

EU DECLARATION OF CONFORMITY

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 Guard														
Product Description	Nitrile Powder Free Examination and Protective 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	868302002NPVQ														
Size	XS, S, M, L, XL														
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)														
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)														
Product Catalogue Number	MGN01-XS, MGN02-S, MGN03-M, MGN04-L, MGN05-XL														
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745														
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5 according to Annex VIII														
Device Classification (PPER)	Category III														
Product Group Reference Number	SNBE20013-XS, SNBE20014-S, SNBE20015-M, SNBE20016-L, SNBE20017-XL														
EU Type-Examination Certificate (PPER)	2777/14815-03/E00-00														
Notified Body Number (PPER)	2777														
EU Type- Examination Certificate Issued by (PPER)	SATRA Technology Europe Limited Bracetown Business Park, Clonee, D15YN2P, Ireland														
Applicable Standards	<table><tr><td>No.</td><td>Regulation/ Standard Number</td><td>Regulation/ Standard Name</td></tr><tr><td>1</td><td>MDR (EU) 2017/745</td><td>Medical Device Regulation</td></tr><tr><td>2</td><td>PPE (EU) 2016/425</td><td>Personal Protective Equipment Regulation</td></tr><tr><td>3</td><td>ISO 13485: 2016</td><td>Medical devices - Quality management systems -</td></tr></table>			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 systems -
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MY Medikal

MY TICARET VE MEDİKAL A.S.

Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –İstanbul Turkey

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Website: www.mymedikal.com.tr.

		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 10993-10: 2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
12	ISO 10993-11: 2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
13	EN 1041: 2008+A1: 2013	Information supplied by the manufacturer of medical devices
14	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
15	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
16	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
17	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
18	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

	19	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
	20	ASTM D 6978-05:2019	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
	21	ASTMF1671/F1671-13	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

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



MY Medikal

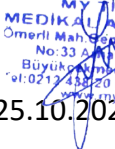
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Authorized Signatory:

Approver : MURAT YILDIZ
Title : General Manager/CEO
Signature : 
Approval Date : 25.10.2022
Place of Approval : Istanbul, Turkey

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
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