




Manufacturer : Kanam Latex Industries (P) Ltd
Address : 12/67C, Ananthanadarkudy,
Asaripallam P.O, Nagercoil 629 201,
Kanyakumari District, Tamil Nadu, India
Product Description : **LATEX GLOVES**
Product Name : **GYNAECOLOGICAL GLOVES (POWDERED)**
Model : DONA SENSITIVE
Size & Batch No. : 6.5 - 20 10 237 A4 65, 7.5 - 20 10 237 A4 75 & 8.5 - 20 10 237 A4 85
Lot size : 5,000 Prs.
Device Class : II a (Rule 6) as per Annex IX of MDD 93/42/EEC
Sterilization Method : EO

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 GL PRESAFE 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. : I0723-2017-CE-IND-NA-PS Rev.3.0
MDD Annex applied : Annex II excluding Section 4
Quality system standards : **ISO 13485 : 2016**
Harmonized Standards : EN ISO 14971:2012, EN 455-1:2000, EN 455-2:2009+A2:2013,
EN 455-3:2006, EN 455-4:2009, EN ISO 11135-1:2014
Non - Harmonized Standards : ASTM D 3577 - 09 (2015), ISO 2859-1:1999, ISO 10282 : 2014.
Guidelines : MEDDEV 2.5/9 Rev.1, MEDDEV 2.4.1:2010 (Rev9),
MEDDEV 2.7.1:2016 (Rev4), MEDDEV 2.12-1:2013 (Rev8),
NB-MED-2_12-1_rev11.

Approved By

29.10.2020
RA / QA Manager
S.K. Donald