MY Medikal

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	Mumu Plus+
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	SMLF00-XS; SMLF01-S; SMLF02-M; SMLF03-L; SMLF04-XL
Product Group Reference Number	MTCLPF
Classification & Rule (MDR)	Class I, Rule 5 transient use
Conformity Assessment Route:	Annex VIII according to EU 2017/745
EU Type-Examination Certificate (PPER)	2777/12719-01/E05-02
Applicable Standards	ISO 13485: 2016; ISO 9001: 2015; EN 455-1, EN455-2, EN 455-3; EN 455-4; EN ISO 374-1:2016; EN 420:2003+A1:2009; EN ISO 374-5:2016

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:

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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 :

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
www.mymedikal.com

Approval Date : 04.08.2022

Place of Approval : Istanbul, Turkey

CE