

Regd. & Sales Office :

Ooppoottil Buildings, K.K.Road
Kottayam District - 686 001,
Kerala, India.
Ph : 91-481-2563513, 2560108
Fax No. : 91-481-2563614
E-mail : ho@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 32AABCK0056E1Z8

Admin. Office :

13/1-423, M.S. Road, Parvathipuram,
Nagercoil - 629 003, Kanyakumari District,
Tamil Nadu, India.
Ph : 91-4652-230330, 230689, 230221
Fax No. : 91-4652-231857
E-mail : officeadmin@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E1Z6

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 : 33AABCK0056E3Z4

Factory : 2

3/13F, West Peruvilai Road,
Pallavilai, Nagercoil - 629 003,
Kanyakumari District, Tamil Nadu, India.
Ph : 04652-227719, 229727
E-mail : officepvl@kanamlatex.com
CIN : U25199KL1974PTC002650
GSTIN : 33AABCK0056E1Z6

Factory : 3

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

DECLARATION OF CONFORMITY

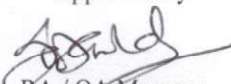
Date : 02.06.2020

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 POLYMER COATED MICRO
SURGERY GLOVES**
Product Name : **DERMAGEL MICRO**
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