

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-ITC-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	INF4MEDIA		
Product Description	Nitrile Powder Free Examination and Protective Gloves		
Intended Purpose	A patient examination glove is a medical device intended for a medical purpose worn on the examiner's hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except 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	IN4MN01-XS, IN4MN02-S, IN4MN03-M, IN4MN04-L, IN4MN05-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



MY Medikal

MY TICARET VE MEDİKAL A.Ş.

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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

	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 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 TICARET VE
MEDİKAL ANONİM ŞİRKETİ
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Approval Date : 15 Feb 2024

Place of Approval : Istanbul, Turkey

