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29 November 2022

NITRILE GLOVES MEDICAL GRADE DECLARATION

In relation to the following products:

- iKON Nitrile gloves blue color long cuff, M5.8g, length 300mm

PRODUCT CODE	PRODUCT DESCRIPTION
IKGLVXLNITLC	IKON NITRILE GLOVE L/CUFF 1XL 100P/1000C
IKGLVLNITLC	IKON NITRILE GLOVE L/CUFF LRG 100P/1000C
IKGLVMNITLC	IKON NITRILE GLOVE L/CUFF MED 100P/1000C
IKGLVSNITLC	IKON NITRILE GLOVE L/CUFF SML 100P/1000C

We hereby confirm that the above mentioned products supplied by DUNNINGHAMS are FDA approved and comply with the following regulation:

Trade/Device Name: Nitrile Examination Gloves (Blue, Violet)
Device Classification Name: polymer patient examination glove

Indications for Use: The Nitrile Examination Gloves is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Review Panel: General Hospital
Decision Date: 11/01/2021

VALIDITY DATE: This declaration is valid until the next relevant legislative and/or regulatory change.