

EU TYPE-EXAMINATION CERTIFICATE Regulation (EU) 2016/425, MODULE B 0598/PPE/25/2385 Issue 1

Product Protective gloves against dangerous chemicals and micro-organisms

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

Trademark Surgicare, Surgicare Plus

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, L, M & P;

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

level 2 (AQL <1.5 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 2030-02-13.

Date of issue 2025-02-13

SGS Fimko Oy

Signature

Kaup

Kelvin Shepherd

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

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Certificate issued by

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Additional information

Powder Free Latex Surgical Gloves for Gynaecological Use (Sterile & Non-Sterile), creamy white natural rubber latex glove, anatomically shaped, beaded cuff, chlorinated external surface and internal surface, single use, which are available in two nominal lengths: 400mm & 480mm, in three nominal hand sizes: 6.5 (S), 7.5 (M), & 8.5 (L).

Sold under brand names: Surgicare, Surgicare Plus.

Contract No: INP-CERT250100003-01/GB-202411007475.

Technical File: TCF/PPE/LGG-PF, Issue 02, Rev 06, Dated: 11.11.2024.



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