

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 <i>Branch Address:</i> Çoraklar Mah. 5003 Sok. No:18/1 ALOSBI Aliğa / İZMİR, Türkiye
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
UDI-DI Code	08682279949239, 08682279949253, 08682279949277, 08682279949291, 08682279949314
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]		
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+A2:2024	Requirements and testing for freedom from holes
	7	EN 455-2: 2024	Requirements and testing for physical properties
	8	EN 455-3: 2023	Requirements and testing for biological evaluation
	9	EN 455-4: 2009	Requirements and testing for shelf-life determination
	10	ISO 10993-10: 2021	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/Amd 1:2025	Symbols to be used with information to be supplied by the manufacturer
	13	EN ISO 374-1:2016+A1:2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
14	EN ISO 374-2:2019	Protective gloves against dangerous chemicals and micro-	

			organisms - Part 2: Determination of resistance to penetration
	15	EN ISO 374-4:2019	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
	18	EN 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 premises 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.
- Met the overall migration requirement under Commission Regulation (EU) No. 10/2011- "Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams of total constituents released per dm² of food contact surface (mg/dm²) (overall migration limit)", except for 3% acetic acid.
- 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 : 25 Aug 2026
Place of Approval : Istanbul, Turkey

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koralıtı Cad
No:33 ALOSBI Aliğa / İZMİR
Büyükdere Mah. No:33 ALOSBI Aliğa / İZMİR
Tel: 0212 438 20 64 Fax: 0212 438 20 65
www.mymedikal.com

