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-007
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	Mumu Maxima
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/Reference Number	MMNPF01-XS, MMNPF02-S, MMNPF03-M, MMNPF04-L, MMNPF05-XL
Product Group Reference Number	SNBE20013, SNBE20014, SNBE20015, SNBE20016, SNBE20017
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)	2777/14815-03/E63-02
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

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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 20417:2021	Medical devices - Information to be supplied by the manufacturer
	13	ISO 15223-1: 2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	14	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
	15	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
	16	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
	17	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology

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			and performance requirements for micro-organisms risks
	18	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
	19	EN ISO 21420:2020	Protective gloves – General requirements and test methods
	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 are 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 :

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ Ömerli Mah. General Şükrü Koraltı Cad No:33 Arnavutköy/İSTANBUL Büyükçekmece V.D.626 040 4605 Tel:0212 438 20 64 Fax:0212 438 20 65 mymedikal.com

Approval Date : 15 Feb 2024

Place of Approval : Istanbul, Turkey

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