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-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
Product Description	Powderfree 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	MLPF02
Conformity Assessment Procedure (MDD)	Annex VII
Classification (MDD)	Class I, Non-sterile
Device Classification (PPER)	Category I with minimum risk only
Applicable Standards	

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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	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 :

Approval Date : 07 Dec 2023

Place of Approval : Istanbul, Turkey