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-SRT-005
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	Douromed
Product Description	Powderfree Latex Examination 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	868227994LPFX3
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)
Global Medical Device Nomenclature (GMDN)	47172 (Hevea-latex Examination/treatment glove, non-powdered, non-antimicrobial)
Product Catalogue Number	ML01-XS, ML02-S, ML03-M, ML04-L
Reference Number	63369, 78564, 125634, 233635
Product Group Reference Number	LO01
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	2777/10467-05/E15-01
Notified Body (PPER)	**EU-Type Examination** and **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
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 10993-5: 2009	Biological evaluation of medical devices –Part 5: Test for in vitro cytotoxicity
	12	ISO 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
	13	ASTM F1671: 2013	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
	14	ASTM D3578: 2019	Standard specification for rubber examination gloves
	15	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	16	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer
	17	ASTM D7160: 2016	Determination of expiration dating for medical gloves
	18	ASTM D7161: 2016	Determination of real time expiration dating of mature medical gloves stored under typical warehouse conditions
	19	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks

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	20	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	21	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
	22	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
	23	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
	24	EN ISO 21420: 2020	Protective gloves - General requirements and test methods

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 2777 by SATRA Technology Europe Ltd.
- Is in conformity to type based on quality assurance of the production process 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 : 15 Feb 2024

Place of Approval : Istanbul, Turkey