

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

ADDRESS:

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EC Representative:

Blossom Europe, S. L
 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

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

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.

Is subject to the procedures set out in Annex VII (Module C2) of the new PPE Regulations (EU) 2016/425 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. 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: September 30, 2020

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	00723860448958	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES- RED COLOR	XS	00723860469250
	S	00723860448965		S	00723860469267
	M	00723860448972		M	00723860469274
	L	00723860448989		L	00723860469281
	XL	00723860448996		XL	00723860469298
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES - ALOE VERA	XS	00723860432261	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES -DARK BLUE COLOR	XS	00723860413253
	S	00723860432278		S	00723860413260
	M	00723860432285		M	00723860413277
	L	00723860432285		L	00723860413284
	XL	00723860432292		XL	00723860413291
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES	S	00723860042262	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES - BLACK COLOR	XS	00723860478252
	M	00723860042279		S	00723860478269
	L	00723860042286		M	00723860478276
	XL	00723860042293		L	00723860478283
				XL	00723860478290
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – AVOCADO GREEN COLOR	XS	00723860494856	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES - EZ-DON (MIRACLE BLUE-100PCS)	XS	00723860423658
	S	00723860494863		S	00723860423665
	M	00723860494870		M	00723860423672
	L	00723860494887		L	00723860423689
	XL	00723860494894		XL	00723860423696
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES - BLUE COLOR	XS	00723860423856	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES- EZ-DON (MIRACLE BLUE-200PCS)	XS	00723860423757
	S	00723860423863		S	00723860423764
	M	00723860423870		M	00723860423771
	L	00723860423887		L	00723860423788
	XL	00723860423894		XL	00723860423795
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES - PINK COLOR	XS	00723860475855	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES- EZ-DON (COBALT BLUE-200PCS)	XS	00723860435552
	S	00723860475862		S	00723860435569
	M	00723860475879		M	00723860435576
	L	00723860475886		L	00723860435583
	XL	00723860475893		XL	00723860435590
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – LILA COLOR	XS	00723860463852	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES- EZ-DON (COBALT BLUE-100PCS)	XS	00723860435553
	S	00723860463869		S	00723860435560
	M	00723860463876		M	00723860435577
	L	00723860463883		L	00723860435584
	XL	00723860485892		XL	00723860435591
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES – WHITE COLOR	XS	00723860485854	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES- BLUE LITE COLOR	XS	00723860462053
	S	00723860485861		S	00723860462060
	M	00723860485878		M	00723860462077
	L	00723860485885		L	00723860462084
	XL	00723860485892		XL	00723860462091

Authorized Signature:



Date: September 30, 2020

Name of responsible Person:

Tim Thai

Position: President