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-ZBS-002
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 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	INFZBSN01-XS, INFZBSN02-S, INFZBSN03-M, INFZBSN04-L, INFZBSN05-XL
Product Group Reference Number	BS0102016, BS0102017, BS0102018, BS0102019, BS0102020
Conformity Assessment Route (MDR):	Article 52(7) and Annex VIII, 4.1 Rule 1, Non-invasive, and/or 5.1 Intended for transient use, Rule 5 of invasive device.
Classification (MDR)	Class I
Device Classification (PPER)	Category III
EU Type-Examination Certificate (PPER)	2777/21024-02/E00-00
Notified Body (PPER)	**EU-Type Examination** and **Ongoing Conformity** by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [**CE 2777**]

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

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	16	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
	17	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 : MY TICARET 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 www.mymedikal.com

Approval Date : 16 Feb 2024

Place of Approval : Istanbul, Turkey

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