Instruction for Use

KL/IFU-E18

KALTEX EC

01 Product Description

Product Name	:	Powder Free Polymer Coated Sterile Latex Surgical Gloves
Material	:	Natural Rubber Latex
Colour	:	White to Pale Yellow
Shape	:	Anatomic
Cuff	:	Beaded
External Surface	:	Antitack Polymer treated
Internal Surface	:	Polymer Coated
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	:	5 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

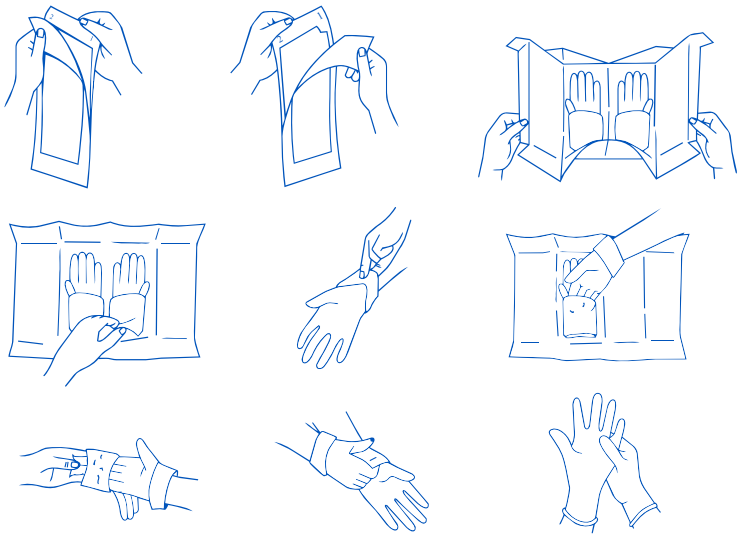
- Do not use if package is damaged or wet.
- Risk of reuse: May cause infection, allergic reaction and poor barrier protection.
- Gloves shall not be worn where there is a risk of entanglement by moving parts of machines is needed.
- The results do not reflect the actual duration of protection in the 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.

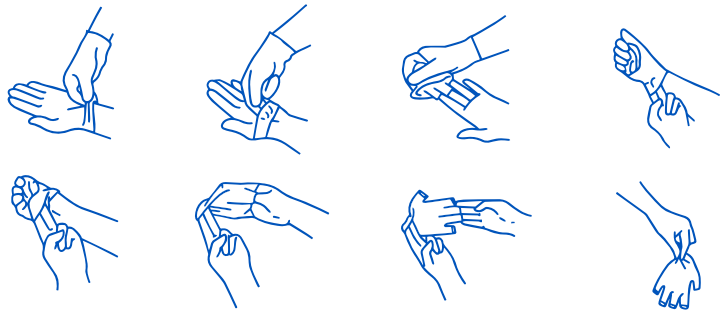
09 Directions for use

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 AMSTERMED B.V., Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, 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

10 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


KMT



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)	272.7	279	281	281.5	282	281.5	286	300
	Circumference (mm)	149	162	170.5	180.5	193	204	219.5	223.7
	Dexterity	Performance Level 5							
	pH value	6.9							

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

Air leak test

EN ISO 374-2 : 2019 (7.2)

Air pressure used: 0.5 kPa
Sample size: : 315
Number on non-confirming gloves : 3
Acceptable Number of Non-confirming gloves : 5
Note : Sampling was carried out as per ISO 2859-1, AQL of <0.65, General inspection level 1 and sample code letter M

Water leak test

EN ISO 374-2 : 2019 (7.3)

Sample size: : 315
Number on non-confirming gloves : 2
Acceptable Number of Non-confirming gloves : 5
Note : Sampling was carried out as per ISO 2859-1, AQL of <0.65, General inspection level 1 and sample code letter M

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 1 2 3 Mean Standard Deviation	Result (%) -16.2 -16.0 -18.1 -16.8 1.197	No change
Nitric acid 65% 7697-37-2	60±5 minutes	Glove sample 1 2 3 Mean Standard Deviation	Result (%) 66.4 68.0 69.0 67.8 1.285	Severe Swelling & Colour change
Formaldehyde 37% 50-00-0	60±5 minutes	Glove sample 1 2 3 Mean Standard Deviation	Result (%) -11.1 -15.4 -12.8 -13.1 2.158	No change
Sulphuric acid 96% 7664-93-9	60±5 minutes	Glove sample 1 2 3 Mean Standard Deviation	Result (%) 91.8 88.8 90.4 90.4 1.452	Severe Swelling & Colour change
Ammonium hydroxide 25% 64-19-7	60±5 minutes	Glove sample 1 2 3 Mean Standard Deviation	Result (%) 21.4 22.3 20.6 21.4 0.816	Slight swelling
Hydrogen peroxide 30% 7722-84-1	60±5 minutes	Glove sample 1 2 3 Mean Standard Deviation	Result (%) 5.9 6.7 8.2 7.0 1.160	Slight swelling

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	0.18 0.17 0.18	>480 >480 >480	6	No change
Nitric acid 65% 7697-37-2	Closed loop /Grade 3 water/350 rpm	Continuous measurement with conductivity electrode	0.17 0.15 0.16	76 83 80	3	Modurate Swelling & Colour change
Formaldehyde 37% 50-00-0	Closed loop /Grade 3 water/350 rpm	Periodic measurement with HPLC	0.17 0.18 0.17	37 40 42	2	No change
Sulphuric acid 96% 7664-93-9	Closed loop /Grade 3 water/350 rpm	Continuous measurement with conductivity electrode	0.17 0.18 0.17	14 12 16	1	Severe Swelling & Colour change
Ammonium hydroxide 25% 1336-21-6	Closed loop /Grade 3 water/350 rpm	Continuous measurement with conductivity electrode	0.17 0.16 0.17	4 5 4	0	Slight Swelling
Hydrogen peroxide 30% 7722-84-1	Closed loop /Grade 3 water/350 rpm	Periodic measurement with HPLC	0.15 0.17 0.16	2 6 4	0	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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