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

EU Declaration of Conformity- Face Mask

PRODUCT DESCRIPTION

1. Product Name: Face Mask (non-woven products)
2. Product Classification: Class I under Medical Device Regulation (EU) 2017/745 Annex VIII Rule 1

ADDRESS:

Mexpo International Inc.
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Single Registration Number (SRN):
US-MF-000032548

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

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

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.

Face Mask Product:

1) **N770 Peppler Care 3 PLY Latex Free Earloop Face Mask (Type II R)**

COLOR:	ITEM #:	UDI #:
Blue	N770BG	00723860011886
Green	N770GG	00723860011893
Lila	N770LG	00723860011916
Pink	N770PG	00723860011923
White	N770WG	00723860011930

2) **N770 Peppler Care 3 PLY Latex Free Tie-On Face Mask (Type II R)**

COLOR:	ITEM #:	UDI #:
Blue	N770BB	00723860015860
Green	N770GB	00723860015877
Lila	N770LB	00723860015884
Pink	N770PB	00723860015891
White	N770WB	00723860015907

Basic UDI-DI: 0723860351778E

INTENDED USE: When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non sterile and for single use only.

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It is declared that above devices meet the requirement of the Medical Device Regulation (EU) 2017/745.

PPE Regulations (EU) 2016/425- Cat III and, where such is the case, with the following standards. DIN EN ISO 14683, ASTM F2299/F2299M-03(2017), ASTM F2101-23, ASTM F2100-23, ASTM F1862/F1862M-17, ASTM F1494-23.

In accordance with Annex VIII, Medical Device Regulation (EU) 2017/745, 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 of this document:

Name and Address: Mexpo International Inc., 2828 Faber Street, Union City, California 94587-1204, USA

Authorized Signature: 

Date: September 29, 2023

Name of responsible Person: Tim Thai

Position: President