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-TG-008
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
Product Description	Nitrile Medical Gloves, Powder Free
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
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	ISONLC01-XS, ISONLC01-S, ISONLC01-M, ISONLC01-L
Conformity Assessment Route	Annex VII
Classification & Rule	Class I, Rule 5
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	79013032
STE Reference for Module C2 Certificate	STE7162T8F7
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	PPE (EU) 2016/425	Personal Protective Equipment Regulation
2	ISO 13485: 2016	Medical devices - Quality management systems -

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		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
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
12	EN ISO 21420:2020	Protective gloves — General requirements and test methods
13	EN ISO 374-1: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
14	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- 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 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.

Authorized Signatory:

Approver : MURAT YILDIZ
Title : General Manager/CEO
Signature :
Approval Date : 01 Mar 2024
Place of Approval : Istanbul, Turkey

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