

EU TYPE-EXAMINATION CERTIFICATE Regulation (EU) 2016/425, MODULE B 0598/PPE/25/2771 Issue 1

Product Protective gloves against dangerous chemicals and micro-organisms

Model Powder Free Latex Surgical Gloves for Orthopaedic Use (Sterile & Non-Sterile)

Trademark Surgicare Ortho, Orthopeg, Dermagel Orthopedic, Med-Comfort, Naturflex Orto

Certificate Holder / Manufacturer

Kanam Latex Industries Private Limited

12/67 C, Ananthanadarkudy, Asaripallam P.O, Nagercoil – 629 201, Kanyakumari

District, Tamil Nadu, India

Product complies with the applicable essential health and safety requirements of

Regulation (EU) 2016/425 and standard(s) mentioned below

Standard(s) EN ISO 374-1:2016+A1:2018 (Protective gloves against dangerous chemicals and

micro-organisms) Type B glove against reagents: K, M, O, P & T;

EN ISO 374-5:2016 (Protective gloves against dangerous chemicals and microorganisms) gloves protecting against bacteria and fungi (EN 374-2:2019 inspection

level 3 (AQL < 0.65 G1), and virus (ISO 16604));

EN ISO 21420:2020 (Protective gloves - General Requirements).

Other Information This certificate shall be used in conjunction with conformity assessment procedure

module C2 or D.

Validity This certificate is valid until 2030-03-14.

Date of issue 2025-03-14

SGS Fimko Oy

Signature

Kaup

Kelvin Shepherd

SGS Fimko Oy is a Notified Body (0598) according to the Personal Protective Equipment Regulation (EU)

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Additional information

Powder Free Latex Surgical Gloves for Orthopaedic Use (Sterile & Non-Sterile), brown natural rubber latex gloves, anatomic with thumb ball effect shape, beaded cuff, micro rough textured (palm/finger) external surface, polymer coated, chlorinated and siliconized internal surface, single use, available in eight nominal hand sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0.

Sold under brand names: Surgicare Ortho, Orthopeg, Dermagel Orthopedic, Med-Comfort, Naturflex Orto.

Contract No: INP-CERT250100004-01/GB-202410007358.

Technical File: TCF/PPE/LOG-PF, Issue 2.0, Rev 07, Dated: 25/02/2025.



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