

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDİKAL-SRT-002
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDİKAL 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
Product Description	Powdered Latex Examination 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	868227994LP5H
Size	XS, S, M, L, XL
EAN Code	8683020022980, 8681695367078, 8681695367085, 8681695367092, 8683020021860
Country of Origin	Thailand
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)
Global Medical Device Nomenclature (GMDN)	47173 (Latex examination/treatment glove, powdered)
Product Catalogue/Reference Number	MLP01-XS, MLP02-S, MLP03-M, MLP04-L, MLP05-XL
Product Group Reference Number	LX01
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 5 transient use according to Annex VIII
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	2777/10468-05/E05-01
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 Medikal

MY TICARET VE MEDİKAL 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 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization	
11	ISO 20417: 2021	Medical Devices- Information to be supplied by the manufacturer	
12	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer	
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 374-2:2014	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration	
15	EN ISO 374-4:2013	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals	
16	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology	

			and performance requirements for micro-organisms risks
	17	EN 16523-1: 2015	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:

- 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 : 23 Sep 2024
Place of Approval : Istanbul, Turkey

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mahallesi General Şükrü Koraltı Cad
No:33 Arnavutköy/İSTANBUL
Büyükdere Şişli V.D.826 040 4605
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www.mymedikal.com



DEKLARACJA ZGODNOŚCI UE

Nr Dokumentu	DOC-MYMEDIKAL-SRT-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, Turkey
Jednolity numer rejestracyjny (SRN)	TR-MF-000018372
Marka	Mumu
Opis produktu	Rękawice lateksowe medyczne, pudrowane
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	868227994LP5H
Kraj pochodzenia	XS, S, M, L, XL
Rozmiary	8683020022980, 8681695367078, 8681695367085, 8681695367092, 8683020021860
KOD EAN	Thailand
Europejska Nomenklatura Wyrobów Medycznych (EMDN)	T010201 (Rękawiczki do badań/leczenia, lateksowe)
Globalna nomenklatura wyrobów medycznych (GMDN)	47173 (Lateksowa rękawica do badań/zabiegów, pudrowana)
Katalog produktów/Numer referencyjny	MLP01-XS, MLP02-S, MLP03-M, MLP04-L, MLP05-XL
Jednolity numer rejestracyjny (SRN)	LX01
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 użytkowanie przejściowe zgodnie z załącznikiem VIII
Klasyfikacja urządzeń (PPER)	Kategoria III
EU Type-Examination Certificate (PPER)	2777/10468-05/E05-01



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Certyfikat badania UE (PPER)	Badanie typu UE i ciągła zgodność przez jednostkę notyfikowaną SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [CE 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 10993-10: 2010	Ocena biologiczna wyrobów medycznych – Część 10: Badanie działania drażniącego i uczulającego na skórę
	11	ISO 20417: 2021	Wyroby medyczne – Informacje dostarczane przez producenta
	12	ISO 15223-1: 2021	ISO 15223-1 Symbole, które należy stosować wraz z informacjami dostarczonymi przez producenta
	13	EN ISO 374-1: 2016	Rękawice ochronne przed niebezpiecznymi chemikaliami i mikroorganizmami - Część 1: Terminologia i wymagania



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			dotyczące skuteczności w odniesieniu do zagrożeń chemicznych
	14	EN ISO 374-2:2014	Rękawice ochronne przed niebezpiecznymi chemikaliami i mikroorganizmami - Część 2: Określanie odporności na przenikanie
	15	EN ISO 374-4:2013	Rękawice ochronne przed chemikaliami i mikroorganizmami - Część 4: Określanie odporności na degradację przez chemikalia
	16	EN ISO 374-5: 2016	Rękawice ochronne przed niebezpiecznymi chemikaliami i mikroorganizmami - Część 5: Terminologia i wymagania dotyczące skuteczności w odniesieniu do zagrożeń mikroorganizmami
	17	EN 16523-1: 2015	Oznaczanie odporności materiałów na przenikanie substancji chemicznych - Część 1: Przenikanie substancji chemicznych w stanie ciekłym w warunkach ciągłego kontaktu

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.

- 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

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
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Büyükdere Meydanı V.D.626 040 4605
Tel:0212 438 20 64 Fax:0212 438 20 65
www.mymedikal.com

Data zatwierdzenia : 24 Września 2024

Miejsce zatwierdzenia : Istanbul, Turcja

CE

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ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

Πιστοποιητικό ΕΚ	Δεν ισχύει (Αυτοδήλωση)		
Κατασκευαστής	MY TICARET VE MEDİKAL A.S.		
Διεύθυνση Κατασκευαστή	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Τουρκία		
Ενιαίος Αριθμός Μητρώου (SRN)	TR-MF-000018372		
Μάρκα	Mumu		
Περιγραφή Προϊόντος	Γάντια εξεταστικά από λάτεξ με πούδρα		
Προβλεπόμενος Σκοπός	Το εξεταστικό γάντι ασθενούς είναι ένα ιατροτεχνολογικό προϊόν που προορίζεται για ιατρικούς σκοπούς που φοριέται στο χέρι ή στο δάχτυλο του εξεταστή για την πρόληψη μόλυνσης μεταξύ του ασθενούς και του εξεταστή. Το εξεταστικό γάντι προορίζεται για ιατρικές δραστηριότητες εκτός από χειρουργική επέμβαση.		
Βασικός UDI-DI	868227994LP5H		
Μέγεθος	XS, S, M, L, XL		
Ευρωπαϊκή Ονοματολογία Ιατροτεχνολογικών Προϊόντων (EMDN)	T010201 (Γάντια Εξεταστικά/Θεραπείας, λατέξ)		
Παγκόσμια Ονοματολογία Ιατροτεχνολογικών Προϊόντων (GMDN)	47173 (Γάντια Εξεταστικά/Θεραπείας λατέξ, με πούδρα)		
Αριθμός Καταλόγου Προϊόντων	MLP01-XS, MLP02-S, MLP03-M, MLP04-L, MLP05-XL		
Διαδρομή Αξιολόγησης Συμμόρφωσης (MDR):	Παράρτημα II και Παράρτημα III σύμφωνα με την ΕΕ 2017/745		
Ταξινόμηση και Κανόνας (MDR)	Κατηγορία I, Κανόνας 5 παροδική χρήση σύμφωνα με το παράρτημα VIII		
Ταξινόμηση Συσκευών (PPER)	Κατηγορία III		
Αριθμός Αναφοράς Ομάδας Προϊόντων	LX01		
Πιστοποιητικό Εξέτασης Τύπου ΕΕ (PPER)	2777/10468-05/E05-01		
Αριθμός Κοινοποιημένου Οργανισμού (PPER)	2777		
Πιστοποιητικό Εξέτασης Τύπου ΕΕ που εκδίδεται από (PPER)	SATRA Technology Europe Limited Bracetown Business Park, Clonee, D15YN2P, Ιρλανδία		
Ισχύοντα Πρότυπα	Αρ.	Αριθμός Κανονισμού/Προτύπου	Ονομασία Κανονισμού/Προτύπου
	1	MDR (ΕΕ) 2017/745	Κανονισμός περί ιατροτεχνολογικών προϊόντων
	2	PPE (ΕΕ) 2016/425	Κανονισμός περί ΜΑΠ
	3	ISO 13485: 2016	Ιατροτεχνολογικά Προϊόντα - Συστήματα Διαχείρισης Ποιότητας

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		- Απαιτήσεις για Ρυθμιστικούς Σκοπούς
4	ISO 9001:2015	Συστήματα Διαχείρισης Ποιότητας – Απαιτήσεις
5	ISO 14971: 2019	Ιατροτεχνολογικά Προϊόντα - Εφαρμογή Διαχείρισης Κινδύνου σε Ιατροτεχνολογικά Προϊόντα
6	EN 455-1:2020	Απαιτήσεις και δοκιμές για την απουσία σπών
7	EN 455-2: 2015	Απαιτήσεις και δοκιμές για φυσικές ιδιότητες
8	EN 455-3: 2015	Απαιτήσεις και δοκιμές για βιολογική αξιολόγηση
9	EN 455-4:2009	Απαιτήσεις και δοκιμές για τον προσδιορισμό του χρόνου αποθήκευσης
10	ISO 10993-10: 2010	Βιολογική αξιολόγηση ιατροτεχνολογικών προϊόντων – Μέρος 10: Δοκιμή για ερεθισμό και ευαισθητοποίηση του δέρματος
11	ISO 20417: 2021	Ιατροτεχνολογικά Προϊόντα - Πληροφορίες που πρέπει να παρέχονται από τον κατασκευαστή
12	ISO 15223-1: 2021	ISO 15223-1 Σύμβολα που θα χρησιμοποιηθούν με πληροφορίες που πρέπει να παρέχονται από τον κατασκευαστή
13	EN ISO 374-1:2016	Προστατευτικά γάντια έναντι επικίνδυνων χημικών ουσιών και μικροοργανισμών - Μέρος 1: Απαιτήσεις ορολογίας και απόδοσης για χημικούς κινδύνους
14	EN ISO 374-2:2014	Προστατευτικά γάντια έναντι επικίνδυνων χημικών και μικροοργανισμών - Μέρος 2: Προσδιορισμός αντοχής στη διείσδυση
15	EN ISO 374-4:2013	Προστατευτικά γάντια έναντι χημικών ουσιών και μικροοργανισμών - Μέρος 4: Προσδιορισμός αντοχής στην αποικοδόμηση από χημικές ουσίες
16	EN ISO 374-5: 2016	Προστατευτικά γάντια έναντι επικίνδυνων χημικών ουσιών και μικροοργανισμών - Μέρος 5: Απαιτήσεις ορολογίας και απόδοσης για κινδύνους μικροοργανισμών
17	EN 16523-1: 2015	Προσδιορισμός της αντοχής του υλικού στη διείσδυση από χημικά - Μέρος 1: Διαπέραση από υγρό χημικό υπό συνθήκες συνεχούς επαφής

ΔΑΜΑΣΚΙΤΩ
ΔΙΚΗΓΟΡ
ΚΟΥΝΤΟΥΡΙΔΟΥ
ΑΦΜ: 0447514
e-mail: ddam

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Εμείς, η My Ticaret ve Medikal AS δηλώνουμε δια του παρόντος ότι η προαναφερθείσα συσκευή:

- Συμμορφώνεται με τη Γενική Απαίτηση Επιδόσεων Ασφαλείας του Κανονισμού περί Ιατροτεχνολογικών Προϊόντων (MDR) 2017/745. Όλη η δικαιολογητική τεκμηρίωση φυλάσσεται υπό τις προϋποθέσεις του κατασκευαστή.
- Τα γάντια κατασκευάζονται σύμφωνα με το Σύστημα Διαχείρισης Ποιότητας EN ISO 9001:2015 και EN ISO 13485:2016.
- Παρακολουθεί την εξέταση τύπου ΕΕ και συμμορφώνεται με τις διατάξεις των νέων κανονισμών ΜΑΠ (ΕΕ) 2016/425 Κατηγορία III του Κοινοποιημένου Οργανισμού με αριθμό 2777 από την SATRA Technology Europe Ltd.
- Είναι σύμφωνο με τον τύπο με βάση τη διασφάλιση ποιότητας της παραγωγικής διαδικασίας υπό την επιτήρηση του κοινοποιημένου οργανισμού με αριθμό 2777 από την SATRA Technology Europe Ltd.
- Η παρούσα Δήλωση Συμμόρφωσης ΕΕ συντάσσεται σύμφωνα με το Παράρτημα IV του Κανονισμού περί Ιατροτεχνολογικών Προϊόντων (ΕΕ) 2017/745.

Εξουσιοδοτημένος Υπογράφοντας:

Εγκριτής : MURAT YILDIZ
Τίτλος : Γενικός Διευθυντής/Διευθύνων Σύμβουλος
Υπογραφή : 29 Νοεμβρίου 2023
Ημερομηνία έγκρισης
Τόπος Έγκρισης : Κωνσταντινούπολη, Τουρκία

(Λογότυπο)

Ακριβής μετάφραση στην Ελληνική του συνημμένου εγγράφου,
συντεταγμένου στην γλώσσα, σύμφωνα με το
άρθρο 36 παρ. 2δ' του Κώδικα περί Δικηγόρων. (N. 4194/2013)
Θεσσαλονίκη, 05-02-2024
Ο μεταφράσας και επικυρών Δικηγόρος
(που βάσει του άρθρου 8 του Ν. 1599/1986 υπευθύνως δηλώνει
'Ότι έχω επαρκή γνώση των δύο γλωσσών)

ΔΑΜΑΣΚΗΝΟΣ Α. ΔΑΜΑΣΚΗΝΙΔΗΣ
ΔΙΚΗΓΟΡΟΣ Α.Μ. 3822
ΚΟΥΝΤΟΥΡΙΩΤΟΥ 21 - Τ.Κ. 546 25 ΘΕΣΣΑΛΟΝΙΚΗ
ΑΦΜ: 044751419 - Α' ΔΟΥ ΘΕΣ/ΝΙΚΗΣ
e-mail: ddamaskinidis@gmail.com

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ΔΑΜΑΣΚΗΝΟΥ Α. ΔΑΜΑΣΚΗΝΙΔΗΣ
ΔΙΚΗΓΟΡΟΣ Α.Μ. 3822
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EU DECLARATION OF CONFORMITY

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												
Product Description	Powdered Latex Examination 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	868227994LP5H												
Size	XS, S, M, L, XL												
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Product Catalogue Number	MLP01-XS, MLP02-S, MLP03-M, MLP04-L, MLP05-XL												
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745												
Classification & Rule (MDR)	Class I, Rule 5 transient use according to Annex VIII												
Device Classification (PPER)	Category III												
Product Group Reference Number	LX01												
EU Type-Examination Certificate (PPER)	2777/10468-05/E05-01												
Notified Body Number (PPER)	2777												
EU Type- Examination Certificate Issued by (PPER)	SATRA Technology Europe Limited Bracetown Business Park, Clonee, D15YN2P, Ireland												
Applicable Standards	<table border="1"><thead><tr><th>No.</th><th>Regulation/ Standard Number</th><th>Regulation/ Standard Name</th></tr></thead><tbody><tr><td>1</td><td>MDR (EU) 2017/745</td><td>Medical Device Regulation</td></tr><tr><td>2</td><td>PPE (EU) 2016/425</td><td>Personal Protective Equipment Regulation</td></tr><tr><td>3</td><td>ISO 13485: 2016</td><td>Medical devices - Quality management</td></tr></tbody></table>	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
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											

ΑΜΑΖΟΝΙΑΝ
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ΔΟΥ ΘΕΣ/ΝΙΚΗΣ
dis@gmail.com



MY TICARET VE MEDİKAL A.S.

Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey

Tel: +902124382064 Fax: +902124382065

Website: www.mymedikal.com.tr.

		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 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
11	ISO 20417: 2021	Medical Devices- Information to be supplied by the manufacturer
12	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer
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 374-2:2014	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
15	EN ISO 374-4:2013	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
16	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
17	EN 16523-1: 2015	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

ΔΑΜΑΣΚΗΝΟΥ
ΔΙΚΗΓΟΡ
ΚΟΥΝΤΟΥΡΙΔΟΥ 21
ΑΦΜ: 04475141
e-mail: ddama



MY Medikal

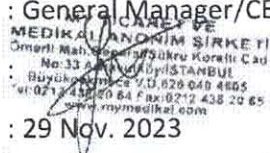
MY TICARET VE MEDİKAL A.S.

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

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 and conformity 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 : 29 Nov. 2023
 Place of Approval : Istanbul, Turkey

MY TICARET VE MEDİKAL A.Ş. ŞİRKETİ
 Ömerli Mah. No:33 Arnavutköy Caddesi
 No:33 Arnavutköy/İSTANBUL
 T. K. 0212 438 20 64 F. K. 0212 438 20 65
www.mymedikal.com

ΑΚΡΙΒΕΣ ΑΝΤΙΓΡΑΦΟ
 ΑΠΟ ΤΟ ΠΡΩΤΟΤΥΠΟ
 ΠΟΥ ΜΟΥ ΕΠΙΔΕΙΧΘΗΚΕ
 ΘΕΣ/ΝΙΚΗ 05-02-2024
 Ο ΕΠΙΚΥΡΩΝ ΔΙΚΗΓΟΡΟΣ

ΔΑΜΑΣΚΗΝΟΣ Α. ΔΑΜΑΣΚΗΝΙΔΗΣ
 ΔΙΚΗΓΟΡΟΣ Α.Μ. 3822
 ΚΟΥΝΤΟΥΡΙΩΤΟΥ 21 - Τ.Κ. 546 25 ΘΕΣΣΑΛΟΝΙΚΗ
 ΑΦΜ: 644751419 - Α/ΔΟΥ ΘΕΣ/ΝΙΚΗΣ
 e-mail: djdamaskinidis@gmail.com



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Website: www.mymedikal.com.tr

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDİKAL-SRT-004						
EC Certificate	Not applicable (Self- declared)						
Manufacturer	MY TICARET VE MEDİKAL A.S.						
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey						
Single Registration Number (SRN)	TR-MF-000018372						
Brand	B-good						
Product Description	Powdered Latex Examination 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	868227994LP5H						
Size	XS, S, M, L, XL						
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)						
Global Medical Device Nomenclature (GMDN)	47173 (Latex examination/treatment glove, powdered)						
Product Catalogue/Reference Number	BGL01-XS, BGL02-S, BGL03-M, BGL04-L, BGL05-XL						
Product Group Reference Number	LX01						
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745						
Classification & Rule (MDR)	Class I, Rule 5 transient use according to Annex VIII						
Device Classification (PPER)	Category III						
EU Type-Examination Certificate (PPER)	2777/10468-05/E05-01						
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	<table border="1"><thead><tr><th>No.</th><th>Regulation/ Standard Number</th><th>Regulation/ Standard Name</th></tr></thead><tbody><tr><td>1</td><td>MDR (EU) 2017/745</td><td>Medical Device Regulation</td></tr></tbody></table>	No.	Regulation/ Standard Number	Regulation/ Standard Name	1	MDR (EU) 2017/745	Medical Device Regulation
No.	Regulation/ Standard Number	Regulation/ Standard Name					
1	MDR (EU) 2017/745	Medical Device Regulation					



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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 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
	11	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	12	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer
	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 374-2:2014	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	15	EN ISO 374-4:2013	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
	16	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
	17	EN 16523-1: 2015	Determination of material resistance to permeation by chemicals - Part 1: Permeation by



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Website: www.mymedikal.com.tr.

		liquid chemical under conditions of continuous contact
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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
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad
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MY TICARET VE MEDİKAL A.S.

Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey

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Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDİKAL-SRT-007															
EC Certificate	Not applicable (Self- declared)															
Manufacturer	MY TICARET VE MEDİKAL 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 Basic															
Product Description	Latex Powdered Disposable Gloves															
Intended Purpose	A disposable glove is intended for general use to provide safety for the user. This is used for minimal risk only.															
Basic UDI-DI	868227994LP5H															
Size	XS, S, M, L, XL															
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)															
Global Medical Device Nomenclature (GMDN)	47173 (Latex examination/treatment glove, powdered)															
Product Catalogue/Reference Number	MBLPPST01-XS, MBLPPST02-S, MBLPPST03-M, MBLPPST04-L, MBLPPST05-XL															
Product Group Reference Number	LX01															
Conformity Assessment Route	Annex II and Annex III															
Classification & Rule	Class I, Rule 5															
Device Classification	Category I- For Minimal Risk only															
Applicable Standards	<table border="1"><thead><tr><th>No.</th><th>Regulation/ Standard Number</th><th>Regulation/ Standard Name</th></tr></thead><tbody><tr><td>2</td><td>PPE (EU) 2016/425</td><td>Personal Protective Equipment Regulation (<i>Category I- For Minimal Risk only</i>)</td></tr><tr><td>3</td><td>ISO 13485: 2016</td><td>Medical devices - Quality management systems - Requirements for regulatory purposes</td></tr><tr><td>4</td><td>ISO 9001: 2015</td><td>Quality management systems – requirements</td></tr><tr><td>11</td><td>ISO 20417: 2021</td><td>Medical Devices- Information to be supplied by the manufacturer</td></tr></tbody></table>	No.	Regulation/ Standard Number	Regulation/ Standard Name	2	PPE (EU) 2016/425	Personal Protective Equipment Regulation (<i>Category I- For Minimal Risk only</i>)	3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes	4	ISO 9001: 2015	Quality management systems – requirements	11	ISO 20417: 2021	Medical Devices- Information to be supplied by the manufacturer
No.	Regulation/ Standard Number	Regulation/ Standard Name														
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3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes														
4	ISO 9001: 2015	Quality management systems – requirements														
11	ISO 20417: 2021	Medical Devices- Information to be supplied by the manufacturer														



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Website: www.mymedikal.com.tr.

	12	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer
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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 the EU-Type Examination with the provisions of the PPE Regulations (EU) 2016/425 Category I-For Minimal Risk only.

Authorized Signatory:

Approver : MURAT YILDIZ
Title : General Manager/CEO
Signature : 
Approval Date : 09 Aug 2024
Place of Approval : Istanbul, Turkey

MEDİKAL ANONİM ŞİRKETİ
Ömerli Mahallesi General Şükrü Koraltı Cad
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MY TICARET VE MEDİKAL A.S.

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Website: www.mymedikal.com.tr

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDİKAL-TG-002																														
EC Certificate	Not applicable (Self- declared)																														
Manufacturer	MY TICARET VE MEDİKAL 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																														
Product Description	Powdered Latex Gloves																														
Intended Purpose	A glove is a personal protective equipment that is designed to be worn for minimum risk only.																														
Size	XS, S, M, L, XL																														
Product Catalogue Number	MLP02																														
Conformity Assessment Procedure (MDD)	Annex VII																														
Classification (MDD)	Class I, Non-sterile																														
Device Classification (PPER)	Category I with minimum risk only																														
Applicable Standards	<table border="1"><thead><tr><th>No.</th><th>Regulation/ Standard Number</th><th>Regulation/ Standard Name</th></tr></thead><tbody><tr><td>1</td><td>PPE (EU) 2016/425</td><td>Personal Protective Equipment Regulation- Category I with minimum risk only</td></tr><tr><td>2</td><td>MDD 93/42/EEC</td><td>Medical Device Directive</td></tr><tr><td>3</td><td>ISO 13485: 2016</td><td>Medical devices - Quality management systems - Requirements for regulatory purposes</td></tr><tr><td>4</td><td>ISO 9001: 2015</td><td>Quality management systems – requirements</td></tr><tr><td>5</td><td>ISO 14971: 2019</td><td>Medical devices - application of risk management to medical devices</td></tr><tr><td>6</td><td>EN 455-1: 2020</td><td>Requirements and testing for freedom from holes</td></tr><tr><td>7</td><td>EN 455-2: 2015</td><td>Requirements and testing for physical properties</td></tr><tr><td>8</td><td>EN 455-3: 2015</td><td>Requirements and testing for biological evaluation</td></tr><tr><td>9</td><td>EN 455-4: 2009</td><td>Requirements and testing for shelf-life determination</td></tr></tbody></table>	No.	Regulation/ Standard Number	Regulation/ Standard Name	1	PPE (EU) 2016/425	Personal Protective Equipment Regulation- Category I with minimum risk only	2	MDD 93/42/EEC	Medical Device Directive	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
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2	MDD 93/42/EEC	Medical Device Directive																													
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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																													
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Website: www.mymedikal.com.tr.

	10	ISO 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
	11	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	12	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer


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 the EU-Type Examination and conforming with the provisions of new PPE Regulations (EU) 2016/425 Category I with minimum risk only.
- Is fully compliance with the Essential Requirement of the EC Council Directive 93/42/EEC 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature : 
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad
No:33 Arnavutköy/İSTANBUL
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Approval Date : 07 Dec 2023

Place of Approval : Istanbul, Turkey





MY Medikal

MY TICARET VE MEDİKAL 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-MYMEDİKAL-TG-004															
EC Certificate	Not applicable (Self- declared)															
Manufacturer	MY TICARET VE MEDİKAL A.S.															
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey															
Single Registration Number (SRN)	TR-MF-000018372															
Brand	Sente															
Product Description	Powdered Latex Examination 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	868302002LPVJ															
Size	S, M, L, XL															
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)															
Global Medical Device Nomenclature (GMDN)	47173 (Latex examination/treatment glove, powdered)															
Product Catalogue Number	SELPP01-S, SELPP02-M, SELPP03-L, SELPP04-XL															
Conformity Assessment Route (MDR):	Annex I and Annex II and Annex IV															
Classification & Rule (MDR)	Class I, Rule 5 transient use															
Applicable Standards	<table border="1"><thead><tr><th>No.</th><th>Regulation/ Standard Number</th><th>Regulation/ Standard Name</th></tr></thead><tbody><tr><td>1</td><td>EN 455-1:2020</td><td>Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.</td></tr><tr><td>2</td><td>EN 455-2:2015</td><td>Medical gloves for single use. Part 2: Requirement and testing for physical properties.</td></tr><tr><td>3</td><td>EN 455-3:2015</td><td>Medical gloves for single use. Part 3: Requirement and testing for biological evaluation.</td></tr><tr><td>4</td><td>EN 455-4:2009</td><td>Medical gloves for single use. Part 4: Requirements and testing for shelf life determination.</td></tr></tbody></table>	No.	Regulation/ Standard Number	Regulation/ Standard Name	1	EN 455-1:2020	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	2	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	3	EN 455-3:2015	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation.	4	EN 455-4:2009	Medical gloves for single use. Part 4: Requirements and testing for shelf life determination.
No.	Regulation/ Standard Number	Regulation/ Standard Name														
1	EN 455-1:2020	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.														
2	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.														
3	EN 455-3:2015	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation.														
4	EN 455-4:2009	Medical gloves for single use. Part 4: Requirements and testing for shelf life determination.														



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MY TICARET VE MEDİKAL A.S.

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Website: www.mymedikal.com.tr.

5	EN ISO 14971:2019	Medical device - Application of risk management to medical device.
6	ISO 2859-1:2011	Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
7	ISO 10993-1:2018	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process
8	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
9	EN ISO 10993-10:2013	Biological evaluation of medical devices- Tests for irritation and skin sensitization.
10	EN ISO 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity
11	ISO 10993-12:2021	Biological evaluation for medical devices- Sample preparation and reference materials
12	ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
13	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
14	MDR 2017/745 (Annex I: Chapter 2)	Requirements Regarding Design and Manufacture
15	MDR 2017/745 (Chapter I: Article 2)	Scope and Definitions
16	MDR 2017/745 (Annex VIII)	Classification rules
17	MDR 2017/745 (Annex II)	Technical Documentation
18	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation
19	MEDDEV 2.7/1	2.7/1 Clinical Evaluation
20	MEDDEV 2.12-1 rev 8	Medical Device Vigilance System
21	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System
22	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance



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Website: www.mymedikal.com.tr.

23	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies
24	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow- up Studies
25	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)
26	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production
27	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
28	EN 62366-1:2015	Medical Devices-Part 1: Application of usability engineering to medical devices
29	MDR 2017/745	Medical Device Regulation
30	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
31	ISO 9001: 2015	Quality management systems – 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
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad
No: 33 Arnavutköy/İSTANBUL
Büyükdere
Tel: 0212 438 20 64 Fax: 0212 438 20 65
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MY Medikal

MY TICARET VE MEDİKAL A.S.

Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –Istanbul Turkey

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EU DECLARATION OF CONFORMITY

We, MY TICARET VE MEDİKAL A.S. herewith declare under our sole responsibility that below mentioned product(s) with CE mark is fully compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC.

DOC No.	DOC-MYMEDİKAL-TG-005																
EC Certificate	Not applicable (Self- declared)																
Manufacturer	MY TICARET VE MEDİKAL A.S.																
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd No:33, 34555 Arnavutkoy/Istanbul, Turkey																
Single Registration Number (SRN)	TR-MF-000018372																
Brand	Safe Gloves																
Product Description	Disposable Latex Gloves Powdered																
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)	T010201 (Examination/Treatment Gloves, Latex)																
Global Medical Device Nomenclature (GMDN)	47173 (Latex examination/treatment glove, powdered)																
Product Catalogue Number	SGLPP01-S; SGLPP01-M; SGLPP01-L; SGLPP01-XL																
Conformity Assessment Route	Annex VII																
Classification & Rule	Class I, Rule 5																
Applicable Standards	<table border="1"><thead><tr><th>No.</th><th>Regulation/ Standard Number</th><th>Regulation/ Standard Name</th></tr></thead><tbody><tr><td>1</td><td>MDD 93/42/EEC</td><td>Medical Device Directive</td></tr><tr><td>2</td><td>ISO 13485: 2016</td><td>Medical devices - Quality management systems - Requirements for regulatory purposes</td></tr><tr><td>3</td><td>ISO 9001: 2015</td><td>Quality management systems – requirements</td></tr><tr><td>4</td><td>ISO 14971: 2019</td><td>Medical devices - application of risk</td></tr></tbody></table>		No.	Regulation/ Standard Number	Regulation/ Standard Name	1	MDD 93/42/EEC	Medical Device Directive	2	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes	3	ISO 9001: 2015	Quality management systems – requirements	4	ISO 14971: 2019	Medical devices - application of risk
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			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		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

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

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature

Approval Date : 07.12.2023

Place of Approval : Istanbul, Turkey

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
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CE



As of 04 Mar 2024



USER INFORMATION

CE 2777	Comply with PPE Regulation 2016/425 Cat III
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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

Product references:

Mumu Latex Powdered Gloves, Non-sterile

MLP01-XS, MLP02-S, MLP03-M, MLP04-L, MLP05-XL

B-good Latex Powdered Gloves, Non-sterile

BGL01-XS, BGL02-S, BGL03-M, BGL04-L, BGL05-XL

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

Colour: Natural/ Pale Yellow, the color may vary due to storage time and conditions

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 C	Level	EN ISO 374-4:2019 Degradation%	EN ISO 374-1:2016+A1:2018 /Type C
96% Sulphuric Acid (L)	1	99.4%	
65% Nitric Acid (M)	1	53.3%	
30% Hydrogen Peroxide (P)	1	-92.5%	
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 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 selection of chemical resistant gloves”

“Before usage, inspect the gloves for any defect 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.)

This product contains natural rubber latex rubber that may lead to allergic reactions for some users.

The Gloves have no mechanical protection offered.

For single use only, do not littering.

Check for damage before use, do not use damaged gloves





MY Medikal

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 out 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 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 MEDİKAL A.Ş.





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

CAUTIONS AND RESTRICTION

1. Keep in dry conditions and avoid sunlight or other ozone sources.
2. For single-use only.
3. For latex gloves: This product contains natural latex which may cause allergic reactions.

DISPOSAL METHOD

Throw it away in the special rubbish can after using it.

INSTRUCTIONS FOR USE

1. Always wash hands before putting on gloves and each time you change to a new pair.
2. Take the gloves out from their original box.
3. Select a glove appropriate for the task and in your size. Inform yourself prior to the application.
4. Touch only a restricted surface of the glove corresponding to the wrist (at the top edge of the cuff)
5. Don the first glove by inserting your hand into the opening and pulling it over by applying a soft pull with the second hand.
6. Take the second glove with a bare hand and touch only a restricted surface of the glove corresponding to the wrist.
7. To avoid touching the skin of the forearm with the gloved hand, turn the external surface of the glove to be donned on the folded fingers of the gloved hand so there is a good hold on it. Thus, permitting to glove the second hand by pulling softly with the first gloved hand.
8. Once gloved, hands should not touch anything else that is not defined by indications and conditions for glove use.
9. Change gloves before beginning a different task to avoid cross-contamination.
10. Pinch one glove at the wrist level to remove it, without touching the skin of the forearm, and peel it away from the hand, thus, allowing the glove to turn inside out.
11. Hold the removed glove in the gloved hand and slide the fingers of the ungloved hand inside between the glove and the wrist of the gloved hand. Remove the second glove by rolling it down the hand and fold the first glove into the outside palm area of the second glove. If done correctly, the user holds a pack of the outer glove turned inside and out and the contaminated surface of both gloves is within the package.
12. Discharge the removed gloves and wash hands thoroughly according to the respective hygiene standards. Be aware to remove any powder residuals from the hands before touching any surfaces, as the powder can carry natural rubber latex proteins.





MY Medikal

13. Not intended to be used as a chemical barrier. The shelf life is normally advised to be five years. Check the original dispenser instructions for details.

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

**MY TİCARET VE
MEDİKAL ANONİM ŞİRKETİ**
Ömerli: Mh.General Şükrü Koralı Cad
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İl:0212 436 20 64 Fax:0212 436 20 65
www.mymedikal.com






As of 09 Aug 2024



USER INFORMATION

	Comply with PPE Regulation 2016/425 Category I- For Minimal Risk Only
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The product complies with PPE Regulation 2016/425 Category I- For Minimal Risk Only which intends to protect users against minimal risks and doesn't provide protection against severe hazards. Due to that, the conformity assessment procedure doesn't include Notified body testing and evaluation. Thus, the manufacturers can self-declare compliance with the respective legislation.

Mumu Basic Latex Powdered Disposable Gloves

Product references:

MBLPPST01-XS, MBLPPST02-S, MBLPPST03-M, MBLPPST04-L, MBLPPST05-XL

Product Group Reference: LX01

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

Intended Use:

A disposable glove is intended for general use to provide safety for the user. This is used for minimal risk only.

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

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





CAUTIONS AND RESTRICTION

1. Keep in dry conditions and avoid sunlight or other ozone sources.
2. For single-use only.
3. For latex gloves: This product contains natural latex which may cause allergic reactions.

DISPOSAL METHOD

Throw it away in the special rubbish can after using it.

INSTRUCTIONS FOR USE









1. Always wash hands before putting on gloves and each time you change to a new pair.
2. Take the gloves out from their original box.
3. Select a glove appropriate for the task and in your size. Inform yourself prior to the application.
4. Touch only a restricted surface of the glove corresponding to the wrist (at the top edge of the cuff)
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13. Not intended to be used as a chemical barrier. Check the original dispenser instructions for details.





MY Medikal

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
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