EU Quality Management System Certificate

Certificate no.:	Initial certification date:	Valid Until:
10000510232-PA-NOMA-IND	24 January 2025	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 Surgical Gloves Powdered, Sterile Latex Surgical Gloves Powder Free, Sterile Synthetic Surgical Gloves Powder Free-Poly Chloroprene, Sterile Synthetic Surgical Gloves Powder Free-Poly Isoprene, Sterile Latex Medical Examination Gloves Powdered, Sterile Latex Medical Examination Gloves Powder Free & Sterile Synthetic Medical Examination Gloves Powder Free-Nitrile.

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, 16 November 2025

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

Palani Damodharan
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

Jurisdiction

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices 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	Correction in Scope	2622133	28 January 2025
2.0	**Class IIa product added**	**2622129**	**16 November 2025**

Products covered by this Certificate:

Product Description	Product Name	Class*
Sterile Latex Surgical Gloves Powdered	**Regular Cuff** **Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0** **Minimum Length (mm): 5.5: 270 mm / 6.0 - 7.0: 280 mm / 7.5 - 9.0: 285 mm.** **Brand: Dexmed, Kaltex, Kaltex EC, Serjun, Surgicare, Surgicare Lowpro, Surgicare E, Surgicare F, Surgicare Style 41, Surgicare Supreme, Bromed, Comfort, Comfort Powdered, Danglove, DOC, Dona Sensitive, EPIC, Handsafe, IDA, IMS, Juski, Kings, Maboko, Master, Med-Comfort, Medix Lowpro, Medimax, Mumu, Naturflex, No.1 Glove, Parasel, Pharco Lowpro, Santex Powdered, Solidor, Sterigant+, Surgicare B & G, Surgicare DH, Tro-Sensosurge, Unicut.** **Long Cuff- Gynaecological Gloves** **Size: 6.0, 6.5 (S), 7.0, 7.5 (M), 8.0, 8.5 (L)** **Length (mm): 350, 400 & 480** **Brand: Dona Sensitive 410, EPIC, Gynamed, Juski, Medix Gyna 480, Mission Pharma, Kings, Sterigant+, Tro-Gynosurge, Surgicare**	**IIa**
Sterile Latex Surgical Gloves **Powder free**	**Sterile Latex Surgical Gloves Powder free** **Regular Cuff** **Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0** **Minimum Length (mm):** **5.5: 270 mm / 6.0 - 7.0: 280 mm / 7.5 - 9.0: 285 mm.** **Brand: Kaltex, Kaltex EC, Kaltex Plus, Serjun, Surgicare, Surgicare Dual,**	**IIa**

	Surgicare Plus, Surgicare Sensitive, Surgicare Supreme, Surgicare Underglove.Bromed, Comfort PF, Comfort Powder-Free, IDA, Medibase, Nobafeel, Surgicare Plus DH. **Long Cuff – Gynaecological Gloves** **Size: 6.0, 6.5 (S), 7.0, 7.5 (M), 8.0, 8.5 (L)** **Length (mm): 350, 400 & 480** **Brand: Surgicare, Surgicare Plus Bromed, Dermagel Gyno, DOC, Gynoglove, Naturflex Gine**	
Sterile Latex Surgical Gloves **Powder free**	**Sterile Latex Surgical Gloves Powder free Polymer Coated** **Regular Cuff** **Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0** **Minimum Length (mm): 5.5: 270 mm / 6.0 - 7.0: 280 mm / 7.5 - 9.0: 285 mm.** **Brand: Kaltex, Kaltex EC, Kaltex Plus, Premed Plus, Proglv Latex, Serjun, Surgicare, Surgicare Dual, Surgicare Dual Premium, Surgicare Premier,** **Surgicare Premier G, Surgicare Premier Plus, Surgicare Style 41 PF, Surgicare Sensitive, Surgicare Underglove.** **Bromed Plus, Dermagel, Dermagel Coated, Dermagel Dual, DOC, Dona Sensi plus, EPIC, Handsafe PF, HSO** **Crystal, IDA, IMS, Juski, Marque Conseil, Med- Comfort, Medibase, Medix Premier, Mumu, Naturflex, Nobafeel, Pharco Premier, Santex PF, Santex Powder Free, Tro-Sensosurge Plus.** **Long Cuff – Gynaecological Gloves** **Size: 6.0, 6.5 (S), 7.0, 7.5 (M), 8.0, 8.5 (L)** **Length (mm): 350, 400, 480** **Brand: Surgicare Premier, Bromed, Dermagel Gyno, EPIC, Gleco glove, Gynoglove, Juski,Medix Premier,** **Naturflex Gine, Nobafeel Gyn, Tro-Gynosurge Plus.**	**IIa**
Sterile Latex Surgical Surgical Gloves **Powder free**	**Sterile Latex Surgical Surgical Gloves** **Powder free Polymer Coated (Micro/Neuro)** **Regular Cuff** **Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0** **Minimum Length (mm): 5.5: 270 mm / 6.0 - 7.0: 280 mm / 7.5 - 9.0:**	**IIa**

	285 mm. **Brand: Surgicare Micro, Surgicare Neuro, Biosafe Micro, Danglove Micro, Dermagel Micro, DOC Micro, Microtex, Nobafeel Sensitive.**	
Sterile Latex Surgical Gloves **Powder free**	**Sterile Latex Surgical Gloves** **Powder free Polymer Coated-(Orthopaedic)** **Regular Cuff** **Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0** **Minimum Length (mm):** **5.5: 270 mm / 6.0 - 7.0: 280 mm / 7.5 - 9.0: 285 mm.** **Brand: Surgicare Ortho, Surgicare Ortho Style 41 PF. Biosafe Ortho, Danglove Ortho, Dermagel Orthopedic,** **DOC Ortho, EPIC, Med-Comfort Ortho, Naturflex Orto, Orthopeg, Tro-Orthosurge**	**IIa**
Sterile Synthetic Surgical Gloves Powder free- Poly Chloroprene	**Regular Cuff** **Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0** **Minimum Length (mm):** **5.5 - 9.0: 290 mm.** **Brand: Surgicare Dual, Surgicare Neoprene, Surgicare Neoprene Soft.** **Bromed Neoprene Soft, Dermagel Neopren, Hosp Neoprene soft, Naturflex Neo, Naturflex Neo 2.0, Nobafeel Syntex, Sterisense green, Syntec Neoprene, Syntec**	**IIa**
Sterile Synthetic Surgical Gloves Powder free- Poly Isoprene	**Regular Cuff** **Size: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0** **Minimum Length (mm):** **5.5 - 9.0: 290 mm.** **Brand: Surgicare Isoprene, Surgicare Dual, Superflex, Nobafeel Supreme.**	**IIa**
Sterile Latex Medical Examination Gloves Powdered	**Regular Cuff** Size: XS, S, M, L & XL Length (mm): 240, 280 Brand: Kaltex, Surgicare, DOC, Juski, Prohand, Naturflex, Santex Sterile, Team Power **Long Cuff** Size: XS, S, M, L & XL Length (mm): 400, 450, 480 Brand: Kaltex	Is

Sterile Latex Medical Examination Gloves Powder free	**Regular Cuff** Size: XS, S, M, L & XL Length (mm): 240, 280 Brand: Kaltex, Surgicare. Danglove, High Protection, HSO Polytex, Juski, Naturflex, Nobaglove **Long Cuff** Size: XS, S, M, L & XL Length (mm): 400, 450, 480 Brand: Kaltex	Is
Sterile Synthetic Medical Examination Gloves Powder free-Nitrile	**Regular Cuff** Size: XS, S, M, L & XL Length (mm): 240, 280 Brand: Kaltex, Kaltex Nitrile, Hosp Nitrile, Naturflex, Nitrylex Sterile, Prohand PF Nitrile. **Long Cuff** Size: XS, S, M, L & XL Length (mm): 400, 450, 480 Brand: Kaltex, Kaltex Nitrile.	Is

The complete list of devices is filed with the Notified Body

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.