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

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

Single Registration Number (SRN) : US-MF-000032548

AUTHORIZED REPRESENTATIVE:

EC Representative:
Blossom Europe, S.L.
Paseo de Recoletos 37-41
28004 Madrid, Spain

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

CH Representative:
CMC Medical Devices GmbH
Bahnhofstrasse 32
CH-6300 Zug
Switzerland
(for only Art.Nr. 414 & 417)

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 Comfort Aloe Vera (Examination Gloves, Powder Free) – (Art. Nr. 413)**
UDI Numbers: 4046144057018(Size Extra Small),4046144057025 (Size Small), 4046144057032 (Size Medium), 4046144057049 (Size Large), 4046144057056 (Size Extra Large)

2) **Peppler Nitril Color Lilac (Examination Gloves, Powder Free) – (Art.Nr. 414)**
UDI Numbers: 4046144001684 (Size Extra Small), 4046144001660 (Size Small), 4046144001653 (Size Medium), 4046144001592 (Size Large), 4046144001677 (Size Extra Large)

3) **Peppler Nitril Color Lime (Examination Gloves, Powder Free) – (Art.Nr. 417)**
UDI Numbers: 4046144003205 (Size Extra Small), 4046144003199 (Size Small), 4046144003196 (Size Medium), 4046144003193 (Size Large), 4046144003202 (Size Extra Large)

Basic UDI-DI: 4046144562867Q

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, EN 420:2003+A1:2009, EN 374-2:2014, EN 374-4:2013, 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:

1. CENTEXBEL Textile Competence Centre, Technologiepark 70, BE 9052 Gent, Belgium is identical to the PPE EU Type Examination Certificate Nr. 049/2019/1261. Notified body No.: 0493

2. 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/E18-01. 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: January 10, 2023

Name of responsible Person: Tim Thai

Position: President