



MY Medikal

## 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](http://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 Care
Product Description	Nitrile Powder Free Examination and Protective 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	868302002NPVQ
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T01020204 (Examination / Treatment Gloves, Nitrile)
Global Medical Device Nomenclature (GMDN)	56286 (Nitrile Examination/Treatment glove, non-powdered, non-sterile)
Product Catalogue Number	MCN01-XS, MCN02-S, MCN03-M, MCN04-L, MCN05-XL
Product Group Reference Number	SNBE20013-XS, SNBE20014-S, SNBE20015-M, SNBE20016-L, SNBE20017-XL
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5
Conformity Assessment Route:	Annex II and Annex III according to EU 2017/745
Applicable Standards	EN ISO 13485:2016; EN ISO 14971:2019; EN 1041:2008; EN 15223-1:2016; EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009; ISO 1003-1:2018; ISO 10993-10:2010; ISO 10993-11:2017

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 :   
MY TICARET VE  
MEDİKAL ANONİM ŞİRKETİ  
Ömerli Mah. General Şükrü Koraltı Cad.  
No: 33 Arnavutkoy / İSTANBUL  
Büyükçekirgeçli V.D.: 626 040 4805  
Tel: 0212 438 2064 Fax: 0212 438 2065  
www.mymedikal.com.tr

Approval Date : 14.07.2022

Place of Approval : Istanbul, Turkey

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