

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	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



MY TICARET VE MEDİKAL A.S.

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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 : 
MEDİKAL ANDRİM ŞİRKETİ
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Approval Date : 09 Aug 2024

Place of Approval : Istanbul, Turkey

