

# 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 micro-organisms) 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).

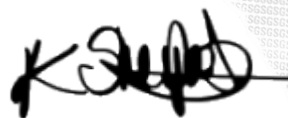
**Other Information** This certificate shall be used in conjunction with conformity assessment procedure module C2 or D.

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

**Date of issue** 2025-03-14

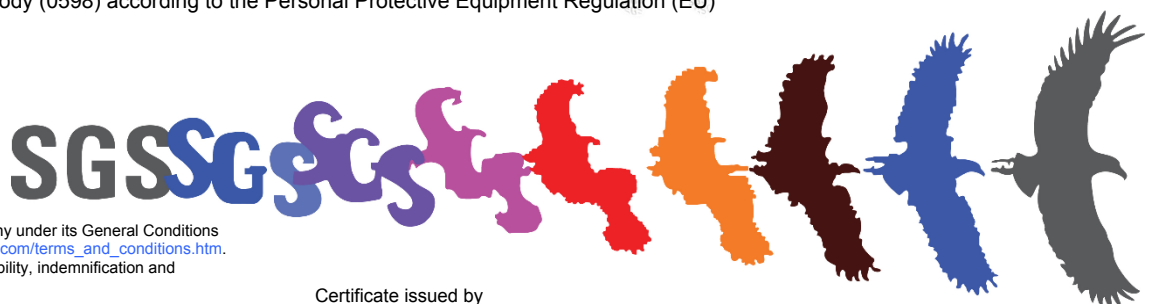
**SGS Fimko Oy**

**Signature**



Kelvin Shepherd

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



**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.