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CIN : U25199KL1974PTC002650

GSTIN : 32AABCK0056E128

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CIN : U25199KL1974PTC002650

GSTIN : 33AABCK0056E126

Factory : 1 ✓

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GSTIN : 33AABCK0056E324

Factory : 2

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CIN : U25199KL1974PTC002650

GSTIN : 33AABCK0056E126

Factory : 3

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CIN : U25199KL1974PTC002650

GSTIN : 33AABCK0056E126

DECLARATION OF CONFORMITY

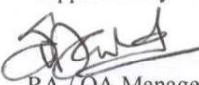
Date : 02.06.2020

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 NON-LATEX SYNTHETIC
POLYCHLOROPRENE SURGICAL GLOVES**
Product Name : DERMAGEL NEOPREN
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