

# AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 45-20-01-R01  
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /  
Certification Date / Certificate Validity Date : 05.10.2020-25.09.2025  
Belge Geçerlilik Tarihi / Document Validity Period : 5 yıl / 5 years  
Firma Unvanı ve Adresi /  
Company Name and Address : Redacted for public use

Ürün Adı /Modeller / Product Name / Models : Mumu Plus MN01  
Mumu MN01  
Simplistic By Mumu MS01  
Direktifi / Directive : 2016/425 REGULATION  
Modülü/Kategori / Module / Category : B MODÜLÜ/ KATEGORİ III  
MODULE B / CATEGORY III  
Test Rapor No/ları / Test Report No : MNA M-2020-00308

Ürün Tipi / Product Type:

- EN 420 Koruyucu Eldivenler / Protective gloves
- EN ISO 374-1 Tehlikeli Kimyasallara Ve Mikroorganizmalara Karşı Koruyucu Eldivenler (Performans Seviyeleri: Tip C) / Protective Gloves Against Dangerous Chemicals And Micro-Organisms (Performance Level: Type C)
- EN ISO 374-5 Tehlikeli Kimyasallara Ve Mikroorganizmalara Karşı Koruyucu Eldivenler - Bölüm 5: Mikroorganizmal riskler için terimler ve performans kuralları / Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks

Ürünün Malzeme Bilgisi / Product Material Information: MN01 ve MS01 model ürünleri sentetik nitril kullanılarak imal edilmiştir./ MN01 and MS01 model products are manufactured using synthetic nitrile.

Revizyon nedeni/ Reason for revision: Model adı revize edilmiştir./ The model name has been revised.

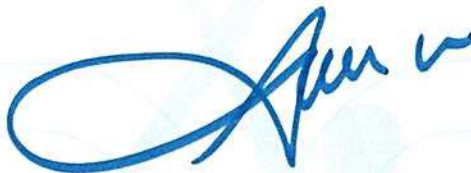
Volkan AKIN  
05.10.2020

Karar Verici / Approver



Okan AKEL  
05.10.2020

Şirket Müdürü / General manager







**ATTACHMENTS (45-20-01-R01)****Model : MN01 and MS01**

PPE SPECIFICATION	PERFORMANCE LEVELS
Ability	5
Material Resistance To Permeation By Chemicals	2 (Type C)
Phi-X174 Bacteriophage	Appropriate

PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:

**PRODUCT SIZE: XS, S, M, L, XL**

MARKING			
<b>COMPANY:</b> redacted for public use			
<b>PPE TYPE:</b>			
<ul style="list-style-type: none"><li>- EN 420+ A1 Protective gloves</li><li>- EN ISO 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms</li><li>- EN ISO 374-5 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks</li></ul>			
<b>PRODUCT SIZE / MODEL:</b> MN01 and MS01 (XS, S, M, L, XL)			
<b>PICTOGRAM AND PERFORMANCE LEVELS:</b>			
	EN 420+A1	EN ISO 374-1/2016 Type C	EN ISO 374-5/2016
			
NB 2841		K	VIRUS

MNA LABORATUVARLARI SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

PRODUCT PICTURES



MN01 and MS01  
(Blue, Violet Blue, Black, Purple, White)

DOCUMENTS IN THE TECHNICAL FILE

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- Review Reports
- Technical Report

# EU DECLARATION OF CONFORMITY

Company Name : Redacted for public use  
Company Address :

## EXAMINATION AND PROTECTIVE GLOVES

Name of Device : Nitrile Examination Gloves  
Type : Powder Free  
Classification : PPE Category III  
Brand : Mumu-Mumu Plus-Simplistic by mumu  
Model : MNOI-MS011

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 and EN ISO 374-1:2016/A1:2018 EN ISO 374-5:2016 edited by the European Committee for Standardization).

The Notified Body **MNA LABORATUVARLARI SANAYI TICARET LIMITED**, notified body n°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.

Date : 25.09.2025

Sign : MURAT YILDIZ



**EC DECLARATION  
OF CONFORMITY**

**Manufacturer's Name and Address** : Redacted for public use

**Name Of Device** : Latex Examination Gloves

**Type and Registration/Catalog No** : Powdered Latex Examination Gloves - MLP02  
Powder Free Latex Examination Gloves - MLPF02

**Brand** : Mumu - Mumu Plus - Simplistic By Mumu

**Classification** : Class I

**Conformity Assessment Procedure** : Annex VII

**Conformity Route** : Self Declaration

We herewith declare with our own responsibility that above mentioned product(s) with CE mark is fully compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC.

**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

**Standards**

: 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** : Redacted for public use

**Position** : CEO

**Signed** :

ME  
Ikitell  
A3  
Tel.1

**Date** : 22.03.2020





MANAGEMENT SYSTEM  
ISO/IEC 17021-1:2015  
NAC-002-MS

# Certificate of Registration

This is to certify that  
**Quality Management System**

complies with requirements of

## ISO 9001:2015

This certificate is valid concerning all activities related to;

PRODUCTION AND SALE OF LATEX POWDERED / POWDER FREE EXAMINATION GLOVES, NITRILE POWDER FREE EXAMINATION GLOVES, STERIL / NON-STERILE SURGICAL GLOVES, STERIL / NON-STERILE SPONGE GAUZE COMPRESS, STERIL / NON-STERIL COMPRESSE ABDOMINALE, STERIL / NON-STERILE COTTON PAD, GAUZE, STERILE / NON-STERILE SURGICAL MASK

LATEKS PUDRALI / PUDRASIZ MUAYENE ELĐİVENİ, NİTRİL PUDRASIZ MUAYENE ELĐİVENİ, STERİL / NON-STERİL CERRAHi ELĐİVEN, STERİL / NON-STERİL SPANÇ GAZ KOMPRES, STERİL / NON-STERİL BATIN KOMPRES, STERİL / NON-STERİL PAMUKLU PED, GAZLI BEZ, STERİL / NON-STERİL CERRAHi MASKE ÜRETİMİ VE SATIŞI

ISO 01 940 1179  
*Certificate No.*

Jun. 5, 2020  
*Date of this Certificate*

Jun. 4, 2021  
*Certification Expiry Date*

May. 28, 2020  
*Date of Audit*

Jun. 5, 2020  
*Date of Registration*

  
*Managing Director / Director*



**Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.**  
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir  
Tel: 0232 327 33 44 [www.medicert.com.tr](http://www.medicert.com.tr) [info@medicert.com.tr](mailto:info@medicert.com.tr)

\* You can query the validity of this certificate by sending an e-mail to [info@medicert.com.tr](mailto:info@medicert.com.tr).