

**MEXPO INTERNATIONAL INC.**

2828 Faber Street  
Union City, CA 94587-1204, USA  
www.blossom-disposables.com

**EU Declaration of Conformity  
Nitrile Examination Gloves**

**PRODUCT DESCRIPTION**

- 1. Product Name: Nitrile Examination Gloves  
Product Classification: Class I under Medical Device Regulation (EU) 2017/745 Annex VIII Rule 1 & 5

**ADDRESS:**

**Mexpo International Inc.**  
2828 Faber Street  
Union City, CA 94587-1204, USA  
  
Tel : +1 (510) 489-6800 ; Fax : +1 (510) 489-3111  
E-mail : [blossomglo@aol.com](mailto:blossomglo@aol.com) ; [tim@mexpo-glove.com](mailto:tim@mexpo-glove.com)  
  
Single Registration Number (SRN): US-MF-000032548

**AUTHORIZED REPRESENTATIVE:**

<b>EC REP</b> <b>Blossom Europe, S.L.</b> C/ Zurbano 45, 1 <sup>st</sup> floor, Madrid, Spain Single Registration Number (SRN): ES-AR-000019689	<b>CH REP</b> <b>CMC Medical Device GmbH</b> Rigistrasse 3 6300 Zug, Switzerland	<b>UK Responsible Person:</b> <b>CMC Medical Devices Ltd.</b> Office 32 19-21 Crawford Street London, W1H 1PJ, United Kingdom
---	--	--

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 Regulation (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: 0723860562869H**

**UDI Numbers: Attachment A**

**INTENDED USE:** A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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 Regulation (EU) 2016/425- Cat III and, where such is the case, with the national standard transposing harmonized standard no. EN ISO 374-1:2016+A1:2018, EN ISO 21420:2020, EN ISO 374-4:2019 and EN ISO 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:

**MEXPO INTERNATIONAL INC.**

2828 Faber Street

Union City, CA 94587-1204, USA

[www.blossom-disposables.com](http://www.blossom-disposables.com)

1. SATRA Technology Europe Ltd. Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland is identical to the PPE EU Certificate of Conformity No: 2777/10648-06/E02-01, 2777/20097-02/E01-01, 2777/15054-01/E01-01, 2777/13038-07/E02-02, 2777/13038-06/E01-01, 2777/12772-03/E01-01 and 2777/24550-01/E00-00. Notified body No. 2777.

**ATTACHMENT A**Declaration of Conformity (*Nitrile Examination Gloves*)

PRODUCT DESCRIPTION	SIZE	Device Identifier (DI)	PRODUCT DESCRIPTION	SIZE	Device Identifier (DI)
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	00723860432254	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/DARK BLUE COLOR (100pcs/box)	XS	00723860413253
	S	00723860432261		S	00723860413260
	M	00723860432278		M	00723860413277
	L	00723860432285		L	00723860413284
	XL	00723860432292		XL	00723860413291
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/BLACK COLOR	XS	00723860478252	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/DARK BLUE COLOR (200pcs/box)	XS	00723860421951
	S	00723860478269		S	00723860421968
	M	00723860478276		M	00723860421975
	L	00723860478283		L	00723860421982
	XL	00723860478290		XL	00723860421999
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES BLUE COLOR	S	00723860042262	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/EZ-DON (MIRACLE BLUE-100pcs/box)	XS	00723860423658
	M	00723860042279		S	00723860423665
	L	00723860042286		M	00723860423672
	XL	00723860042293		L	00723860423689
				XL	00723860423696
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/ AVOCADO GREEN COLOR	XS	00723860494856	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/EZ-DON (MIRACLE BLUE-200pcs/box)	XS	00723860423757
	S	00723860494863		S	00723860423764
	M	00723860494870		M	00723860423771
	L	00723860494887		L	00723860423788
	XL	00723860494894		XL	00723860423795
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES// SOFT BLUE COLOR	XS	00723860423856	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/EZ-DON (COBALT BLUE-200pcs/box)	XS	00723860435552
	S	00723860423863		S	00723860435569
	M	00723860423870		M	00723860435576
	L	00723860423887		L	00723860435583
	XL	00723860423894		XL	00723860435590
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/ PINK COLOR	XS	00723860475855	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/EZ-DON (COBALT BLUE-100pcs/box)	XS	00723860425553
	S	00723860475862		S	00723860425560
	M	00723860475879		M	00723860425577
	L	00723860475886		L	00723860425584
	XL	00723860475893		XL	00723860425591
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/ LILA COLOR	XS	00723860463852	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/BLUE LITE COLOR (100pcs/box)	XS	00723860468956
	S	00723860463869		S	00723860468963
	M	00723860463876		M	00723860468970
	L	00723860463883		L	00723860468987
	XL	00723860463890		XL	00723860468994
BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/WHITE COLOR	XS	00723860485854	BLOSSOM NITRILE POWDER FREE EXAMINATION GLOVES/BLUE LITE (200pcs/box)	XS	00723860462053
	S	00723860485861		S	00723860462060
	M	00723860485878		M	00723860462077
	L	00723860485885		L	00723860462084
	XL	00723860485892		XL	00723860462091

**MEXPO INTERNATIONAL INC.**

2828 Faber Street  
Union City, CA 94587-1204, USA  
[www.blossom-disposables.com](http://www.blossom-disposables.com)

In accordance with Annex VIII, Medical Device Regulation (EU) 2017/745, the devices listed above are non-invasive transient devices and are Class I devices under Rule 1 & 5 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 Inc., 2828 Faber Street, Union City, California 94587-1204, USA

**Authorized Signature:**



**Date:** February 27, 2024

**Name of responsible Person:** Tim Thai

**Position:** President

MEXPO INTERNATIONAL INC.