



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

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	E-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	ENVXS00, ENVS01, ENVM02, ENVL03, ENVXL04
Product Group Reference Number	SNBE20013, SNBE20014, SNBE20015, SNBE20016, SNBE20017
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5
Conformity Assessment Route:	Annex II and Annex III according to EU 2017/745
EU Type-Examination Certificate (PPER)	2777/14815-03/E00-00
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



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.

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

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