

MEXPO INTERNATIONAL, INC.

2828 Faber Street

Union City, CA 94587-1204, USA

www.blossom-disposables.com

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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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

CH Representative:
 CMC Medical Devices GmbH
 Bahnhofstrasse 32
 CH-6300 Zug
 Switzerland
 (For only N770)

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

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) N700 Sensitive New 3 PLY Latex Free Earloop Face Mask

COLOR:	ITEM #:	UDI #:
Blue	N700BG	4046144024003
Green	N700GG	4046144024027
Lila	N700LG	4046144024065
Pink	N700PG	4046144024034
White	N700WG	4046144024041

2) N770 Peppler Care 3 PLY Latex Free Earloop Face Mask

COLOR:	ITEM #:	UDI #:
Blue	N770BG	4046144011881
Green	N770GG	4046144011898
Lila	N770LG	4046144011911
Pink	N770PG	4046144011928
White	N770WG	4046144011935

Basic UDI-DI: 4046144351776M

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 14683, ASTM F2299/F2299M-03(2017), ASTM F2101-22, ASTM F2100-21, ASTM F1862/F1862M-17, ASTM F1494-14.

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: January 10, 2023

Name of responsible Person: Tim Thai

Position: President