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	Powdered 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	868227994LP5H
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)
Global Medical Device Nomenclature (GMDN)	47173 (Latex examination/treatment glove, powdered)
Product Catalogue Number	SMLP00-XS; SMLP01-S; SMLP02-M; SMLP03-L; SMLP04-XL
Product Group Reference Number	SSLPLP
Classification & Rule (MDR)	Class I, Rule 5 transient use
Conformity Assessment Procedure (MDR)	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, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN 420:2003+A1:2009

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

- 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