

# EU Quality Management System Certificate

Certificate no.:  
10000510232-PA-NOMA-IND

Initial certification date:  
24 January 2025

Valid Until:  
23 January 2030

This is to certify that the quality system of

## **KANAM LATEX INDUSTRIES PRIVATE LIMITED**

12/67C, Ananthanadarkudy,  
Asaripallam P.O., Nagercoil 629201,  
Kanyakumari District,  
Tamil Nadu, India  
SRN: (IN-MF-000022741)

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

**Sterile Latex Examination Gloves Powdered, Sterile Latex Examination Gloves Powder free, Sterile Synthetic Nitrile Examination Gloves Powder free**

Has been assessed and found to comply with respect to:

**The conformity assessment procedure described in Annex IX,  
(Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices**

Place and date:  
Høvik, 28 January 2025



For the issuing office:  
**DNV Product Assurance AS – Notified Body 2460**  
Veritasveien 1, 1363 Høvik, Norway

**Tone Kolpus**  
Management Representative

## Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forordning (EU) 2017/745 om medisinsk utstyr (MDR)” by the Norwegian Ministry of Health and Care Services.

## Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2622133	24 January 2025
1.0	<b>Correction in Scope</b>	2622133	28 January 2025

## Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
Sterile Latex Examination Gloves Powdered	<b>Regular Cuff</b> Size : XS, S, M, L & XL Length: 240 mm & 280 mm Brand: Kaltex Surgicare, DOC, Juski, Prohand, Naturflex, Santex Sterile, Team Power <b>Long Cuff</b> Size : XS, S, M, L & XL Length: 400 mm, 450 mm, 480 mm Brand: Kaltex	Is
Sterile Latex Examination Gloves Powder free	<b>Regular Cuff</b> Size : XS, S, M, L & XL Length: 240 mm & 280 mm Brand: Kaltex, Surgicare. Danglove, High Protection, HSO Polytex, Juski, Naturflex, Nobaglove <b>Long Cuff</b> Size : XS, S, M, L & XL Length: 400 mm, 450 mm, 480 mm Brand: Kaltex	Is
Sterile Synthetic Nitrile Examination Gloves Powder free	<b>Regular Cuff</b> Size : XS, S, M, L & XL Length: 240 mm & 280 mm Brand: Kaltex, Kaltex Nitrile Hosp Nitrile, Naturflex, Nitrylex Sterile, Prohand PF Nitrile. <b>Long Cuff</b> Size : XS, S, M, L & XL Length: 400 mm, 450 mm, 480 mm Brand: Kaltex, Kaltex Nitrile.	Is

\* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: NA

The complete list of devices is filed with the Notified Body



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### Sites covered by this certificate

Site Name	Address
KANAM LATEX INDUSTRIES PRIVATE LIMITED	12/67C, Ananthanadarkudy, Asaripallam P.O., Nagercoil 629201, Kanyakumari District, Tamil Nadu, India

### EU Representative

AMSTERMED B.V., Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands



## 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 Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices and IIb devices falling under Article 52 (4) covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

## Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.