EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10722-2017-CE-IND-NA-PS Rev. 0.0	**PRJC-84149-2008-PRC-IND**	**20 December 2018**

This is to certify that the quality system of:

Kanam Latex Industries Pvt. Ltd.
3/13 F, West Peruvilai-629 003,
Nagercoil, India

For design, production and final product inspection/testing of:

Sterile and Non-Sterile Surgical Gloves

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) 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, 08 August2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Ragnar Stranger Christiansen

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

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

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNV GL (NB 0434) certificate No. 45406-2009-CE-NOR-NA Rev. 3.0 following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	2017-08-08

Products covered by this Certificate:

Product Description	Product Name	Class
Latex Surgical Gloves (Regular and Long Cuff)	Sterile Surgical- Powdered Surgicare, Kaltex, Surgicare Supreme, Dexmed	IIa
	Sterile Surgical – Powder free Surgicare, Surgicare Plus, Surgicare Premier, Surgicare Sensitive, Surgicare Supreme Surgicare Premier - G	IIa
	Sterile – Gynaecological - Powdered Surgicare	IIa
	Sterile – Gynaecological - Powder free Surgicare	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	IIa

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	-Surgicare, Surgicare -E, Kaltex, Kaltex-E, Kaltex-EC	
	Non-Sterile Surgical gloves Powder free -Surgicare	IIa
Synthetic Surgical Gloves	Sterile Surgical Powder Free- Surgicare Neoprene	IIa
Latex Examination Gloves	Sterile Examination- Powdered Kaltex	Is
	Sterile Examination- Powder free Kaltex	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address	Site Scope
Kanam Latex Industries Pvt. Ltd.	3/13 F, West Peruvilai Road, Pallavilai, Nagercoil-629 003, Kanyakumari District., Tamilnadu, India	Manufacture and Marketing of Powdered / Powder free Sterile and Non-Sterile Surgical, Gynaecological & Examination Latex Gloves And Powder free Sterile and Non-Sterile Surgical, Gynaecological and Examination Synthetic Gloves.

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