KANAM LATEX INDUSTRIES PRIVATE LIMITED

The trusted name the world over

ISO 9001 : 2015, EN ISO 13485 : 2016 & ISO 14001 : 2015 Certified Company

Regd. & Sales Office :
Ooppoottil Buildings, K.K.Road
Kottayam Dist. - 686 001,
Kerala, India.
Ph : 91-481-2563513, 2560108
Fax No. : 91-481-2563614
E-mail : ho@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 32AABCK0056E1Z8

Admin. Office :
13/1-423, M.S. Road, Parvathipuram,
Nagercoil, Kanyakumari Dist. - 629 003,
Tamil Nadu, India.
Ph : 91-4652-230330, 9442290633
Fax No. : 91-4652-231857
E-mail : officeadmin@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E1Z6

Factory : 1 ✓
12/67C, Ananthanadarkudy,
Asaripallam P.O, Nagercoil,
Kanyakumari Dist.- 629 201,
Tamil Nadu, India.
Ph : 91-4652-225651, 9443364301
E-mail : officeank@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E3Z4

Factory : 2
3/13F, West Peruvilai Road, Pallavilai,
Nagercoil, Kanyakumari Dist. - 629 003,
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Ph : 91-4652-227719, 9443364908
E-mail : officepvl@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E1Z6

Factory : 3
9/284A, Kanyakumari Road,
Kavalkinaru, Tirunelveli Dist. - 627 105,
Tamil Nadu, India.
Ph : 9443364909
E-mail : officekvl@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E1Z6

Factory : 4
Plot Number:24, AMRL HI-TECH CITY LTD,
SEZ, Rajakkalmangalam, Nanguneri,
Tirunelveli Dist. - 627 108,
Tamil Nadu, India.
Ph :
E-mail : officengn@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E2Z5

TECHNICAL DATA SHEET



comfort powder-free

PRODUCT DESCRIPTION

Type of the glove	Sterile powder-free surgical and protective gloves for single use
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. Single use.
Material	Natural rubber latex
Donning powder	None
Colour	Light yellow
Shape	Anatomic, curved fingers, hand specific
Cuff	Beaded
External surface	Textured, chlorinated
Internal surface	Chlorinated
Packaging	1 pair per pouch, 50 pairs per dispenser, 400 pairs per carton

PHYSICAL PROPERTIES

Size		5.5*	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Length [mm]	EN 455-2 normative value	250	260	260	270	270	270	280	280
	Spec. [min]	270	280	280	280	285	285	285	285
Width [mm]	EN 455-2 normative value	72 ±4	77 ±5	83 ±5	89 ±5	95 ±5	102 ±6	108 ±6	114 ±6
Thickness single wall [mm]	Middle finger [min]	0,19							
	Palm [min]	0,17							
	Cuff [min]	0,14							
Force at break [N] Minimum	Before aging EN 455-2 normative value	9,0							
	After aging EN 455-2 normative value	9,0							
Tensile Strength [Mpa] Minimum	Before aging ASTM D 3577 normative value	24							
	After aging ASTM D 3577 normative value	18							
Ultimate Elongation [%] Minimum	Before aging ASTM D 3577 normative value	750							
	After aging ASTM D 3577 normative value	560							
Stress at 500% Elongation [Mpa] Maximum	Before aging ASTM D 3577 normative value	5.5							
	After aging ASTM D 3577 normative value	NA							
Powder content [mg/glove]	EN 455-3 normative value	<2							
Latex protein content [µg/g glove]	EN 455-3 modified Lowry's assay	<50							

MANUFACTURING AND SAFETY STANDARDS

Manufacturer	Kanam Latex Industries (P) Ltd. 12/67 Ananthanadarkudy, Asaripallam P.O, Nagercoil 629 201, Kanyakumari District,Tamil Nadu, India
EC Representative	AMSTERMED B.V. Saturnusstraat 46-62 Unit 032, 2132 HB Hoofddorp The Netherlands

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Factory : 1 ✓
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9/284A, Kanyakumari Road,
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Factory : 4
Plot Number:24, AMRL HI-TECH CITY LTD,
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Tamil Nadu, India.
Ph :
E-mail : officengn@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E2Z5

Importer	Mercator Medical S.A. H. Modrzejewskiej 30 street 31-327 Cracow, Poland	
AQL	Manufacturing final release: G-I inspection level AQL 0.65 in accordance with ISO 2859-1.	
Sterilization	**Ethylene oxide (EO) / Gamma (R)**	
Classification	**Medical Device:** class IIa Rule classification acc. to declaration of conformity	**Personal Protective Equipment:** Category III (Regulation (EU) 2016/425) Type B (EN ISO 374-1)
Conformity assessment body	DNV Product Assurance AS, Notified Body No 2460 Veritasveien 3, 1363 Høvik, Norway	SGS FIMKO OY, Notified Body No 0598 Takomotie 8, 00380, Helsinki, Finland
Product compliances	EN 455-1, EN 455-2, EN 455-3, EN 455-4, EN ISO 15223-1, EN ISO 20417, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, EN ISO 11737-1, EN ISO 11737-2, EN ISO 11607-1, EN ISO 11607-2, EN ISO 14971, EN 556-1	EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN ISO 374-5, EN 16523-1, EN ISO 21420
	EO sterilization: EN ISO 11135, EN ISO 11138-2, EN ISO 10993-7	
	R sterilization: EN ISO 11137-1, EN ISO 11137-2	
Quality management standards	EN ISO 13485, ISO 9001, ISO 14001	
Viral test penetration	Test in accordance with ASTM F1671. Product complies with the requirements of EN ISO 374-5 (ISO 16604).	
Bacteria and fungi penetration	Test in accordance with EN ISO 374-5 (EN ISO 374-2).	
Chemical substances permeation test	Test in accordance with EN 16523-1.	
Biocompatibility/ biological evaluation	Test in accordance with EN ISO 10993-5. No cytotoxic evidence observed. Test in accordance with EN ISO 10993-10. No skin irritation and sensitization evidence observed.	
REACH	The product does not contain substances listed in candidate list according to Regulation (EC) 1907/2006.	

STORAGE AND DISPOSAL

Long-term storage instructions	It is recommended to store the gloves in dry place, in the temperature of 5-38°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).
Shelf life	3 years from manufacturing date
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, in accordance with local regulations. 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.

PRODUCT REFERENCES

Size / REF number

Sterilization	5.5*	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Ethylene oxide (EO)	N/A	RC10003060_0016	RC10003065_0016	RC10003070_0016	RC10003075_0016	RC10003080_0016	RC10003085_0016	RC10003090_0016
	RC10070055_0016	RC10070060_0016	RC10070065_0016	RC10070070_0016	RC10070075_0016	RC10070080_0016	RC10070085_0016	RC10070090_0016
Gamma (R)	N/A	RC10004060_0016	RC10004065_0016	RC10004070_0016	RC10004075_0016	RC10004080_0016	RC10004085_0016	RC10004090_0016
	RC10071055_0016	RC10071060_0016	RC10071065_0016	RC10071070_0016	RC10071075_0016	RC10071080_0016	RC10071085_0016	RC10071090_0016

* size available on request