Performance level accordance to BS EN ISO 374-1:2016+ A1.2018 Table 1 | Observation |
|---|---|---|---|---|---|---|
| Sodium hydroxide 40% 1310-73-2 | Closed loop /Grade 3 water/350 rpm | Continuous measurement with conductivity electrode | 0.16<br>0.15<br>0.16 | >480<br>>480<br>>480 | 6 | No change |
| Sulphuric acid 96% 7664-93-9 | Closed loop /Grade 3 water/350 rpm | Continuous measurement with conductivity electrode | 0.15<br>0.16<br>0.16 | 26<br>28<br>24 | 1 | Severe Swelling & Colour change |
| Nitric acid 65% 7697-37-2 | Closed loop /Grade 3 water/350 rpm | Continuous measurement with conductivity electrode | 0.16<br>0.15<br>0.16 | 58<br>52<br>55 | 2 | Severe Swelling & Colour change |
| Acetic acid 99% 64-19-7 | Closed loop /Grade 3 water/350 rpm | Continuous measurement with conductivity electrode | 0.16<br>0.15<br>0.15 | 2<br>2<br>3 | 0 | Slight Swelling |
| Hydrogen peroxide 30% 7722-84-1 | Closed loop /Grade 3 water | Periodic measurement with HPLC | 0.15<br>0.16<br>0.15 | 215<br>218<br>211 | 4 | Slight Swelling |
| Formaldehyde 37% 50-00-0 | Closed loop /Grade 3 water | Periodic measurement with HPLC | 0.16<br>0.15<br>0.15 | 42<br>45<br>40 | 2 | Slight Swelling |

## 5. EN ISO 374-5:2016

Protective gloves against dangerous chemicals and microorganisms - Part 5 : Terminology and Performance Requirements for microorganisms risks

Protected against viruses according to ISO 16604 procedure B

| Specimen | Observe the Presence of Plaques on Agar Plate (PFU) | Results at 20 Kpa | Assay Titer Ratio |
|---|---|---|---|
| 1 | <1 | Pass | 1.2 |
| 2 | <1 | Pass | |
| 3 | <1 | Pass | |
| Negative control | No | NA | |
| Positive control | Yes | NA | |

Plate exposes during testing (Settle Plate): No plaque formation observed.

➢ Declaration of conformity is supplied with the product.

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