

S002 GUANTES NITRILO SIN POLVO AZUL/1623



100 % NITRILO SIN LATEX,
SIN POLVO



TALLAS M, L, XL



Azul
Blue



4,5 gr

Certificado CE de conformidad
(Indonesia, ver adjuntada imagen)

Certificado SGS en chino
(para poder declarar en aduana china)



EU Declaration of Conformity
According to Medical Device Directive 93/42/EEC
As amended by Council Directive MDD 2007/47/EEC
For the following Equipment.

Product : Disposable Nitrile Examination Gloves (Non-Sterile) Class I

Powder Free Type

ECRI No. : 11882 (base on ECRI Universal Medical Device Nomenclature System)

is herewith confirmed to comply with the requirements set out in the Council Directive 93/42/EEC on the Approximation of the Laws of the Member States relating to Medical Device Directives. For the evaluation of the compliance with this Directive, the following standards were applied:

Standard	Title	Edition/date
EN 455-1	Medical Gloves for single use: Requirements and testing for freedom from holes	2000
EN 455-2	Medical Gloves for single use: Requirements and testing for physical properties	2009+A2 2013
EN 455-3	Medical Gloves for single use: Requirements and testing for biological evaluation	2006
EN 455-4	Medical Gloves for single use: Requirements and testing for shelf life determination	2009
ISO 2859-1	Sampling procedures for inspection by attributes – Part 1: sampling plans indexed by acceptable quality level (AQL) for lot by lot inspection	1993
ASTM D-6319	Standard Specification for Nitrile Examination Gloves for Medical Application	2015 (10)

Responsible for making this declaration is the:

(x) Manufacturer () Authorized representative established within the EU

Authorized representative established within the EU (if applicable):

Company name : ---
Address : ---

Person responsible for making this declaration

Name : Trivic
Position : Marketing Manager
Manufacturer's Name : PT. UNIVERSAL GLOVES
Jln. Pertahanan No.17, Patumbak – 20361
Deli Serdang – Sumatera Utara, Indonesia
(T) 62-61-7883055 – (F) 62-61-7883411

January 07, 2019

PT. UNIVERSAL GLOVES



Caducidad: 3 años desde agosto 2019

Temperatura Almacenaje: conservar en lugares de humedad <80%,
y temperatura < 40grados, con buena ventilación

Unidades de Venta: cada embalaje contiene 10 cajas

Envasado: 100 guantes en cada caja

Textil Manly, s.a.

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