As of 04 Mar 2024

USER INFORMATION

CE 2777	Comply with PPE Regulation 2016/425 Cat III

These products are classed as Category III Personal Protective Equipment (PPE) by the European PPE REGULATION 2016/425 and have been shown to comply with this Regulation through the Harmonized European Standard(s): EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016.

Product reference:

Blue:

Mumu Guard: MGN01-XS, MGN02-S, MGN03-M, MGN04-L, MGN05-XL
Mumu Care: MCN01-XS, MCN02-S, MCN03-M, MCN04-L, MCN05-XL
E-care: NRB32XS, NRB32S, NRB32M, NRB32L, NRB32XL
Inf4media: IN4MN01-XS, IN4MN02-S IN4MN03-M, IN4MN04-L, IN4MN05-XL
Mumu Maxima: MMNPF01-XS, MMNPF02-S, MMNPF03-M, MMNPF04-L, MMNPF05-XL

Black:

Mumu Guard Black: MGBN01-XS, MGBN02-S, MGBN03-M, MGBN04-L, MGBN05-XL
Mumu Protect: MP01-XS, MP02-S, MP03-M, MP04-L, MP05-XL

Sizes available: XS, S, M, L, XL

Colour: Blue, Black

Intended Use:

A patient examination glove is a medical device intended for a medical purpose that is worn on the examiner's hand or finger to prevent contamination between the patient and examiner. Examination glove is intended for medical activities except for surgery.

Performance and limitation of use –This product has been tested and achieved the following performance levels:

Classification:

EN ISO 374-1:2016+A1:2018 /Type B	Level	EN ISO 374-4:2019 Degradation%
40% Sodium Hydroxide (K)	6	-68.1
30% Hydrogen Peroxide (P)	2	30.5
37% Formaldehyde (T)	5	9.5

EN ISO 374-1:2016+A1:2018 /Type B

KPT

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EN ISO 374-5:2016

Virus

EN ISO 374-5:2016	
Protection against Bacteria and Fungi	**Pass**
Protection against Viruses	**Pass**

EN ISO 374-1:2016+A1:2018 Permeation levels are based on breakthrough times as follows:

Permeation performance level	1	2	3	4	5	6
Measured breakthrough time (min)	＞10	＞30	＞60	＞120	＞240	＞480

EN ISO 374-4:2019 Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.

The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture.

It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type of test depending on temperature, abrasion, and degradation.

When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by chemical contact, etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in the selection of chemical-resistant gloves.

Before usage, inspect the gloves for any defects or imperfections.

Storage and transport: When not in use, store the product in a well-ventilated area away from extremes of temperature

The glove performance quoted is based on laboratory data and may not reflect the actual duration of protection in the workplace due to other factors influencing the performance such as temperature, abrasion, degradation, etc.)

The glove does not contain any substances that are known to cause allergies.

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The Gloves have no mechanical protection offered.
For single use only, do not littering.
Check for damage before use, do not use damaged gloves

Donning:

1. Remove all hand and wrist jewelry, and wash the hands before donning.
2. Place the gloves on the prepared work surface.
3. The user puts a glove on his/her dominant hand by grabbing it with the other hand, remembering to only touch the inside of the gloves, and slipping it over the dominant hand until it reaches the final level.
4. The wearer uses the gloved dominant hand to slip the other glove onto the non-dominant hand.
5. Once both gloves are on, the users can touch the outside of the gloves to ensure a proper fit

Doffing:

1. Using the dominant hand, users start by grabbing the outside of the glove on the non-dominant hand on the palm side near the cuff.
2. Pull the glove off the non-dominant hand and place it in the gloved hand, balling it up.
3. Slip two fingers under the cuff of the other hand glove and carefully peel it off the hand without touching the wrist, turning the remaining glove inside put as it is removed and in turn encasing the first glove.
4. The gloves can be disposed.

The DOC (Declaration of Conformity) will be shown on the website: www.mymedikal.com.tr/documents

Notified Body responsible for certification and ongoing conformity:

SATRA Technology Europe Ltd

Bracetown Business Park

Clonee, Dublin

D15 YN2P, Ireland (NB2777)

Product manufactured by: MY TICARET VE MEDIKAL A.Ş.

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CE	These products also comply with Medical Device Regulation (EU) 2017/745 under the Class I category.

Other Common Graphical Symbols:

SYMBOLS	TITLE
	Manufacturer
	Date of Manufacture
	Use-by date/ Expiration Date
	Batch Code/ Lot Number
	Keep away from sunlight
	Keep dry
	Do not re-use
	Non-sterile
EN455	European Standard

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