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

EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDIKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 3455 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	B-good
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 examiners hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except 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 (Latex Examination/treatment glove, non-powdered, non-sterile)
Product Catalogue Number	BGLP01-XS, BGLP02-S, BGLP03-M, BGLP04-L, BGLP05-XL
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
Product Group Reference Number	LO01
EU Type-Examination Certificate (PPER)	2777/10467-05/E02-01
Notified Body Number (PPER)	2777
EU Type- Examination Certificate Issued by (PPER)	SATRA Technology Europe Limited Bracetown Business Park, Clonee, D15YN2P, Ireland
Applicable Standards	ISO 13485: 2016; ISO 9001: 2015; ISO 14971: 2019; EN 455-1: 2000; EN 455-2: 2015; EN 455-3: 2015; EN 455-4: 2009; ISO 10993-1: 2018; ISO 10993-5: 2009; ISO 10993-10: 2010; EN 1041: 2008+A1: 2013; EN ISO 15223-1: 2016; EN 420: 2003+A1: 2009; EN ISO 374-1: 2016+A1: 2018; EN 374-2: 2014; EN 374-4: 2013; EN ISO 374-5: 2016; EN 16523-1: 2015+A1: 2018

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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 documentations are retained under the premise of manufacturer.
- The gloves manufacture according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System:

Verification Certificates: EN ISO 13486:2016 Quality Management System
Certificate No: ISO 02 836 1179

EN ISO 9001:2015 Quality Management System
Certificate No.: ISO 01 940 1179

- Is following to the EU-Type Examination and conformity with the provisions of new PPE Regulations (EU) 2016/425 Category III.
- 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 : 13.07.2022

Place of Approval : Istanbul, Turkey

CE