MY TICARET VE MEDIKAL 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

DOC No.	DOC-MYMEDIKAL-ITC-009
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	ISO PLUS
Product Description	Nitrile Medical Gloves, Powderfree
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
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	ISOPITCNPF01-XS, ISOPITCNPF02-S, ISOPITCNPF03-M, ISOPITCNPF04-L
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
EU Type-Examination Certificate (PPER)	79013032
STE Reference for Module C2 Certificate	STE7162TBF7
Notified Body (PPER)	**EU-Type Examination** by MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ. Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ Istanbul, Turkey [Notified Body No.2841] **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation

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	2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
	3	ISO 13485: 2016	Medical devices - Quality management 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 10993-10: 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	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	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

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	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 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 the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2841 by MNA Laboratuvarlari San. Tic.Ltd.Sti.
- Is in conformity to type based on the quality control system for the final product under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 01 Mar 2024

Place of Approval : Istanbul, Turkey