



MY TICARET VE MEDİKAL 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

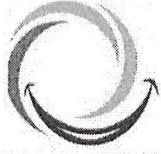
EC Certificate	Not applicable (Self- declared)
Manufacturer	MY TICARET VE MEDİKAL A.S.
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 3455 Arnavutkoy/Istanbul, Turkey
Single Registration Number (SRN)	TR-MF-000018372
Brand	Mumu Plus +
Product Description & Registration/Reference No.	Powderfree Latex Examination Gloves- MLPF02
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
EMDN/CRN	T010201 (EXAMINATION / TREATMENT GLOVES, LATEX)
Product Catalogue Number	SMLF00-XS; SMLF01-S; SMLF02-M; SMLF03-L; SMLF04-XL
Classification & Rule (MDR)	Class I, Rule 5 transient use
Conformity Assessment Route:	Annex VIII according to EU 2017/745
Applicable Standards	ISO 13485: 2016; ISO 9001: 2015; EN 455-1, EN455-2, EN 455-3; EN 455-4

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



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- 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 TICARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad
No:33 Arnavutköy/İSTANBUL
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Revision : 00

Approval Date : 13.04.2022

Place of Approval : Istanbul, Turkey

