

EU DECLARATION OF CONFORMITY

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|---|---|-----------------------------|--|
| 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 | Powderfree Latex Examination 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. | | |
| 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 (Hevea-latex Examination/treatment glove, non-powdered, non-antimicrobial) | | |
| Product Catalogue Number | ML01-XS, ML02-S, ML03-M, ML04-L, ML05-XL | | |
| Conformity Assessment Route (MDR): | Annex II and Annex III according to EU 2017/745 | | |
| Classification & Rule (MDR) | Class I, Rule 1 & Rule 5 | | |
| Device Classification (PPER) | Category III | | |
| Product Group Reference Number | LO01 | | |
| EU Type-Examination Certificate (PPER) | 2777/10467-05/E02-01 | | |
| Notified Body Number (PPER) | 2777 | | |
| EU Type- Examination Certificate Issued by (PPER) | SATRA Technology Europe Limited Bracetown Business Park, Clonee, D15YN2P, Ireland | | |
| 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 |



MY Medikal

MY TICARET VE MEDİKAL A.Ş.

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Website: www.mymedikal.com.tr.

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| | | 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 |
| 10 | ISO 10993-1: 2018 | Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process |
| 11 | ISO 10993-5: 2009 | Biological evaluation of medical devices –Part 5: Test for in vitro cytotoxicity |
| 12 | ISO 10993-10: 2010 | Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization |
| 13 | ASTM F1671: 2013 | Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using phi-x174 bacteriophage penetration as a test system |
| 14 | ASTM D3578: 2019 | Standard specification for rubber examination gloves |
| 15 | EN 1041: 2008+A1: 2013 | Information supplied by the manufacturer of medical devices |
| 16 | ISO 15223-1: 2021 | ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer |
| 17 | ASTM D7160: 2016 | Determination of expiration dating for medical gloves |
| 18 | ASTM D7161: 2016 | Determination of real time expiration dating of mature medical gloves stored under typical warehouse conditions |
| 19 | EN ISO 374-1: 2016+A1: 2018 | Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks |

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| | 20 | EN ISO 374-2: 2019 | Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration |
| | 21 | EN ISO 374-4: 2019 | Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals |
| | 22 | EN ISO 374-5: 2016 | Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks |
| | 23 | EN 16523-1: 2015+A1: 2018 | Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact |
| | 24 | EN ISO 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 documentations are retained under the premise of 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

- Is following to the EU-Type Examination and conformity 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 surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.



MY TICARET VE MEDİKAL A.S.

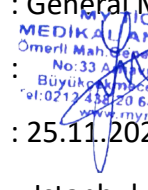
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- This EU Declaration of Conformity is prepared in accordance to Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ
Title : General Manager/CEO
Signature : 
Approval Date : 25.11.2022
Place of Approval : Istanbul, Turkey

MY TICARET VE
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