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
2. Product Classification: Class I under Medical Device Regulation (EU) 2017/745 Annex VIII Rule 1 & 5

ADDRESS:

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

Brand Owner
white-med GmbH
Marburger Straße 251
35396 Gießen, Germany

AUTHORIZED REPRESENTATIVE:

EC REP

Blossom Europe, S.L.
C/ Zurbano 45, 1st floor,
28010 Madrid, Spain

Single Registration Number (SRN):
ES-AR-000019689

CH REP

CMC Medical Device GmbH
Rigistrasse 3
6300 Zug,
Switzerland

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.

1) Peppler Nitril Color Lilac (Examination Gloves, Powder Free) – (Art.Nr. 414)

PRODUCT DESCRIPTION	SIZE	DEVICE IDENTIFIER (DI)
Peppler Nitril Color Lilac (Examination Gloves, Powder Free) – (Art.Nr. 414)	Extra Small; (XS)	00723860001689
	Small; (S)	00723860001665
	Medium; (M)	00723860001658
	Large; (L)	00723860001597
	Extra Large; (XL)	00723860001672

2) Peppler Nitril Color Lime (Examination Gloves, Powder Free) – (Art.Nr. 417)

PRODUCT DESCRIPTION	SIZE	DEVICE IDENTIFIER (DI)
Peppler Nitril Color Lime (Examination Gloves, Powder Free) – (Art.Nr. 417)	Extra Small; (XS)	00723860012715
	Small; (S)	00723860012708
	Medium; (M)	00723860012692
	Large; (L)	00723860012685
	Extra Large; (XL)	00723860012753

Basic UDI-DI: 0723860562869H

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, 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 body:

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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. Notified body No. 2777.

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:** March 5, 2024

Name of responsible Person: Tim Thai **Position:** President