

Regd. & Sales Office :

Ooppoottil Buildings, K.K.Road
Kottayam District - 686 001,
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Ph : 91-481-2563513, 2560108

Fax No. : 91-481-2563614

E-mail : ho@kanamlatex.com

CIN : U25199KL1974PTC002650

GSTIN : 32AABCK0056E1Z8

Admin. Office :

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Nagercoil - 629 003, Kanyakumari District,
Tamil Nadu, India.

Ph : 91-4652-230330, 230689, 230221

Fax No. : 91-4652-231857

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CIN : U25199KL1974PTC002650

GSTIN : 33AABCK0056E1Z6

Factory : 1 ✓

12/67C, Ananthanadarkudy,
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CIN : U25199KL1974PTC002650

GSTIN : 33AABCK0056E3Z4

Factory : 2

3/13F, West Peruvilai Road,
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CIN : U25199KL1974PTC002650

GSTIN : 33AABCK0056E1Z6

Factory : 3

9/284A Kanyakumari Road,
Kavalkinaru-627 105,
Tirunelveli District, Tamil Nadu, India.

Ph : 9443364909

E-mail : officekvl@kanamlatex.com

CIN : U25199KL1974PTC002650

GSTIN : 33AABCK0056E1Z6

EC DECLARATION OF CONFORMITY**Manufacturer:**

Kanam Latex Industries Pvt. Ltd. 100% EOU
12/67C, Ananthanadarkudy, Asaripallam (PO),
Nagercoil - 629 201, Kanyakumari District,
Tamil Nadu, India

EC Representative:

Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands.

Importer:

Mercator Medical S.A.
ul. H. Modrzejewskiej 30
31-327 Kraków, Poland

Medical Device Classification:

Is
according to Rule 5 as per Annex IX of the Council Directive
93/42/EEC

Product Category:

Sterile Latex and Synthetic (Nitrile) Examination Gloves

Brand Names:	Type of Glove
PROHAND® SANTEX® STERILE	Powdered Sterile Latex Examination Gloves
PROHAND® PF NITRILE NITRYLEX® STERILE	Powder Free Sterile Synthetic (Nitrile) Examination Gloves

conforms to the applicable essential requirements of Annex I of the Council Directive 93/42/EEC and Directive 2007/47/EEC with production system and sterilization system certified through

Notified Body:

DNV GL Presafe AS (2460)
Veritasveien 3, N-1363 Høvik, Norway



KANAM LATEX INDUSTRIES PRIVATE LIMITED

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

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EC-Certificate No:

Certificate No. 10723-2017-CE-IND-NA-PS

Full Quality Assurance System

Annex II excluding section 4 (Module H2) of Council Directive
93/42/EEC on Medical Devices, as amended

Valid until : 26 May 2024

The above mentioned Sterile Latex and Synthetic (Nitrile) Examination Gloves meet the following
European standards:

EN 455-1:2000

EN 455-2:2009 + A2:2013

EN 455-3:2006

EN 455-4:2009

EN ISO 15223-1:2016

EN 1041:2008

EN ISO 13485:2016

EN ISO 14971:2012

EN 556-1:2001

EN ISO 11135:2007

Issue date: 28.05.2020

Sign on behalf of the Manufacturer:

Mr. S. K. Donald
QA Manager.



SURGICARE