DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10000307233-PA-NA-IND	PRJC-84149-2008-PRC-IND	27 May 2024

This is to certify that the quality system of:

Kanam Latex Industries Pvt. Ltd.

3/13F, West Peruvilai Road, Pallavilai, Nagercoil – 629 003
Kanyakumari District, Tamil Nadu, India

For design, production and final product inspection/testing of:
SURGICAL GLOVES-STERILE & NON-STERILE
EXAMINATION GLOVES-STERILE

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 11 December 2019

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Cathrine Wisbech

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The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	11 December 2019

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical Gloves -Latex (Regular and Long Cuff)- Sterile	**Sterile Surgical- Powdered** Surgicare, Kaltex, Surgicare Supreme, Dexmed, Kaltex EC, Surgicare E, Surgicare F, Surgicare Lowpro	IIa
	Sterile Surgical – Powder free Surgicare, Surgicare Plus, Surgicare Sensitive, Surgicare Supreme, Kaltex, Kaltex EC, Serjun, Premed Plus, Surgicare Dual	IIa
	Sterile surgical – **Powder free Polymer coated** Surgicare Premier, Surgicare Premier-G, Kaltex	IIa
	Sterile – Gynaecological - Powdered Surgicare 350 / 400 / 480mm	IIa
	Sterile – Gynaecological - Powder free Surgicare 350 / 400 / 480 mm Surgicare Plus 350 / 400 / 480mm	IIa
	Sterile – Gynaecological - Powder free Polymer coated Surgicare Premier 350 / 400 / 480mm	IIa
	Sterile Orthopaedic Surgical -Powder free Surgicare ortho	IIa
	Sterile Ophthalmic Micro Surgical -Powder free Surgicare Micro, Surgicare Neuro	IIa
	Non-Sterile surgical gloves-powdered Surgicare, Surgicare -E, Kaltex, Kaltex-E, Kaltex-EC	IIa
	Non-Sterile Surgical gloves-Powder free Surgicare	IIa
Surgical Gloves-Synthetic	**Sterile Surgical Powder Free-Neoprene**	IIa

	Surgicare Neoprene Surgicare Neoprene Soft	
	Sterile Surgical Powder Free-Polyisoprene Surgicare Isoprene	IIa
Examination Gloves-Latex (Regular & Long cuff)-Sterile	**Sterile Examination- Powdered** Kaltex 240 / 280 / 400 / 480mm	Is
	Sterile Examination- Powder free Kaltex 240 / 280 / 400 / 480mm	Is
Examination Gloves-Synthetic (Regular & Long cuff)-Sterile	**Sterile Synthetic Examination - Powder free** Kaltex Nitrile 240 / 290 / 400/ 480mm	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	**Address**
Kanam Latex Industries Pvt. Ltd.	3/13F, West Peruvilai Road, Pallavilai, Nagercoil – 629 003 Kanyakumari District Tamil Nadu, India

EU Representative
EMERGO EUROPE, Prinsessegracht 20, 2514 AP The Hague, The Netherlands

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate