MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-CDS-002
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd No:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Simplistic by Mumu
Product Description	Nitrile Powderfree Examination and Protective Gloves
Intended Purpose	A patient examination glove is a medical device intended for a medical purpose that is worn on the examiners hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except surgery.
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue Number	MN01
Conformity Assessment Route	Annex VII
Classification & Rule	Class I, Rule 5
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	79013032
STE Reference for Module C2 Certificate	STE7162T8F7
Notified Body (PPER)	**EU-Type Examination** by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ. Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ Istanbul, Turkey [Notified Body No.**2841**] / **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [Notified Body No.**2777**]

Applicable Standards

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	PPE (EU) 2016/425	Personal Protective Equipment Regulation
2	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	3	ISO 9001: 2015	Quality management systems – requirements
	4	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	5	EN 455-1: 2020	Requirements and testing for freedom from holes
	6	EN 455-2: 2015	Requirements and testing for physical properties
	7	EN 455-3: 2015	Requirements and testing for biological evaluation
	8	EN 455-4: 2009	Requirements and testing for shelf-life determination
	9	ISO 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
	10	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	11	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer
	12	EN ISO 21420:2020	Protective gloves – General requirements and test methods
	13	EN ISO 374-1: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	14	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

We, My Ticaret ve Medikal A.S., herewith declare that the above-mentioned device:

- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following to the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2841 by MNA Laboratuvarlari San. Tic.Ltd.Sti.
- Is in conformity to type based on the quality control system for the final product under the surveillance of the notified body number 2777 by SATRA TECHNOLOGY EUROPE LTD.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

MY TICARET VE MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad
No:33 Arnavutköy/İSTANBUL
Büyükçekmece V.D.626 040 4605
Tel:0212 438 20 64 Fax:0212 438 20 65
www.mymedikal.com

Approval Date : 09 May 2024

Place of Approval : Istanbul, Turkey

CE

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ITC-001
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Mumu Care
Product Description	Nitrile Powder Free Examination and Protective Gloves
Intended Purpose	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.
Basic UDI-DI	868302002NPVQ
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue/Reference Number	MCN01-XS, MCN02-S, MCN03-M, MCN04-L, MCN05-XL
Product Group Reference Number	SNBE20013-XS, SNBE20014-S, SNBE20015-M, SNBE20016-L, SNBE20017-XL
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	2777/14815-03/E63-02
Notified Body (PPER)	**EU-Type Examination** and **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
	3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	4	ISO 9001: 2015	Quality management systems – requirements
	5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	6	EN 455-1: 2020	Requirements and testing for freedom from holes
	7	EN 455-2: 2015	Requirements and testing for physical properties
	8	EN 455-3: 2015	Requirements and testing for biological evaluation
	9	EN 455-4: 2009	Requirements and testing for shelf-life determination
	10	ISO 10993-1: 2018	Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process
	11	ISO 10993-10: 2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
	12	ISO 10993-11: 2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
	13	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	14	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	15	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	16	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	17	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	18	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
	19	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
	20	ASTM D 6978-05:2019	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
	21	ASTMF1671/F1671-13	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2777 by SATRA Technology Europe Ltd.
- Is in conformity to type based on quality assurance of the production process under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 05 Nov 2024

Place of Approval : Istanbul, Turkey

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ITC-002
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Mumu Guard
Product Description	Nitrile Powder Free Examination and Protective Gloves
Intended Purpose	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.
Basic UDI-DI	868302002NPVQ
Country of Origin	China
Size	XS, S, M, L, XL
EAN Code	**Blue:** 8684266525679, 8684266525686, 8684266525693, 8684266525709, 8684266525716; 8683020022409, 8683020022416, 8683020022423, 8683020022430, 8683020022447 **Black:** 8683020022669, 8683020022676, 8683020022683, 8683020022690, 8683020022706, 8684266525969, 8684266525976, 8684266525983, 8684266525990, 8684266526003
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue/ Reference Number	**Blue:** MGN01-XS, MGN02-S, MGN03-M, MGN04-L, MGN05-XL **Black:** MGBN01-XS, MGBN02-S, MGBN03-M, MGBN04-L, MGBN05-XL

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

Product Group Reference Number	**Blue:** SNBE10013-XS, SNBE10014-S, SNBE10015-M, SNBE10016-L, SNBE10017-XL; SNBE20013-XS, SNBE20014-S, SNBE20015-M, SNBE20016-L, SNBE20017-XL **Black:** SNBE20043-XS, SNBE20044-S, SNBE20045-M, SNBE20046-L SNBE20047-XL, SNHE10043-XS, SNHE10044-S, SNHE10045-M, SNHE10046-L, SNHE10047-XL
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	2777/14815-03/E63-02
Notified Body (PPER)	**EU-Type Examination** and **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**2777**]
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation
2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
4	ISO 9001: 2015	Quality management systems – requirements
5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
6	EN 455-1: 2020	Requirements and testing for freedom from holes
7	EN 455-2: 2015	Requirements and testing for physical properties
8	EN 455-3: 2015	Requirements and testing for biological evaluation
9	EN 455-4: 2009	Requirements and testing for shelf-life determination
10	ISO 10993-1: 2018	Biological evaluation of medical devices –Part 1: Evaluation and

			testing within a risk management process
	11	ISO 10993-10: 2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
	12	ISO 10993-11: 2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
	13	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	14	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	15	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	16	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	17	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
	18	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
	19	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
	20	EN ISO 21420:2020	Protective gloves – General requirements and test methods
	21	ASTM D 6978-05:2019	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
	22	ASTMF1671/F1671-13	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

			Phi-X174 Bacteriophage Penetration as a Test System

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following to the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2777 by SATRA Technology Europe Ltd.
- Is in conformity to type based on quality assurance of the production process under surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance to Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 06 Nov 2024

Place of Approval : Istanbul, Turkey

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

DEKLARACJA ZGODNOŚCI UE

Nr Dokumentu	DOC-MYMEDIKAL-ITC-002
Certyfikat EC	Nie dotyczy (oświadczenie własne)
Producent	MY TICARET VE MEDIKAL A.S.
Ars Producenta	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turcja
Jednolity numer rejestracyjny (SRN)	TR-MF-000018372
Marka	Mumu Guard
Opis produktu	Rękawice ochronne i diagnostyczne bez pudrowe z nitrylu
Przeznaczenie	Rękawica do badań pacjenta to wyrób medyczny przeznaczony do celów medycznych, który jest noszony na dłoni lub palcach osoby przeprowadzającej badanie, aby zapobiec zanieczyszczeniu między pacjentem a osobą przeprowadzającą badanie. Rękawica do badań jest przeznaczona do czynności medycznych, z wyjątkiem operacji.
Podstawowy kod UDI-DI	868302002NPVQ
Kraj pochodzenia	Chiny
Rozmiary	XS, S, M, L, XL
KOD EAN	**Niebieski:** 8684266525679, 8684266525686, 8684266525693, 8684266525709, 8684266525716; 8683020022409, 8683020022416, 8683020022423, 8683020022430, 8683020022447 **Czarny:** 8683020022669, 8683020022676, 8683020022683, 8683020022690, 8683020022706
Europejska Nomenklatura Wyrobów Medycznych (EMDN)	T01020204 (Rękawiczki do badań/zabiegów, nitrylowe)
Globalna nomenklatura wyrobów medycznych (GMDN)	56286 (Rękawice nitrylowe do badań/leczenia, bez pudrowe, niejałowe)
Katalog produktów/Numer referencyjny	**Niebieski:** MGN01-XS, MGN02-S, MGN03-M, MGN04-L, MGN05-XL **Czarny:** MGBN01-XS, MGBN02-S, MGBN03-M, MGBN04-L, MGBN05-XL

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

Numer referencyjny grupy produktów	**Niebieski:** SNBE10013-XS, SNBE10014-S, SNBE10015-M, SNBE10016-L, SNBE10017-XL; SNBE20013-XS, SNBE20014-S, SNBE20015-M, SNBE20016-L, SNBE20017-XL **Czarny:** SNBE20043-XS, SNBE20044-S, SNBE20045-M, SNBE20046-L SNBE20047-XL
Środowisko oceny zgodności (MDR):	Aneks II i aneks III zgodnie z rozporządzeniem UE 2017/745
Klasyfikacja i zasady (MDR)	Klasa I, Reguła 1 i Reguła 5 zgodnie z Załącznikiem VIII
Klasyfikacja urządzeń (PPER)	Kategoria III
EU Type-Examination Certificate (PPER)	2777/14815-03/E63-02
Certyfikat badania UE (PPER)	**Badanie typu UE i ciągła zgodność przez jednostkę notyfikowaną** SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**2777**]
Obowiązujące normy	

No.	Numer rozporządzenia/normy	Nazwa rozporządzenia/normy
1	MDR (EU) 2017/745	Rozporządzenie w sprawie wyrobów medycznych
2	PPE (EU) 2016/425	Rozporządzenie w sprawie środków ochrony osobistej
3	ISO 13485: 2016	Wyroby medyczne — Systemy zarządzania jakością — Wymagania dla celów regulacyjnych
4	ISO 9001: 2015	Systemy zarządzania jakością — wymagania
5	ISO 14971: 2019	Wyroby medyczne — zastosowanie zarządzania ryzykiem
6	EN 455-1: 2020	Wymagania i badania dotyczące braku dziur
7	EN 455-2: 2015	Wymagania i badania dotyczące właściwości fizycznych
8	EN 455-3: 2015	Wymagania i badania dotyczące oceny biologicznej

	9	EN 455-4: 2009	Wymagania i badania w celu określenia okresu przydatności do spożycia
	10	ISO 10993-1: 2018	Wymagania i badania dotyczące określania okresu trwałości
	11	ISO 10993-10: 2010	Ocena biologiczna wyrobów medycznych — Część 10: Badania działania drażniącego i uczulającego na skórę
	12	ISO 10993-11: 2017	Ocena biologiczna wyrobów medycznych — Część 11: Badania toksyczności układowej
	13	ISO 20417:2021	Wyroby medyczne — Informacje dostarczane przez producenta
	14	ISO 15223-1: 2021	Wyroby medyczne — Symbole, które należy stosować wraz z informacjami, które ma dostarczyć producent — Część 1: Wymagania ogólne
	15	EN ISO 374-1: 2016+A1: 2018	Rękawice ochronne przed niebezpiecznymi substancjami chemicznymi i mikroorganizmami — Część 1: Terminologia i wymagania dotyczące skuteczności w odniesieniu do zagrożeń chemicznych
	16	EN ISO 374-2: 2019	Rękawice ochronne przed niebezpiecznymi substancjami chemicznymi i mikroorganizmami — Część 2: Określanie odporności na przenikanie
	17	EN ISO 374-4: 2019	Rękawice ochronne przed substancjami chemicznymi i mikroorganizmami — Część 4: Określanie odporności na degradację pod wpływem substancji chemicznych
	18	EN ISO 374-5: 2016	Rękawice ochronne przed niebezpiecznymi substancjami chemicznymi i mikroorganizmami — Część 5:

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

			Terminologia i wymagania dotyczące skuteczności w odniesieniu do zagrożeń mikroorganizmami
	19	EN 16523-1: 2015+A1: 2018	Oznaczanie odporności materiałów na przenikanie substancji chemicznych - Część 1: Przenikanie substancji chemicznych w stanie ciekłym w warunkach ciągłego kontaktu
	20	EN ISO 21420:2020	Rękawice ochronne - Ogólne wymagania i metody badań
	21	ASTM D 6978-05:2019	Standardowa praktyka oceny odporności rękawiczek medycznych na przenikanie leków chemioterapeutycznych
	22	ASTMF1671/F1671-13	Standardowa metoda badania odporności materiałów stosowanych w odzieży ochronnej na przenikanie patogenów przenoszonych drogą krwi z wykorzystaniem penetracji bakteriofaga Phi-X174 jako systemu testowego

My, My Ticaret ve Medikal A.S. niniejszym oświadczamy, że wyżej wymienione produkt:

• Jest zgodny z ogólnym wymogiem bezpieczeństwa w zakresie wydajności rozporządzenia w sprawie wyrobów medycznych (MDR) 2017/745. Wszelka dokumentacja pomocnicza jest przechowywana w siedzibie producenta.

• Rękawice są produkowane zgodnie z normami EN ISO 9001:2015 i EN ISO 13485:2016 System zarządzania jakością.

• Przeszedł badanie typu UE zgodnie z przepisami nowych przepisów dotyczących środków ochrony osobistej (UE) 2016/425 kategorii III jednostki notyfikowanej nr 2777 przez SATRA Technology Europe Ltd.

• Jest zgodny z typem w oparciu o zapewnienie jakości procesu produkcji pod nadzorem jednostki notyfikowanej nr 2777 przez SATRA Technology Europe Ltd.

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

• Niniejsza Deklaracja zgodności UE została sporządzona zgodnie z Załącznikiem IV do rozporządzenia w sprawie wyrobów medycznych (UE) 2017/745

Podpisujący upoważniony:

Zatwierdzający : MURAT YILDIZ

Tytuł : General Manager/CEO

Podpis :

Data zatwierdzenia : 24 Września 2024

Miejsce zatwierdzenia : Istanbul, Turcja

CE

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ITC-003
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	E-Care
Product Description	Nitrile Powder Free Examination and Protective Gloves
Intended Purpose	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.
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue Number	ENVXS00, ENVS01, ENVM02, ENVL03, ENVXL04
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation
2	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
3	ISO 9001: 2015	Quality management systems – requirements
4	EN 455-1: 2020	Requirements and testing for freedom from holes
5	EN 455-2: 2015	Requirements and testing for physical properties
6	EN 455-3: 2015	Requirements and testing for biological evaluation

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	7	EN 455-4: 2009	Requirements and testing for shelf-life determination
	8	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	9	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- This EU Declaration of Conformity is prepared in accordance to Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 07 Dec 2023

Place of Approval : Istanbul, Turkey

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ITC-004
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Mumu Guard DV
Product Description	Nitrile Powder Free Examination and Protective Gloves
Intended Purpose	A patient examination glove is a medical device intended for a medical purpose that is worn on the examiners hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except surgery.
Basic UDI-DI	868302002NPVQ
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue/Reference Number	MGDV01-XS, MGDV02-S, MGDV03-M, MGDV04-L, MGDV05-XL
Product Group Reference Number	SNBE20013, SNBE20014, SNBE20015, SNBE20016, SNBE20017
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	2777/14815-03/E00-00
Notified Body (PPER)	**EU-Type Examination** and **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation
2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
3	ISO 13485: 2016	Medical devices - Quality management systems -

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

			Requirements for regulatory purposes
	4	ISO 9001: 2015	Quality management systems – requirements
	5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	6	EN 455-1: 2020	Requirements and testing for freedom from holes
	7	EN 455-2: 2015	Requirements and testing for physical properties
	8	EN 455-3: 2015	Requirements and testing for biological evaluation
	9	EN 455-4: 2009	Requirements and testing for shelf-life determination
	10	ISO 10993-1: 2018	Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process
	11	ISO 10993-10: 2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
	12	ISO 10993-11: 2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
	13	ISO 20417:2021	Medical Devices- Information to be supplied by the manufacturer
	14	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	15	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	16	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	17	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
	18	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	19	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
	20	ASTM D 6978-05:2019	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
	21	ASTMF1671/F1671-13	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentations are retained under the premise of manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following to the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2777 by SATRA Technology Europe Ltd.
- Is in conformity to type based on quality assurance of the production process under surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance to Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ Ömerli Mah. General Şükrü Koraltı Cad No:33 Arnavutköy/İSTANBUL Büyükçekmece V.D.626 040 4605 Tel:0212 438 20 64 Fax:0212 438 20 65 www.mymedikal.com

Signature :

Approval Date : 15 Feb 2024

Place of Approval : Istanbul, Turkey

CE

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ITC-005
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	INF4MEDIA
Product Description	Nitrile Powder Free Examination and Protective Gloves
Intended Purpose	A patient examination glove is a medical device intended for a medical purpose worn on the examiner's hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except surgery.
Basic UDI-DI	868302002NPVQ
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue/Reference Number	IN4MN01-XS, IN4MN02-S, IN4MN03-M, IN4MN04-L, IN4MN05-XL
Product Group Reference Number	SNBE20013, SNBE20014, SNBE20015, SNBE20016, SNBE20017
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	2777/14815-03/E63-02
Notified Body (PPER)	**EU-Type Examination** and **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
	3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	4	ISO 9001: 2015	Quality management systems – requirements
	5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	6	EN 455-1: 2020	Requirements and testing for freedom from holes
	7	EN 455-2: 2015	Requirements and testing for physical properties
	8	EN 455-3: 2015	Requirements and testing for biological evaluation
	9	EN 455-4: 2009	Requirements and testing for shelf-life determination
	10	ISO 10993-1: 2018	Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process
	11	ISO 10993-10: 2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
	12	ISO 10993-11: 2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
	13	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	14	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	15	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	16	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	17	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	18	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
	19	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
	20	ASTM D 6978-05:2019	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
	21	ASTMF1671/F1671-13	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2777 by SATRA Technology Europe Ltd.
- Is in conformity to type based on quality assurance of the production process under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad
No:33 Arnavutköy/İSTANBUL
Büyükçekmece V.D.626 040 4605
Tel:0212 438 20 64 Fax:0212 438 20 65
www.mymedikal.com

Approval Date : 15 Feb 2024

Place of Approval : Istanbul, Turkey

CE

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ITC-006
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Mumu Protect
Product Description	Nitrile Powder Free Examination and Protective Gloves
Intended Purpose	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 surgery.
Basic UDI-DI	868302002NPVQ
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue/Reference Number	MP01-XS, MP02-S, MP03-M, MP04-L, MP05-XL
Product Group Reference Number	SNBE20013, SNBE20014, SNBE20015, SNBE20016, SNBE20017
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	2777/14815-03/E63-02
Notified Body (PPER)	**EU-Type Examination** and **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
	3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	4	ISO 9001: 2015	Quality management systems – requirements
	5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	6	EN 455-1: 2020	Requirements and testing for freedom from holes
	7	EN 455-2: 2015	Requirements and testing for physical properties
	8	EN 455-3: 2015	Requirements and testing for biological evaluation
	9	EN 455-4: 2009	Requirements and testing for shelf-life determination
	10	ISO 10993-1: 2018	Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process
	11	ISO 10993-10: 2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
	12	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	13	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	14	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	15	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	16	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
	17	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

			and performance requirements for micro-organisms risks
	18	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
	19	EN ISO 21420:2020	Protective gloves – General requirements and test methods
	20	ASTM D 6978-05:2019	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
	21	ASTMF1671/F1671-13	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2777 by SATRA Technology Europe Ltd.
- Is in conformity to type based on quality assurance of the production process under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 15 Feb 2024

Place of Approval : Istanbul, Turkey

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ITC-007
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Mumu Maxima
Product Description	Nitrile Powder Free Examination and Protective Gloves
Intended Purpose	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.
Basic UDI-DI	868302002NPVQ
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue/Reference Number	MMNPF01-XS, MMNPF02-S, MMNPF03-M, MMNPF04-L, MMNPF05-XL
Product Group Reference Number	SNBE20013, SNBE20014, SNBE20015, SNBE20016, SNBE20017
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	2777/14815-03/E63-02
Notified Body (PPER)	**EU-Type Examination** and **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
	3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	4	ISO 9001: 2015	Quality management systems – requirements
	5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	6	EN 455-1: 2020	Requirements and testing for freedom from holes
	7	EN 455-2: 2015	Requirements and testing for physical properties
	8	EN 455-3: 2015	Requirements and testing for biological evaluation
	9	EN 455-4: 2009	Requirements and testing for shelf-life determination
	10	ISO 10993-1: 2018	Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process
	11	ISO 10993-10: 2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
	12	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	13	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	14	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	15	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	16	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
	17	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

			and performance requirements for micro-organisms risks
	18	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
	19	EN ISO 21420:2020	Protective gloves – General requirements and test methods
	20	ASTM D 6978-05:2019	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
	21	ASTMF1671/F1671-13	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation are retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2777 by SATRA Technology Europe Ltd.
- Is in conformity to type based on quality assurance of the production process under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ Ömerli Mah. General Şükrü Koraltı Cad No:33 Arnavutköy/İSTANBUL Büyükçekmece V.D.626 040 4605 Tel:0212 438 20 64 Fax:0212 438 20 65 mymedikal.com

Approval Date : 15 Feb 2024

Place of Approval : Istanbul, Turkey

CE

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ITC-008
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Simplistic
Product Description	Nitrile Powderfree Gloves
Intended Purpose	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.
Basic UDI-DI	868302002NPVQ
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue Number	SMITCNPF01-XS, SMITCNPF02-S, SMITCNPF03-M, SMITCNPF04-L, SMITCNPF05-XL
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII
Device Classification (PPER)	Category I (For minimal risk only)
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation
2	PPE (EU) 2016/425	Personal Protective Equipment Regulation (Category I- *For minimal risk only*)
3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
4	ISO 9001: 2015	Quality management systems – requirements
5	ISO 14971: 2019	Medical devices - application of risk

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

			management to medical devices
	6	EN 455-1: 2020	Requirements and testing for freedom from holes
	7	EN 455-2: 2015	Requirements and testing for physical properties
	8	EN 455-3: 2015	Requirements and testing for biological evaluation
	9	EN 455-4: 2009	Requirements and testing for shelf-life determination
	10	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	11	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following the PPE Regulations (EU) 2016/425 Category I (For minimal risk only).
- This EU Declaration of Conformity is prepared in accordance to Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 19 Aug 2024

Place of Approval : Istanbul, Turkey

CE

MY TICARET VE MEDIKAL A.S.

Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ITC-009
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	ISO PLUS
Product Description	Nitrile Medical Gloves, Powderfree
Intended Purpose	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.
Basic UDI-DI	868302002NPVQ
Size	XS, S, M, L
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue Number	ISOPITCNPF01-XS, ISOPITCNPF02-S, ISOPITCNPF03-M, ISOPITCNPF04-L
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	79013032
STE Reference for Module C2 Certificate	STE7162TBF7
Notified Body (PPER)	**EU-Type Examination** by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ. Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ Istanbul, Turkey [Notified Body No.2841] **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
	3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	4	ISO 9001: 2015	Quality management systems – requirements
	5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	6	EN 455-1: 2020	Requirements and testing for freedom from holes
	7	EN 455-2: 2015	Requirements and testing for physical properties
	8	EN 455-3: 2015	Requirements and testing for biological evaluation
	9	EN 455-4: 2009	Requirements and testing for shelf-life determination
	10	ISO 10993-1: 2018	Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process
	11	ISO 10993-10: 2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
	12	ISO 10993-11: 2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
	13	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	14	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	15	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	16	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	17	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	18	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
	19	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
	20	ASTM D 6978-05:2019	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
	21	ASTMF1671/F1671-13	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2841 by MNA Laboratuvarlari San. Tic.Ltd.Sti.
- Is in conformity to type based on the quality control system for the final product under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 01 Mar 2024

Place of Approval : Istanbul, Turkey

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ITC-010
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	MUMU PLUS+
Product Description	Nitrile Powderfree Examination and Protective Gloves
Intended Purpose	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.
Basic UDI-DI	868302002NPVQ
Size	XS, S, M, L
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue Number	MN01
Conformity Assessment Route	Annex II and Annex III
Classification & Rule	Class I, Rule 1 & Rule 5
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	79013032
STE Reference for Module C2 Certificate	STE7162TBF7
Notified Body (PPER)	**EU-Type Examination** by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ. Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ Istanbul, Turkey [Notified Body No.2841] **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	PPE (EU) 2016/425	Personal Protective Equipment Regulation
2	ISO 13485: 2016	Medical devices - Quality management systems -

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

			Requirements for regulatory purposes
	3	ISO 9001: 2015	Quality management systems – requirements
	4	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	5	EN 455-1: 2020	Requirements and testing for freedom from holes
	6	EN 455-2: 2015	Requirements and testing for physical properties
	7	EN 455-3: 2015	Requirements and testing for biological evaluation
	8	EN 455-4: 2009	Requirements and testing for shelf-life determination
	9	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	10	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	11	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	12	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	13	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
	14	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
	15	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2841 by MNA Laboratuvarlari San. Tic.Ltd.Sti.
- Is in conformity to type based on the quality control system for the final product under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 19.April.2024

Place of Approval : Istanbul, Turkey

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-SSG-001
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Mumu Plus+
Product Description	Nitrile Powder Free Examination and Protective Gloves
Intended Purpose	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.
Basic UDI-DI	868302002NPVQ
Size	S, M, L, XL
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue Number	MPNSS01-S; MPNSS02-M; MPNSS03-L; MPNSS04-XL
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	79013032
STE Reference for Module C2 Certificate	STE7162TBF7
Notified Body (PPER)	**EU-Type Examination** by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ. Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ Istanbul, Turkey [Notified Body No.2841] **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]
Applicable Standards	No. / Regulation/ Standard Number / Regulation/ Standard Name

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	1	MDR (EU) 2017/745	Medical Device Regulation
	2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
	3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	4	ISO 9001: 2015	Quality management systems – requirements
	5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	6	EN 455-1: 2020	Requirements and testing for freedom from holes
	7	EN 455-2: 2015	Requirements and testing for physical properties
	8	EN 455-3: 2015	Requirements and testing for biological evaluation
	9	EN 455-4: 2009	Requirements and testing for shelf-life determination
	10	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	11	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	12	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	13	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	14	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
	15	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
	16	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

			liquid chemical under conditions of continuous contact
	17	EN ISO 21420:2020	Protective gloves – General requirements and test methods

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2841 by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.
- Is in conformity to type based on the quality control system for the final product under the surveillance of the notified body number 2777 by SATRA TECHNOLOGY EUROPE LTD.
- This EU Declaration of Conformity is prepared in accordance to Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 01 Mar 2024

Place of Approval : Istanbul, Turkey

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-SSG-002
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Aldena
Product Description	Nitrile Powder Free Gloves
Intended Purpose	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.
Basic UDI-DI	868302002NPVQ
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue Number	NBK30XS, NBK30S, NBK30M, NBK30L, NBK30XL
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	79013032
STE Reference for the Module C2 Certificate	STE7162TBF7
Notified Body Number (PPER)	**EU-Type Examination** by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ. Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ Istanbul, Turkey [Notified Body No.2841] / **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	1	MDR (EU) 2017/745	Medical Device Regulation
	2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
	3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	4	ISO 9001: 2015	Quality management systems – requirements
	5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	6	EN 455-1: 2020	Requirements and testing for freedom from holes
	7	EN 455-2: 2015	Requirements and testing for physical properties
	8	EN 455-3: 2015	Requirements and testing for biological evaluation
	9	EN 455-4: 2009	Requirements and testing for shelf-life determination
	10	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	11	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	12	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	13	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	14	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
	15	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
	16	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

			liquid chemical under conditions of continuous contact
	17	EN ISO 21420:2020	Protective gloves – General requirements and test methods

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2841 by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.
- Is in conformity to type based on the quality control system for the final product under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance to Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 01 Mar 2024

Place of Approval : Istanbul, Turkey

MY TICARET VE MEDIKAL A.S.

Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-TG-006
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd No:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Mumu Plus+
Product Description	Nitrile Powderfree Examination and Protective Gloves
Intended Purpose	A patient examination glove is a medical device intended for a medical purpose that is worn on the examiners hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except surgery.
Size	XS, S, M, L, XL
Colors	Blue, Cool Blue, Black
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue Number	MN01
Conformity Assessment Route	Annex VII
Classification & Rule	Class I, Rule 5
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	67070898
Notified Body (PPER)	**EU-Type Examination** by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ. Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ Istanbul, Turkey [Notified Body No.**2841**] / **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [Notified Body No. **2777]**
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	PPE (EU) 2016/425	Personal Protective Equipment Regulation
2	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
3	ISO 9001: 2015	Quality management systems – requirements

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	4	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	5	EN 455-1: 2020	Requirements and testing for freedom from holes
	6	EN 455-2: 2015	Requirements and testing for physical properties
	7	EN 455-3: 2015	Requirements and testing for biological evaluation
	8	EN 455-4: 2009	Requirements and testing for shelf-life determination
	9	ISO 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
	10	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	11	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer
	12	EN ISO 21420:2020	Protective gloves – General requirements and test methods
	13	EN ISO 374-1: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	14	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
	15	MDR 2017/745	Medical Device Regulation

We, My Ticaret ve Medikal A.S., herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following to the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2841 by MNA Laboratuvarlari San. Tic.Ltd.Sti.
- Is in conformity to type based on the quality control system for the final product under the surveillance of the notified body number 2777 by SATRA TECHNOLOGY EUROPE LTD.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 05 Aug 2024

Place of Approval : Istanbul, Turkey

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-TG-008
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd No:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	ISO
Product Description	Nitrile Medical Gloves, Powder Free
Intended Purpose	A patient examination glove is a medical device intended for a medical purpose that is worn on the examiners hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except surgery.
Size	XS, S, M, L
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue Number	ISONLC01-XS, ISONLC01-S, ISONLC01-M, ISONLC01-L
Conformity Assessment Route	Annex VII
Classification & Rule	Class I, Rule 5
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	79013032
STE Reference for Module C2 Certificate	STE7162T8F7
Notified Body (PPER)	**EU-Type Examination** by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ. Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ Istanbul, Turkey [Notified Body No.**2841**] / **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	PPE (EU) 2016/425	Personal Protective Equipment Regulation
2	ISO 13485: 2016	Medical devices - Quality management systems -

MY TICARET VE MEDIKAL A.S.

Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

		Requirements for regulatory purposes
3	ISO 9001: 2015	Quality management systems – requirements
4	ISO 14971: 2019	Medical devices - application of risk management to medical devices
5	EN 455-1: 2020	Requirements and testing for freedom from holes
6	EN 455-2: 2015	Requirements and testing for physical properties
7	EN 455-3: 2015	Requirements and testing for biological evaluation
8	EN 455-4: 2009	Requirements and testing for shelf-life determination
9	ISO 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
10	EN 1041: 2008+A1: 2013	Information supplied by the manufacturer of medical devices
11	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer
12	EN ISO 21420:2020	Protective gloves — General requirements and test methods
13	EN ISO 374-1: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
14	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following to the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2841 by MNA Laboratuvarlari San. Tic.Ltd.Sti.
- Is in conformity to type based on the quality control system for the final product under the surveillance of the notified body number 2777 by SATRA TECHNOLOGY EUROPE LTD.

Authorized Signatory:

Approver : MURAT YILDIZ
Title : General Manager/CEO
Signature :
Approval Date : 01 Mar 2024
Place of Approval : Istanbul, Turkey

CE

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ZBS-001
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Mumu Guard
Product Description	Nitrile Powder Free Examination and Protective Gloves
Intended Purpose	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.
Basic UDI-DI	868302002NPVQ
Size	XS, S, M, L, XL
EAN Codes	**Blue:** 8684266526195, 8684266526201, 8684266526218, 8684266526225, 8684266526232 8683020024878, 8683020024885, 8683020024892, 8683020024908, 8683020024915 **Black:** 8684266526317, 8684266526324, 8684266526331, 8684266526348, 8684266526355 8684266521374, 8684266521381, 8684266521398, 8684266521404, 8684266521411
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue/ Reference Number	**Blue:** MGBSNPF01-XS, MGBSNPF02-S, MGBSNPF03-M, MGBSNPF04-L, MGBSNPF05-XL

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	Black: MGBBSNPF01-XS, MGBBSNPF02-S, MGBBSNPF03-M, MGBBSNPF04-L, MGBBSNPF05-XL
Product Group Reference Number	**Blue:** BS0102016, BS0102017, BS0102018, BS0102019, BS0102020 **Black:** BS0102056, BS0102057, BS0102058, BS0102059, BS0102060
Conformity Assessment Route (MDR):	Article 52(7) and Annex VIII, 4.1 Rule 1, Non-invasive, and/or 5.1 Intended for transient use, Rule 5 of invasive device
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	2777/21024-02/E13-02
Notified Body (PPER)	**EU-Type Examination** and **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation
2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
4	ISO 9001: 2015	Quality management systems – requirements
5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
6	EN 455-1: 2020	Requirements and testing for freedom from holes
7	EN 455-2: 2015	Requirements and testing for physical properties
8	EN 455-3: 2015	Requirements and testing for biological evaluation

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	9	EN 455-4: 2009	Requirements and testing for shelf-life determination
	10	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	11	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	12	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	13	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	14	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
	15	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
	16	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
	17	EN ISO 21420:2020	Protective gloves — General requirements and test methods

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System
- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2777 by SATRA Technology Europe Ltd.

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

- Is in conformity to type based on quality assurance of the production process under surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 04 Feb 2024

Place of Approval : Istanbul, Turkey

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ZBS-002
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Inf4media
Product Description	Nitrile Powder Free Examination and Protective Gloves
Intended Purpose	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.
Basic UDI-DI	868302002NPVQ
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue/Reference Number	INFZBSN01-XS, INFZBSN02-S, INFZBSN03-M, INFZBSN04-L, INFZBSN05-XL
Product Group Reference Number	BS0102016, BS0102017, BS0102018, BS0102019, BS0102020
Conformity Assessment Route (MDR):	Article 52(7) and Annex VIII, 4.1 Rule 1, Non-invasive, and/or 5.1 Intended for transient use, Rule 5 of invasive device.
Classification (MDR)	Class I
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	2777/21024-02/E00-00
Notified Body (PPER)	**EU-Type Examination** and **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

Applicable Standards

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation
2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
4	ISO 9001: 2015	Quality management systems – requirements
5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
6	EN 455-1: 2020	Requirements and testing for freedom from holes
7	EN 455-2: 2015	Requirements and testing for physical properties
8	EN 455-3: 2015	Requirements and testing for biological evaluation
9	EN 455-4: 2009	Requirements and testing for shelf-life determination
10	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
11	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
12	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
13	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
14	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
15	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

MY TICARET VE MEDIKAL A.S.
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey
Tel: +902124382064 Fax: +902124382065
Website: www.mymedikal.com.tr.

	16	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
	17	EN ISO 21420:2020	Protective gloves — General requirements and test methods

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2777 by SATRA Technology Europe Ltd.
- Is in conformity to type based on quality assurance of the production process under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature : MY TICARET VE MEDİKAL ANONİM ŞİRKETİ Ömerli Mah. General Şükrü Koraltı Cad No:33 Arnavutköy/İSTANBUL Büyükçekmece V.D.626 040 4605 Tel:0212 438 20 64 Fax:0212 438 20 65 www.mymedikal.com

Approval Date : 16 Feb 2024

Place of Approval : Istanbul, Turkey

CE

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

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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.

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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.

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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
T. +90 212 438 20 64
F. +90 212 438 20 65

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.

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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.

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

	Non-sterile
EN455	European Standard

MY TİCARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mh.General Şükrü Koraltı Cad
No:33 Arnavutkoy/İSTANBUL
B.ÇEKMECE V.D.6260404505
tl:0212 436 20 64 Fax:0212 436 20 65
www.mymedikal.com

As of 23 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 Harmonised 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 Guard	MGBSNPF01-XS, MGBSNPF02-S, MGBSNPF03-M, MGBSNPF04-L, MGBSNPF05-XL MGBBSNPF01-XS, MGBBSNPF02-S, MGBBSNPF03-M, MGBBSNPF04-L, MGBBSNPF05-XL
Mumu Plus	MPZBSN01-XS, MPZBSN02-S, MPZBSN03-M, MPZBSN04-L, MPZBSN05-XL
Inf4media	INFZBSN01-XS, INFZBSN02-S, INFZBSN03-M, INFZBSN04-L, INFZBSN05-XL
Aldena	NRB35XS, NRB35S, NRB35M, NRB35L, NRB35XL ALBZBSN01-XS, ALBZBSN02-S, ALBZBSN03-M, ALBZBSN04-L, ALBZBSN05-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%**	EN ISO 374-1:2016+A1:2018/Type B

40% Sodium Hydroxide (K)	6	-33.5
30% Hydrogen Peroxide (P)	4	22.1
37% Formaldehyde (T)	6	-0.3

KPT

EN ISO 374-5:2016

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

Virus

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 penetration resistance and 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 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 the 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 defect or imperfections.”

“This product is free from Natural Rubber Allergies”.

“After use wearers should visually check the gloves and remove any contamination from the outer surface before removing the gloves from the hand. Alternatively, carefully peel the glove off the hand so that the contaminated glove outer does not touch your skin.”

“Gloves are worn on the hands of the healthcare and similar personnel to prevent contamination between the healthcare personnel and the patient/user.”

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

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 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 (2777)

Product manufactured by: MY TICARET VE MEDIKAL A.Ş.
Omerli Mahallesi General Sukru Koralti Cad. No. 33, 34555
Arnavutkoy/Istanbul/Turkiye

. 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

MY TİCARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mh.General Şükrü Koraltı Cad
No:33 Arnavutkoy/İSTANBUL
B.ÇEKMECE V.D.6260404605
tl:0212 436 20 64 Fax:0212 436 20 65
www.mymedikal.com

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:
Mumu Plus: MPNSS01-S, MPNSS02-M, MPNSS03-L, MPNSS04-XL
Aldena: NBK30S, NBK30M, NBK30L, NBK30XL

Sizes available: S, M, L, XL

Colour: Black

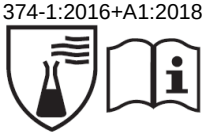
Intended Use:
A patient examination glove is a medical device intended for a medical purpose that is worn on the examiner's hand or finger to prevent contamination between the patient and examiner. Examination glove is intended for medical activities except for surgery.

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	-36.4
30% Hydrogen Peroxide (P)	2	37.5
37% Formaldehyde (T)	5	-5.3

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



KPT

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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.

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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.

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

MY TİCARET VE

As of 05 Aug 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.

Nitrile Powderfree Examination and Protective Gloves

Brand	Catalog No./Ref. No./ Models
Mumu Plus	MN01

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

Color: 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:

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.

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

Notified Bodies responsible for certification and ongoing conformity:

EU-Type Examination	**Ongoing Conformity**
by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ. Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ Istanbul, Turkey [Notified Body No.**2841**]	by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]

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

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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

As of 17 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

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

Color: Blue

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:

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

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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.

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

Notified Bodies responsible for certification and ongoing conformity:

EU-Type Examination	**Ongoing Conformity**
by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ. Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ Istanbul, Turkey [Notified Body No.**2841**]	by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]

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

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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

As of 19 Aug 2024

USER INFORMATION

CE	This product complies with PPE Regulation 2016/425 Cat I (For minimal risk only).

Product reference:
Blue:
Simplistic Nitrile Powder Free Gloves: SMITCNPF01-XS, SMITCNPF02-S, SMITCNPF03-M, SMITCNPF04-L, SMITCNPF05-XL

Colour: Blue

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.

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.

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65

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.

CE	This product also complies 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

MY TİCARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mh.General Şükrü Koraltı Cad
No:33 Arnavutkoy/İSTANBUL
B.ÇEKMECE V.D.6260404505
tl:0212 436 20 64 Fax:0212 436 20 65
www.mymedikal.com

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No: 33 Arnavutköy/İstanbul
T. +90 212 438 20 64
F. +90 212 438 20 65