



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

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 examiner's hand or finger to prevent contamination between the patient and examiner. Examination glove is intended for medical activities except for 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/E63-01												
Notified Body Number (PPER)	2777												
EU Type- Examination Certificate Issued by (PPER)	SATRA Technology Europe Limited Bracetown Business Park, Clonee, D15YN2P, Ireland												
Applicable Standards	<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>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></tbody></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 -
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 -											



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.

		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



MY Medikal

MY TICARET VE MEDİKAL A.S.

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

Tel: +902124382064 Fax: +902124382065

Website: www.mymedikal.com.tr

	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	EN ISO 21420:2020	Protective gloves – General requirements and test methods
	21	ASTM D 6978-05:2019	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
	22	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 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 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.

Authorized Signatory:

Approver : MURAT YILDIZ
Title : General Manager/CEO
Signature : 
Approval Date : 03 May 2023
Place of Approval : Istanbul, Turkey

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mahallesi General Şükrü Koraltı Cad
• No:33 Arnavutköy/İSTANBUL
• Büyükdere Şişli V.D.628 040 4605
Tel:0212 438 20 64 Fax:0212 438 20 65
www.mymedikal.com

