

DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 68085-2009-CE-IND-NA 2.0 This Certificate consists of 4 pages

This is to certify that the Quality Management System of

Kanam Latex Industries Pvt. Ltd, 100% EOU

AN Kudy, Tamil Nadu, 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 11.5 and Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 08 December 2014

For DET NORSKE VERITAS CERTIFICATION AS



This Certificate is valid until:

24 November 2019

NORWAY

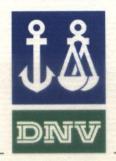
Aud Løken Eiklid

Certification Manager

Notified Body No .: 0434

Cecilie Gudesen Torp Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info



Cert. No.: 68085-2009-CE-IND-NA

Rev. No.: 2.0

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

Jurisdiction

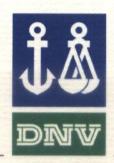
Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date	
	Original certificate No.2103-2007-CE-NOR	2004-11-24	
	Recertification	2009-11-24	
1.0	Revised with corrected brand names	2010-04-06	
2.0	Recertification	2014-11-24	

Products covered by this Certificate

Product Description	Product name	Class
	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	
Latex Gloves	Gynaecological Gloves Models: Biogyn Free, Danglove, DOC, Dona Sensitive 410, Gleçoglove, Gynamed, Gynoglove, Naturflex Gine, Surgicare, Sterigant+ DiaClassic, DiaMedical, Bioplus 500	IIa
	Micro Surgery Gloves	
	Models: Biomed Free Micro, Biosafe Micro, Danglove Micro, DOC Micro, Microtex, Naturflex Micro, Surgicare Micro, Surgicare Neuro, DiaClassic, DiaMedical	
	Surgical Orthopaedic gloves	
	Models: Biosafe Ortho, Danglove Ortho, DOC Ortho, Naturflex Orto, Orthomea, Orthomed Free, Orthopeg, Surgicare Ortho, DiaClassic, DiaMedical	



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Product Description	Product name	Class
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	IIa ,
Latex Examination Gloves	Sterile Examination gloves Models: Danglove, DOC, Kaltex, Naturflex, Prohand, Surgicare, DiaClassic, DiaMedical, High protection	Is
Synthetic Examination gloves	Sterile Examination gloves Models: Naturflex Nitrilo, Kaltex, DiaClassic, DiaMedical, ProHand PF Nitrile	Is

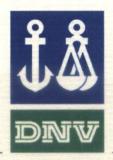
The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Site Name	Address	
Kanam Latex Industries Pvt. Ltd. 100% EOU	12-67C, Anandanadarkudy, Kanyakumari District- 629 201, Tamil Nadu, India	

EU Representative:

Emergo Europe, Molenstraat 15, 2513.BH. 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 the local DNV Office of any intended updating of the quality system and DNV 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 DNV
 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 DNV.

END OF CERTIFICATE