



# KANAM LATEX INDUSTRIES PRIVATE LIMITED

ISO 9001 : 2015, EN ISO 13485 : 2016 & ISO 14001 : 2015 Certified Company

**Regd. & Sales Office :**

Oppoottill Buildings, K.K.Road  
Kottayam District - 686 001,  
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E-mail : ho@kanamlatex.com  
CIN : U25199KL1974PTC002650  
GSTIN : 32AABCK0056E128

**Admin. Office :**

13/1-423, M.S. Road, Parvathipuram,  
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GSTIN : 33AABCK0056E126

**Factory : 1 ✓**

12/67C, Ananthanadarkudy,  
Asaripallam P.O, Nagercoil - 629 201,  
Kanyakumari District, Tamil Nadu, India.  
Ph : 91-4652-225651, 229234, 225122  
E-mail : officeank@kanamlatex.com  
CIN : U25199KL1974PTC002650  
GSTIN : 33AABCK0056E324

**Factory : 2**

3/13F, West Peruvilai Road,  
Paliavilai, Nagercoil- 629 003,  
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Ph : 04652-227719, 229727  
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CIN : U25199KL1974PTC002650  
GSTIN : 33AABCK0056E126

**Factory : 3**

9/284A Kanyakumari Road,  
Kavalkinaru-627 105,  
Tirunelveli District, Tamil Nadu, India.  
Ph : 9443364909  
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CIN : U25199KL1974PTC002650  
GSTIN : 33AABCK0056E126

## DECLARATION OF CONFORMITY

Date : 02.06.2020

Manufacturer : Kanam Latex Industries (P) Ltd

Address : 12/67C, Ananthanadarkudy,  
Asaripallam P.O, Nagercoil 629 201,  
Kanyakumari District, Tamil Nadu, India

Product description : **STERILE POWDER FREE POLYMER COATED  
GYNAECOLOGICAL LATEX SURGICAL GLOVES**

Product Name : DERMAGEL GYNO

Size : 6.5 (S), 7.5 (M) & 8.5 (L)

Lot size : -

Device Class : II a (Rule 6) as per Annex IX of MDD 93/42/EEC

Sterilization Method : Gamma

**We herewith declare under sole responsibility that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC, all prior amendments and as transposed into national laws. All supporting documentation is retained under the premises of the manufacturer.**

Name of Notified Body : DNV Product Assurance AS  
Veritasveien 3, N-1363 HØvik, Norway

EC REP Address : EMERGO EUROPE  
Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

Notified Body No : 2460

CE Certificate No. : 10723-2017-CE-IND-NA-PS Rev.3.0

MDD Annex applied : Annex II excluding Section 4

Quality system standards : EN ISO 13485:2016/A11:2021

Product Compliance Standards : EN ISO 14971:2019, EN ISO 15223-1:2016, EN 1041:2008+A1:2013,  
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009,  
EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013,  
EN 556-1:2001 | AC:2006, EN ISO 11737-1:2018, EN ISO 11737-2:2020,  
EN ISO 11137-1:2015/A2:2019, EN ISO 11137-2:2015

Approved By

RA / QA Manager  
S.K. Donald