

EU TYPE-EXAMINATION CERTIFICATE Regulation (EU) 2016/425, MODULE B 0598/PPE/25/2138 Issue 1

Product Protective gloves against dangerous chemicals and micro-organisms

Model Powder Free Synthetic Polyisoprene Surgical Gloves (Sterile & Non-Sterile)

Trademark Surgicare Isoprene, Superflex, Surgicare Dual

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, 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 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 2030-01-20.

Date of issue 2025-01-20

SGS Fimko Oy

Signature

Kall

Kelvin Shepherd

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

Page 1 of 2

This document is issued by the Company under its General Condition of Service accessible at http://www.sgs.com/erms and conerrors. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Certificate issued by

SGS Fimko Oy

Takomotie 8 FI-00380 Helsinki, Finland

t. +358 9 696 361 www.sgs.com Business ID 0634247-4 Member of the SGS Group (SGS SA)





Page 2 of 2 to Certificate: 0598/PPE/25/2138 Issue 1 page 2

Additional information

Powder free synthetic polyisoprene surgical gloves (sterile & non-sterile), white synthetic rubber latex (polyisoprene) glove, anatomically shaped, beaded cuff, textured external surface, polymer coated internal surface, single use, which are 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 Isoprene, Superflex, Surgicare Dual.

Contract No: INP-CERT241200196-01/GB-202410007407.

Technical File: TCF/PPE/SIG-PF, Issue 01, Rev 00, Dated: 25.11.2024.



Page 2 of 2

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Certificate issued by

SGS Fimko Oy

Takomotie 8 FI-00380 Helsinki, Finland t. +358 9 696 361 www.sgs.com

Business ID 0634247-4 Member of the SGS Group (SGS SA)