



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](http://www.mymedikal.com.tr)

### 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.

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 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	MLP02															
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 management to medical devices</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 management to medical devices
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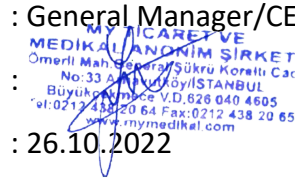
5	EN 455-1: 2020	Requirements and testing for freedom from holes
6	EN 455-2: 2015	Requirements and testing for physical properties
7	EN 455-3: 2015	Requirements and testing for biological evaluation
8	EN 455-4: 2009	Requirements and testing for shelf-life determination
9	ISO 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
10	EN 1041: 2008+A1: 2013	Information supplied by the manufacturer of medical devices
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:

Verification Certificates: EN ISO 13486:2016 Quality Management System  
Certificate No: ISO 02 836 1179

EN ISO 9001:2015 Quality Management System  
Certificate No.: ISO 01 940 1179

### **Authorized Signatory:**

Approver : MURAT YILDIZ  
Title : General Manager/CEO  
Signature :   
Approval Date : 26.10.2022  
Place of Approval : Istanbul, Turkey

MY TICARET VE  
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