

MEXPO INTERNATIONAL INC.

2828 Faber Street
Union City, CA 94587-1204

**Declaration of Conformity
Nitrile Examination Gloves**

PRODUCT DESCRIPTION

1. Product Name: Nitrile Examination Gloves
Product Classification: Class I under Medical Device Regulations (EU) 2017/745 Annex VIII Rule 1

ADDRESS:

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Paseo de Recoletos, 37-41
28004 Madrid, Spain

We, **Mexpo International, Inc.** as the legal manufacturer declare under our sole responsibility that the medical devices listed below conform to the requirement of the medical device regulations (EU) 2017/745.

Nitrile Examination Gloves

- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – COATS
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – WITH ALOE VERA
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – BLUE COLOR
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – AVOCADO GREEN COLOR
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – SOFT BLUE COLOR
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – PINK COLOR
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – LILA COLOR
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – WHITE COLOR
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – RED COLOR
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – DARK BLUE COLOR (100 PCS/ 200PCS)
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – BLACK COLOR
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – EZ-DON (MIRACLE BLUE COLOR- 100PCS/ 200PCS)
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – EZ-DON (COBALT BLUE COLOR- 100PCS/200PCS)
- BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – BLUE LITE COLOR(100 PCS/ 200 PCS)

Basic UDI-DI: 72386056286SD

UDI Numbers: Attachment A

It is declared that above devices meet the requirement of the Medical Device Regulation EU/2017/745.

The undersigned, hereby declare that the disposable device(s) specified above are following the EU Type Examination and conformity with the provisions of the new PPE Regulations (EU) 2016/425- Cat III and, where such is the case, with the national standard transposing harmonized standard no. EN ISO 374-1:2016, EN 420:2003+A1:2009, EN 374-2:2014, EN 374-4:2013 and EN 374-5:2016.

The fulfilment of the applicable essential health and safety requirements set out in Annex II has been demonstrated under the supervision of the following notified bodies:

1. SATRA Technology Europe Ltd. Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland is identical to the PPE EU Certificate of Conformity No: 2777/10648-04/E01-01, 2777/12772-01/E01-01, 2777/10783-02/E02-01, 2777/15054-01/E01-01, 2777/13038-01/E02-01. Notified body No. 2777.
2. CENTEXBEL Textile Competence Centre, Technologie park 70, BE 9052 Zwijnaarde Notified body No.: 0493, EU Type Examination Certificate Nr. 001/2019/1260. Also, under the supervision of the notified body TUV SUD PSB Pte. Ltd. No. 1 Science Park Drive Singapore 118221, test report: 7191221625-CHM19-02-JS.

In accordance with Annex VIII, Medical Device Regulation EU/2017/745, the device is listed above are non-invasive transient devices and are Class I devices under Rule 1 as Rules 2, 3, and 4 do not apply.

The following person is responsible for the signature of this document:

Name and Address: Mexpo International, 2828 Faber Street, Union City, California 94587-1204, USA

Authorized Signature:



Date: July 14, 2021

Name of responsible Person: Tim Thai

Position: President

ATTACHMENT A

Declaration of Conformity (Nitrile Examination Gloves)

PRODUCT DESCRIPTION	SIZE	UDI No.	PRODUCT DESCRIPTION	SIZE	UDI No.
BLOSSOM COATS NITRILE POWDER FREE EXAMINATION GLOVES	XS S M L XL	00723860448958 00723860448965 00723860448972 00723860448989 00723860448996	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/RED COLOR	XS S M L XL	00723860469250 00723860469267 00723860469274 00723860469281 00723860469298
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/ALOE VERA	XS S M L XL	00723860432254 00723860432261 00723860432278 00723860432285 00723860432292	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/DARK BLUE COLOR (100pcs/box)	XS S M L XL	00723860413253 00723860413260 00723860413277 00723860413284 00723860413291
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/BLACK COLOR	XS S M L XL	00723860478252 00723860478269 00723860478276 00723860478283 00723860478290	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/DARK BLUE COLOR (200pcs/box)	XS S M L XL	00723860421951 00723860421968 00723860421975 00723860421982 00723860421999
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES BLUE COLOR	S M L XL	00723860042262 00723860042279 00723860042286 00723860042293	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/EZ-DON (MIRACLE BLUE-100pcs/box)	XS S M L XL	00723860423658 00723860423665 00723860423672 00723860423689 00723860423696
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/ AVOCADO GREEN COLOR	XS S M L XL	00723860494856 00723860494863 00723860494870 00723860494887 00723860494894	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/EZ-DON (MIRACLE BLUE-200pcs/box)	XS S M L XL	00723860423757 00723860423764 00723860423771 00723860423788 00723860423795
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/ / SOFT BLUE COLOR	XS S M L XL	00723860423856 00723860423863 00723860423870 00723860423887 00723860423894	BLOSSOM COATS NITRILE POWDER FREE EXAMINATION GLOVES/EZ-DON (COBALT BLUE-200pcs/box)	XS S M L XL	00723860435552 00723860435569 00723860435576 00723860435583 00723860435590
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/ PINK COLOR	XS S M L XL	00723860475855 00723860475862 00723860475879 00723860475886 00723860475893	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/EZ-DON (COBALT BLUE-100pcs/box)	XS S M L XL	00723860435553 00723860435560 00723860435577 00723860435584 00723860435591
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/ LILA COLOR	XS S M L XL	00723860463852 00723860463869 00723860463876 00723860463883 00723860485892	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/BLUE LITE COLOR (100pcs/box)	XS S M L XL	00723860468956 00723860468963 00723860468970 00723860468987 00723860468994
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/WHITE COLOR	XS S M L XL	00723860485854 00723860485861 00723860485878 00723860485885 00723860485892	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/BLUE LITE (200pcs/box)	XS S M L XL	00723860462053 00723860462060 00723860462077 00723860462084 00723860462091

Authorized Signature: 

Date: July 14, 2021

Name of responsible Person: Tim Thai

Position: President