



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
NORWAY



This Certificate is valid until:

24 November 2019

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

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300,000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



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 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 |
|---------------------|---|-------|
| 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 | IIa |
| | Gynaecological Gloves Models: Biogyn Free, Danglove, DOC, Dona Sensitive 410, Gleçoglove, Gynamed, Gynoglove, Naturflex Gine, Surgicare, Sterigant+ DiaClassic, DiaMedical, Bioplus 500 | |
| | 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



DNV

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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