



MY Medikal

**EU DECLARATION
OF CONFORMITY**

Manufacturer's Name and Address	:	MY TİCARET VE MEDİKAL A.Ş. Ömerli Mah. General Şükrü Koraltı Cad. No :33 Arnavutköy-İstanbul/TURKEY
Name Of Device	:	Nitrile Examination Gloves
Type and Registration/Catalog No	:	Powder Free Nitrile Examination Gloves - MN01/MS01
Brand	:	Mumu/Mumu Plus/Simplistic By Mumu
Classification	:	Class I
Conformity Assessment Procedure	:	Annex VII
Conformity Route	:	Self Declaration

It complies with the provisions of the EU Regulation 2016/425 – Cat III of March 9, 2016 and in particular with the specifications of the harmonized standards EN 420:2003+A1:2009, EN 16523-1+A1, EN ISO 374-1:2016/A1:2008, EN ISO 374-2:2019, EN ISO 374-3, EN ISO 374-4, EN ISO 374-5 edited by the European Committee for Standardization.

The Notified Body MNA LABORATUVARLARI SANAYİ TİCARET LIMITED, notified body № 2841 in Kucukbakkalkoy Mah, Yenidogan Cad., No. 21 Atasehir/Istanbul/Turkey, has carried out the EU Type Examination (Module B) and has issued the EU Type 45-20-01-R01 certificate

This EU declaration of conformity is issued under the sole responsibility MY TİCARET VE MEDİKAL A.S.

Verification Certificates	:	Quality Management System EN ISO13485:2016 Certificate No: ISO 02 836 1179
	:	Quality Management System EN ISO9001:2015 Certificate No: ISO 01 940 117

MY TİCARET VE MEDİKAL A.Ş

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MY Medikal
Standards

: EN:374-1 Protective gloves against dangerous chemicals and micro-organisms Terminology and performance requirements for chemical risks

EN 374-2 Protective gloves against dangerous chemicals and microorganisms-Part 2: Determination of resistance to penetration.

EN 16523-1+A1 Determination of material resistance to permeation by chemicals-Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (EN 374-3 standard has been revised as EN 16523-1+A1)

EN 374-4 Protective gloves against dangerous chemicals and microorganisms-Part 4: Determination of resistance to degradation by chemicals.

EN 374-5 Protective gloves against dangerous chemicals and microorganisms-Part 2: Terms and performance rules for microorganism risks.

EN 455-1 Medical gloves for single use Part 1: Requirements and testing for freedom from holes.

EN 455-2 Medical gloves for single use Part 2: Requirements and testing for physical properties.

EN 455-3 Medical gloves for single use Part 3: Requirements and testing for biological evaluation.

EN 455-4 Medical gloves for single use Part 4: Requirements and testing for shelf life determination.

EN ISO 10993-1 Biological evaluation of medical devices-Part-1: Evaluation and testing within a risk management process.

Authorised Signatory

Name-Surname : MURAT YILDIZ

Position : CEO

Signed :

Date : 26.07.2021

**MY TİCARET VE
MEDİKAL ANONİM ŞİRKETİ**
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