



KANAM LATEX INDUSTRIES PRIVATE LIMITED

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

Regd. & Sales Office :

Ooppoottil Buildings, K.K.Road
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Kerala, India.
Ph : 91-481-2563513, 2560108
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CIN : U25199KL1974PTC002650
GSTIN : 32AABCK0056E1Z8

Admin. Office :

13/1-423, M.S. Road, Parvathipuram,
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Factory : 1 ✓

12/67C, Ananthanadarkudy,
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Factory : 2

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GSTIN : 33AABCK0056E1Z6

Factory : 3

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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 LATEX SURGICAL GLOVES**
Product Name : COMFORT POWDER FREE
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 : EO / 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
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 10993-7:2008 (EO sterilized gloves), EN ISO 10993-10:2013,
EN 556-1:2001 | AC:2006, EN ISO 11737-1:2018, EN ISO 11737-2:2020,
EN ISO 11135:2014/ A1:2019 (EO sterilized gloves),
EN ISO 11138-2:2017 (EO sterilized gloves)
EN ISO 11137-1:2015/ A2:2019 (Gamma sterilized gloves),
EN ISO 11137-2:2015 (Gamma sterilized gloves),

Approved By

RA / QA Manager
S.K. Donald