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-003
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	E-Care
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.
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	ENVXS00, ENVS01, ENVM02, ENVL03, ENVXL04
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
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation
2	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
3	ISO 9001: 2015	Quality management systems – requirements
4	EN 455-1: 2020	Requirements and testing for freedom from holes
5	EN 455-2: 2015	Requirements and testing for physical properties
6	EN 455-3: 2015	Requirements and testing for biological evaluation

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	7	EN 455-4: 2009	Requirements and testing for shelf-life determination
	8	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	9	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

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.
- 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 : 07 Dec 2023

Place of Approval : Istanbul, Turkey