

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10723-2017-CE-IND-NA-PS Rev. 3.0

Project No.:
PRJC-188486-2009-PRC-IND

Valid Until:
26 May 2024

This is to certify that the quality system of:

KANAM LATEX INDUSTRIES PRIVATE LIMITED

12/67C, Ananthanadarkudy, Asaripallam (PO), Nagercoil -629 201, Kanyakumari District, Tamil Nadu, India

For design, production and final product inspection/testing of:
Sterile and Non-Sterile Surgical Latex Gloves, Sterile Surgical Synthetic Gloves, Sterile Examination Latex Gloves and Sterile Examination Synthetic Gloves

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, 02 June 2020



For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Eugenie Winger Husebye

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



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

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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	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).	08 August 2017
1.0	Extension in scope - new products (in bold) added	27 April 2018
2.0	Recertification Audit	18 May 2020
3.0	New Brand addition in bold	02 June 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Latex Gloves (Regular & Long Cuff)	1.Surgical Gloves Powdered Size:5.5 to 9.0 Brand: Comfort, Danglove, DOC, IDA, Kaltex, Kings, Master, Naturflex, Parasel, Surgicare DH, Serjun, Sterigant+, Surgicare B& G, Surgicare Lowpro, Surgicare E, Kaltex EC, Comfort Powdered, Santex Powdered, Medimax, Surgicare, Handsafe, Med - Comfort, Medix Lowpro, Pharco Lowpro, Solidor, Maboko, Bromed, Unicut	IIa
	2. Gynaecological Gloves (Powdered) Size: 6.0,6.5 (S),7.0,7.5 (M),8.0,8.5 (L) Brand: Dona Sensitive 410, Gynamed, Sterigant+, Surgicare,Medix Gyna 480, Kings	IIa
	3. Surgical Gloves (Powder Free) Size:5.5 to 9.0 Brand: Comfort PF, Kaltex Plus,Surgicare Plus, Surgicare Plus	IIa

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	DH, Surgicare Supreme, Comfort Powder-Free, Medibase, Bromed, IDA	
	4. Gynaecological Gloves (Powder Free) Size: 6.0,6.5 (S),7.0,7.5 (M),8.0,8.5 (L) Brand: Dermagel Gyno, DOC, Gynoglove, Naturflex Gine, Surgicare Plus, Bromed, Surgicare	IIa
	5. Surgical Gloves (Powder Free Polymer Coated) Size:5.5 to 9.0 Brand: Surgicare Sensitive, Dermagel, Dermagel Dual, DOC, Surgicare Dual, Surgicare Premier, Surgicare Premier G, Handsafe PF, HSO Crystal, Med-Comfort, Pharco Premier, Dermagel Coated, Medix Premier, Bromed Plus, Santex Powder free, Marque Conseil, Kaltex EC, Naturflex,Santex PF	IIa
	6. Gynaecological Gloves (Powder Free Polymer Coated) Size: 6.0,6.5 (S),7.0,7.5 (M),8.0,8.5 (L) Brand: Medix Premier, Surgicare Premier, Gleco glove, Naturflex Gine , Bromed, Dermagel Gyno, GynoGlove	IIa
	7. Micro Surgery Gloves (Powdered & Powder Free) Size:5.5 to 9.0 Brand: Biosafe Micro, Danglove Micro, Micro, Dermagel Micro, DOC Micro, Microtex, Surgicare Micro, Surgicare Neuro	IIa
	8. Surgical Orthopaedic Gloves (Powdered & Powder Free) Size:5.5 to 9.0 Brand: Biosafe Ortho, Danglove Ortho, Dermagel Orthopedic, DOC Ortho, Naturflex Orto, Orthopeg, Surgicare Ortho, Med-Comfort Ortho	IIa
2. Synthetic Surgical	1.Non-Latex synthetic Surgical Gloves	IIa

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<p>Gloves (Regular and Long cuff)</p>	<p>(Powder Free)- Poly chloroprene Size:5.5 to 9.0 Brand: Dermagel Neopren, Naturflex Neo,Naturflex Neo 2.0, Surgicare Neoprene, Surgicare Neoprene Soft, Syntec Neoprene, Hosp Neoprene Soft, Bromed Neoprene Soft, Sterisense green,Syntec</p>	
	<p>2. Non-Latex synthetic Surgical Gloves (Powder Free)- Poly Isoprene Size:5.5 to 9.0 Brand: Surgicare Isoprene, Superflex Poly Isoprene</p>	<p>IIa</p>
<p>3. Latex Examination Gloves (Regular and Long cuff)</p>	<p>1. Sterile Examination Gloves (Powdered) Size: XS, S, M, L & XL Brand: DOC, Santex Sterile, Prohand, Naturflex,Kaltex, Team Power, Surgicare</p>	<p>Is</p>
	<p>2. Sterile Examination Gloves (Powder Free) Size: XS, S, M, L & XL Brand: Danglove, High Protection, Kaltex, Naturflex, HSO Polytex, Surgicare</p>	<p>Is</p>
<p>4.Synthetic Examination Gloves (Regular and Long cuff)</p>	<p>1. Sterile Nitrile Examination Gloves (Powder Free) Size: XS, S, M, L & XL Brand: Kaltex, Naturflex Nitrilo, Nitrylex Sterile, Prohand PF Nitrile, Hosp Nitrile</p>	<p>Is</p>

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
<p>KANAM LATEX INDUSTRIES PRIVATE LIMITED</p>	<p>12/67C, Ananthanadarkudy , Asaripallam (PO), Nagercoil -629 201, Kanyakumari District, Tamil Nadu, India.</p>

EU Representative

EMERGO EUROPE, Prinsessegracht 20,2514 AP, The Hague, The Netherlands Tel: (+31) 70 345 8570; Fax: (+31) 70 346 7299 mail: europe@emergogroup.com

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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