EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10723-2017-CE-IND-NA-PS Rev. 0.0	**PRJC-188486-2009-PRC-IND**	**24 November 2019**

This is to certify that the quality system of:

Kanam Latex Industries Pvt. Ltd, 100% EOU
AN Kudy, Tamilnadu, India

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

Sterile and Non-Sterile Surgical Gloves and Sterile Examination 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 August 2017

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. 68085-2009-CE-IND-NA Rev. 4.0 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 Gloves	Surgical gloves Models: Biomed, Biomed Free, Bioplus Salus DM, Maboko, Comfort, Comfort PF, Danglove, Surgicare sensitive, Dermagel, DOC, Generics, IDA, Kaltex, Kaltex Plus, Kings, Master, Naturflex, Dermagel Dual, Parasel, Surgicare DH, Serjun, Sterigant +, Surgicare, Surgicare B&G, Surgicare Dual, Surgicare Lowpro, Surgicare Plus, Surgicare Plus DH, Surgicare Premier, Surgicare Supreme, DiaClassic, DiaMedical,Surgicare E,Kaltex EC, Surgicare Premier G, Comfort Powdered, Comfort Powder-Free, Dermagel Coated, Santex Powdered, Santex Powder-Free, Medimax	IIa
	Gynaecological Gloves Models: Biogyn Free, Danglove, DOC, Dona Sensitive 410, Glecoglove, Gynamed, Gynoglove, Naturflex Gine, Surgicare, Sterigant+ DiaClassic, DiaMedical, Bioplus 500, Dermagel Gyno	IIa
	Micro Surgery Gloves	IIa

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	Models : Biomed Free Micro, Biosafe Micro, Danglove Micro, DOC Micro, Microtex, Naturflex Micro, Surgicare Micro, Surgicare Neuro,DiaClassic, DiaMedical,Micro, Dermagel Micro	
	Surgical Orthopaedic gloves Models : Biosafe Ortho, Danglove Ortho, DOC Ortho, Naturflex Orto, Orthomed, Orthomed Free, Orthopeg, Surgicare Ortho, DiaClassic, DiaMedical, Dermagel Orthopedic	IIa
Synthetic Surgical Gloves	Non-latex powder free synthetic surgical gloves Models : Naturflex Neo 2.0, Naturflex Neo, Surgicare Neoprene,Surgicare Iso Prene,Superflex Poly Isoprene, Syntec Neoprene, DiaClassic, DiaMedical,Surgicare Neoprene Soft, Dermagel Neopren	IIa
Latex Examination Gloves	Sterile Examination gloves Models : Danglove, DOC, Kaltex, Naturflex, Prohand, Surgicare, DiaClassic, DiaMedical,High protection, Santex Sterile	Is
Synthetic Examination gloves	Sterile Examination gloves Models : Naturflex Nitrilo, Kaltex, DiaClassic, DiaMedical,ProHand PF Nitrile, Nitrylex Sterile	Is

The complete list of devices is filed with the Notified Body

Kanam Latex Industries Pvt. Ltd. 100% EOU

12-67C, Anandanadarkudy, Kanyakumari District- 629 201, 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