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

We, MY TICARET VE MEDIKAL A.S. herewith declare under our sole responsibility that below mentioned product{s) with CE mark is fully compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC.

DOC No.	DOC-MYMEDIKAL-TG-005
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	Safe Gloves
Product Description	Disposable Latex Gloves Powdered
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.
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	SGLPP01-S; SGLPP01-M; SGLPP01-L; SGLPP01-XL
Conformity Assessment Route	Annex VII
Classification & Rule	Class I, Rule 5
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDD 93/42/EEC	Medical Device Directive
2	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
3	ISO 9001: 2015	Quality management systems – requirements
4	ISO 14971: 2019	Medical devices - application of risk

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			management to medical devices
	5	EN 455-1: 2020	Requirements and testing for freedom from holes
	6	EN 455-2: 2015	Requirements and testing for physical properties
	7	EN 455-3: 2015	Requirements and testing for biological evaluation
	8	EN 455-4: 2009	Requirements and testing for shelf-life determination
	9	ISO 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
	10	ISO 20417	Medical Devices- Information to be supplied by the Manufacturer
	11	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer

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 : 07.12.2023

Place of Approval : Istanbul, Turkey