*MEXPO INTERNATIONAL INC.*
*2828 Faber Street*
*Union City, CA 94587-1204*

# Declaration of Conformity

## *(Latex Examination Gloves)*

**PRODUCT DESCRIPTION**

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

**ADDRESS:**

| | | |
|---|---|---|
| **Mexpo International Inc.** | **EC Representative:** | **Brand Owner** |
| 2828 Faber Street | **Blossom Europe, S. L** | Royal Sulgerins SL |
| Union City, CA 94587-1204, USA | Paseo de Recoletos, 37-41 | CL cuzco 23-25 |
| Tel : +1 (510) 489-6800 | 28004 Madrid, Spain | 08030 Barcelona |
| Fax: +1 (510) 489-3111 | | Spain |
| E-mail : blossomglo@aol.com | | |
| E-mail: tim@mexpo-glove.com | | |

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) EU/2017/425.**

**Latex Examination Gloves:**
**Royal Dent Latex Examination (Examination Gloves, Powdered)**

| Size | UDI # |
|---|---|
| XS | 00723860116758 |
| S | 00723860116765 |
| M | 00723860116772 |
| L | 00723860116789 |
| XL | 00723860116796 |

**Basic UDI-DI: 72386047173RT**

It is declared that above devices meet the requirement of the **Medical Device Regulation EU/2017/425.**

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, EN ISO 374-5:2016, EN ISO 455

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: 2777/10905-01/E11-01. Notified body No. 2777.

In accordance with Annex VIII, Medical Device Regulation EU/2017/425, 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 signing this Document:
***Name and Address:*** Mexpo International Inc., 2828 Faber Street, Union City, California 94587-1204, USA

**Authorized Signature:** _____ **Date:** February 10, 2022

**Name of responsible Person:** TIM THAI **Position:** President

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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) EU/2017/425.**

**Latex Examination Gloves:**
**Royal Dent Latex Examination (Examination Gloves, Powder Free)**

| Size | UDI # |
|---|---|
| XS | 00723860638656 |
| S | 00723860638663 |
| M | 00723860638670 |
| L | 00723860638687 |
| XL | 00723860638694 |

**Basic UDI-DI: 72386047172RR**

It is declared that above devices meet the requirement of the **Medical Device Regulation EU/2017/425.**

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, EN ISO 374-5:2016, EN ISO 455

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: 2777/10906-03/E02-01. Notified body No. 2777.

In accordance with Annex VIII, Medical Device Regulation EU/2017/425, 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 signing this Document:
***Name and Address:*** Mexpo International Inc., 2828 Faber Street, Union City, California 94587-1204, USA

**Authorized Signature:** _____ **Date:** February 10, 2022

**Name of responsible Person:** TIM THAI **Position:** President