As of 28 Jan 2025

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.

Nitrile Powderfree Examination and Protective Gloves

Brand	Catalog No./Ref. No./ Models
Mumu Plus	MN01, MPN, MPNB, MPNSS01-S, MPNSS02-M, MPNSS03-L, MPNSS04-XL
Mumu	MN01, MN, MNB
Simplistic	SMITCNPF01-XS, SMITCNPF02-S, SMITCNPF03-M, SMITCNPF04-L, SMITCNPF05-XL
Simplistic by Mumu	MN01, SBM, SBMB
Simplistic Max	MN01, SM
B-good	BM1N-S, BM1N-M, BM1N-L,
Aldena	AL01-XS, AL02-S, AL03-M, AL04-L, AL05-XL, NBK30XS, NBK30S, NBK30M, NBK30L, NBK30XL
Mumu Guard	MGBSNPF01-XS, MGBSNPF02-S, MGBSNPF03-M, MGBSNPF04-L, MGBSNPF05-XL MGBBSNPF01-XS, MGBBSNPF02-S, MGBBSNPF03-M, MGBBSNPF04-L, MGBBSNPF05-XL
Mumu Care	MCN01-XS, MCN02-S, MCN03-M, MCN04-L, MCN05-XL

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:

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
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PPE SPECIFICATION	PERFORMANCE LEVELS
Dexterity	5
Material Resistance To Permeation By Chemicals	2 (Type C)
Phi-X174 Bacteriophage	Appropriate

OBTAINED VALUE: EN 374-1/Type C, EN ISO 374-5

Protection against virus:

Evaluation	Limit Value
Results	Appropriate

Determination of material resistance to permeation by chemicals (%40 NaOH):

Evaluation	Limit Value
PERFORMANCE LEVEL:2	> 30 min

The permeation performance against Sodium hydroxide 40%

Evaluation	Limit Value
PERFORMANCE LEVEL:2	> 30 min

Recommendations for use:

- The PPE is Made from Synthetic Nitrile Rubber
- Powder-free
- Not made with natural rubber latex
- Ambidextrous

Warnings:

- Gloves not valid in an explosive atmosphere.
- This product is not flame resistant and must not be used in areas with open flames.
- The user must know the use and gloves handling.
- Do not use risk zones of explosion.
- This PPE must not be used against risks other than those previously described
- For single-use only.

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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

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

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

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EU-Type Examination (Module B)
by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.
Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21
Ataşehir/ Istanbul, Turkey [Notified Body No.2841]

Ongoing Conformity (Module C2)
by Notified Body SATRA TECHNOLOGY EUROPE LTD
Bracetown Business Park,
Clonee, D15YN2P, Ireland [**CE 2777**]

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

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	Non-sterile
EN455	European Standard

MY TİCARET VE
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