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-ITCM-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	The Latex Examination Gloves is a disposable device intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
Basic UDI-DI	868227994LPFX3
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)
Global Medical Device Nomenclature (GMDN)	47172 (Latex examination/treatment glove, non-powdered)
Product Catalogue/Reference Number	MLPF02
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class 1, as per rule 5 of annex VIII of Regulation (EU) 2017/745 on Medical Device (MDR), All invasive devices with respect to body orifices, which are not intended for connection to an active device or which are intended for connection to a class 1 active device are classified as class 1, if they are intended for transient use.
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	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 management to medical devices
6	EN 455-1: 2020	Requirements and testing for freedom from holes

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	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	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:

- 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 with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ
Title : General Manager/CEO
Signature :
Approval Date : 02Jan2025
Place of Approval : Istanbul, Turkey