

**Regd. & Sales Office :**

Ooppoottil Buildings, K.K.Road  
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CIN : U25199KL1974PTC002650  
GSTIN : 32AABCK0056E1Z8

**Admin. Office :**

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CIN : U25199KL1974PTC002650  
GSTIN : 33AABCK0056E1Z6

**Factory : 1 ✓**

12/67C, Ananthanadarkudy,  
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CIN : U25199KL1974PTC002650  
GSTIN : 33AABCK0056E3Z4

**Factory : 2**

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CIN : U25199KL1974PTC002650  
GSTIN : 33AABCK0056E1Z6

**Factory : 3**

9/284A Kanyakumari Road,  
Kavalkinaru-627 105,  
Tirunelveli District, Tamil Nadu, India.  
Ph : 9443364909  
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CIN : U25199KL1974PTC002650  
GSTIN : 33AABCK0056E1Z6

## DECLARATION OF CONFORMITY

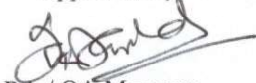
Date : 02.06.2020

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 DOUBLE LATEX SURGICAL  
WITH PUNCTURE IDENTIFICATION SYSTEM**  
Product Name : DERMAGEL DUAL  
Size : 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0  
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