KANAM LATEX INDUSTRIES PRIVATE LIMITED

Kanam 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,
Tamil Nadu, India.
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

EU DECLARATION OF CONFORMITY

Manufacturer:	Kanam Latex Industries Private Limited				
Address:	12/67C, Ananthanadarkudy, Asaripallam P.O, Nagercoil 629 201, Kanyakumari District, Tamil Nadu, India				
SRN:	IN-MF-000022741				
European Authorized Representative:	AMSTERMED B.V				
Address:	Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands				
SRN:	NL-AR-000001971				
Product description:	sterile powdered latex surgical and protective gloves, for single use				
Product name:	**comfort powdered**				
Size:	5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0				
Reference numbers:	5.5	N/A	RC11072055_0016	N/A	RC11073055_0016
	6.0	RC11001060_0016	RC11072060_0016	RC11002060_0016	RC11073060_0016
	6.5	RC11001065_0016	RC11072065_0016	RC11002065_0016	RC11073065_0016
	7.0	RC11001070_0016	RC11072070_0016	RC11002070_0016	RC11073070_0016
	7.5	RC11001075_0016	RC11072075_0016	RC11002075_0016	RC11073075_0016
	8.0	RC11001080_0016	RC11072080_0016	RC11002080_0016	RC11073080_0016
	8.5	RC11001085_0016	RC11072085_0016	RC11002085_0016	RC11073085_0016
	9.0	RC11001090_0016	RC11072090_0016	RC11002090_0016	RC11073090_0016
Basic UDI DI:	806363LSGPMQ				
Sterilization Method:	Ethylene oxide (EO) / Gamma (R)				
Intended use:	Sterile, powdered, natural latex surgical gloves, made of natural rubber latex, 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				

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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
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Factory : 2
3/13F, West Peruvilai Road, Pallavilai,
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GSTIN : 33AABCK0056E1Z6

Factory : 4
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CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E2Z5

	environments during surgical procedures. Single use.
We herewith declare under sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, all prior amendments and as transposed into national laws. All supporting documentation is retained under the premises of the manufacturer.	
Device Class (MD):	IIa (Rule 6) as per Annex VIII of Regulation (EU) 2017/745
Conformity assessment procedure (MD):	Annex IX (Chapter I and III) of Regulation (EU) 2017/745
Name of Notified Body (MD):	DNV Product Assurance AS, Notified Body No 2460 Veritasveien 1, N–1363 Høvik, Norway
CE Certificate number:	10000510232-PA-NOMA-IND
Quality system standards:	EN ISO 13485:2016
Product Compliance Standards (MD):	EN ISO 14971:2019/A11:2021, EN ISO 15223-1:2021, EN ISO 20417:2021, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN ISO 10993-1:2020, EN ISO 10993-5:2009/A11:2025, EN ISO 10993-7:2008/A1:2022 (EO sterilized gloves), EN ISO 10993-10:2023, EN 556-1:2024, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, EN ISO 11135:2014/A1:2019 (EO sterilized gloves), EN ISO 11138-2:2017 (EO sterilized gloves), EN ISO 11137-1:2015/A2:2019 (R sterilized gloves), EN ISO 11137-2:2015/A1:2023 (R sterilized gloves), EN ISO 11607-1:2020/A1:2023, EN ISO 11607-2:2020/A1:2023
We herewith declare under sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, all prior amendments and as transposed into national laws.	
Device category (PPE):	Category III as per Annex I of Regulation (EU) 2016/425
Conformity assessment procedure (PPE):	EU Type-examination (Module B), Annex V & Module D, Annex VIII of Regulation (EU) 2016/425
The above-mentioned products are subject to EU Type Examination (Module B) under Certificate 0598/PPE/23/4061 issued by the notified body SGS FIMKO OY (0598), Takomotie 8, 00380, Helsinki, Finland.	

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GSTIN : 33AABCK0056E1Z6

Factory : 3
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E-mail : officekvl@kanamlatex.com
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Tamil Nadu, India.
Ph :
E-mail : officengn@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E2Z5

The above-mentioned products are subject to the conformity assessment procedure based on quality assurance of the production process (Module D) under Certificate No. FI15/93028 under surveillance of the notified body: SGS FIMKO OY (0598), Takomotie 8, 00380, Helsinki, Finland.	
Product Compliance Standards (PPE):	EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016
Date and place of issue:	02.12.2025, Ananthanadarkudy

Signed for and on behalf of the manufacturer:

2.12.25

S.K.Donald
QA/RA Manager

KANAM LATEX INDUSTRIES (P) LTD. 12/67C, Ananthanadar Kudy, Asaripallam Post, Kanyakumari Dist. NAGERCOIL - 629 201