EC DECLARATION OF CONFORMITY

Manufacturer's Name and Address	:	MY TİCARET VE MEDİKAL A.Ş. Ömerli Mah. General Şükrü Koraltı Cad. No :33 Arnavutköy-İstanbul/TURKEY
Name Of Device	:	Latex Examination Gloves Nitrile Examination Gloves
Type and Registiration/Catalog No	:	Powdered Latex Examination Gloves - MLP02 Powder Free Latex Examination Gloves - MLPF02 Powder Free Nitrile Examination Gloves - MN01
Brand	:	Mumu – Mumu Plus
Classification	:	Class I
Conformity Assessment Procedure	:	Annex VII
Conformity Route	:	Self Declaration

We herewith declare with our own responsibility that above mentioned product(s) with CE mark is fully compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC.

Verification Certificates	:	Quality Management System EN ISO13485:2016 Certificate No: ISO 02 836 1179 Quality Management System EN ISO9001:2015 Certificate No: ISO 01 940 117

Digitally signed by Nebora Vera
Date: 2021.08.26 16:37:50 EEST
Reason: MoldSign Signature
Location: Moldova

Standards : EN 374-2 Protective gloves against dangerous chemicals and microorganisms-Part 2: Determination of resistance to penetration.

EN 16523-1+A1 Determination of material resistance to permeation by chemicals-Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (EN 374-3 standard has been revised as EN 16523-1+A1)

EN 374-4 Protective gloves against dangerous chemicals and microorganisms-Part 4: Determination of resistance to degradation by chemicals.

EN 374-5 Protective gloves against dangerous chemicals and microorganisms-Part 2: Terms and performance rules for microorganism risks.

EN 455-1 Medical gloves for single use Part 1: Requirements and testing for freedom from holes.

EN 455-2 Medical gloves for single use Part 2: Requirements and testing for physical properties.

EN 455-3 Medical gloves for single use Part 3: Requirements and testing for biological evaluation.

EN 455-4 Medical gloves for single use Part 4: Requirements and testing for shelf life determination.

EN ISO 10993-1 Biological evaluation of medical devices-Part-1: Evaluation and testing within a risk management process.

Authorised Signatory

Name-Surname : MURAT YILDIZ

Position : CEO

Signed :

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ
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Date : 22.03.2020

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