



Date: 02.09.2025

Manufacturer : Kanam Latex Industries (P) Ltd
Address : 12/67C, Ananthanadarkudy,
Asaripallam P.O, Nagercoil 629 201,
Kanyakumari District, Tamil Nadu, India
Product Description : **SYNTHETIC EXAMINATION GLOVES**
Product Name : NON-LATEX SYNTHETIC EXAMINATION GLOVES (POWDER FREE)
Model : Naturflex
Size & Batch No. : X-Small, Small, Medium, Large & X-Large
Lot size : -
Device Class : Is (Rule 5) as per Regulation (EU) 2017/745
Basic UDI-DI : 806363SNGFMU
Manufacturer's SRN : IN-MF-000022741
Authorized Representative's SRN : NL-AR-000001971
Sterilization Method : EO

We herewith declare under sole responsibility that the above-mentioned products meet the Regulation (EU) 2017/745, 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 1, N-1363 Høvik, Norway
EC REP Address : **Amstermed B.V.**
Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands
Notified Body No : 2460
CE Certificate No. : 10000510232-PA-NOMA-IND
MDR Annex applied : Annex IX, (Chapter I & III) of Regulation (EU) 2017/745
Quality system standards : **ISO 13485 : 2016**
Harmonized Standards : EN ISO 14971:2019/A11:2021, EN 455-1:2020+A2:2024, EN 455-2:2024,
EN 455-3:2023, EN 455-4:2009, EN ISO 11135:2014/A1:2019.
Non - Harmonized Standards : ASTM D 3577: 2019, ISO 2859-1:1999, ISO 10282: 2023.
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

2.9.25
RA / QA Manager

S.K. Donald