

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDIKAL-SRT-006		
EC Certificate	Not applicable (Self- declared)		
Manufacturer	MY TICARET VE MEDIKAL A.S.		
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey		
Single Registration Number (SRN)	TR-MF-000018372		
Brand	E-care		
Product Description	Powderfree Latex Examination Gloves		
Intended Purpose	A patient examination glove is a medical device intended for a medical purpose that is worn on the examiner’s hand or finger to prevent contamination between the patient and examiner. Examination glove is intended for medical activities except for surgery.		
Size	XS, S, M, L, XL		
Global Medical Device Nomenclature (GMDN)	47172 (Hevea-latex Examination/treatment glove, non-powdered, non-antimicrobial)		
Product Catalogue Number	ENBXS00, ENBS01, ENBM02, ENBL03, ENBXL04		
Conformity Assessment Route (MDR):	Annex II and Annex III		
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5		
Applicable Standards			
	No.	Regulation/ Standard Number	Regulation/ Standard Name
	1	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	2	ISO 9001: 2015	Quality management systems – requirements
	3	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	4	EN 455-1: 2020	Requirements and testing for freedom from holes
	5	EN 455-2: 2015	Requirements and testing for physical properties
	6	EN 455-3: 2015	Requirements and testing for biological evaluation
	7	EN 455-4: 2009	Requirements and testing for shelf-life determination



MY TICARET VE MEDİKAL A.S.

Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutkoy –İstanbul Turkey

Tel: +902124382064 Fax: +902124382065

Website: www.mymedikal.com.tr.

	8	ISO 10993-1: 2018	Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process
	9	ISO 10993-5: 2009	Biological evaluation of medical devices –Part 5: Test for in vitro cytotoxicity
	10	ISO 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
	11	ISO 20417:2021	Medical devices- Information to be supplied by the manufacturer of medical devices
	12	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer

We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature

Approval Date

Place of Approval

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad
: No:33 Arnavutköy/İSTANBUL
Büyükdere V.D.628 040 4605
Tel:0212 438 20 64 Fax:0212 438 20 65
www.mymedikal.com

: 08 Dec 2023

: Istanbul, Turkey