

Regd. & Sales Office :
Ooppotttil Buildings, K.K.Road
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Ph : 91-481-2563513, 2560108
Fax No. : 91-481-2563614
E-mail : ho@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 32AABCK0056E128

Admin. Office :
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Fax No. : 91-4652-231857
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CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E126

Factory : 1 ✓
12/67C, Ananthanadarkudy,
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Kanyakumari Dist. - 629 201,
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Ph : 91-4652-225651, 9443364301
E-mail : officeank@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E324

Factory : 2
3/13F, West Peruvilai Road, Pallavilai,
Nagercoil, Kanyakumari Dist. - 629 003,
Tamil Nadu, India.
Ph : 91-4652-227719, 9443364908
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CIN : U25199KL1974PTC002650
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Factory : 3
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Kavalkinaru, Tirunelveli Dist. - 627 105,
Tamil Nadu, India.
Ph : 9443364909
E-mail : officekvl@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E126

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 gloves, for single use
Product name:	santex powdered
Size:	6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0
Reference numbers:	(6.0) RC11050060_0016 (6.5) RC11050065_0016 (7.0) RC11050070_0016 (7.5) RC11050075_0016 (8.0) RC11050080_0016 (8.5) RC11050085_0016 (9.0) RC11050090_0016
Basic UDI DI:	806363LSGPMQ
Sterilization Method:	EO
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 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



KANAM LATEX INDUSTRIES PRIVATE LIMITED

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

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CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E1Z6

Factory : 1 ✓
12/67C, Ananthanadarkudy,
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GSTIN : 33AABCK0056E3Z4

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Factory : 3
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Ph :
E-mail : officengn@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E2Z5

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 11607-1:2020/A1:2023, EN ISO 11607-2:2020/A1:2023
Date and place of issue:	02.12.2025, Ananthanadarkudy

Signed for and on behalf of the manufacturer:


S.K. Donald
QA/RA Manager

