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

DOC No.	DOC-MYMEDIKAL-CDS-001
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	Simplistic
Product Description	Powder-Free Latex Gloves
Intended Purpose	This is a personal protective equipment that is designed to be worn for minimum risk only.
Size	XS, S, M, L, XL
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)
Global Medical Device Nomenclature (GMDN)	47172 (Hevea-latex Examination/treatment glove, non-powdered, non-antimicrobial)
Product Catalogue Number	SLPF01-XS, SLPF02-S, SLPF03-M, SLPF04-L, SLPF05-XL
Conformity Assessment Route (MDD)	Annex VII
Classification & Rule (MDD)	Class I, Rule 5
Device Classification (PPER)	Category I (For minimal risk only)
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDD 93/42/EEC	Medical Device Directive
2	PPE (EU) 2016/425	Personal Protective Equipment Regulation (Category I-For minimal risk only)
3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
4	ISO 9001: 2015	Quality management systems – requirements
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

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	8	EN 455-4: 2009	Requirements and testing for shelf-life determination
	9	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	10	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:

- 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.
- Is following the PPE Regulations (EU) 2016/425 Category I (For minimal risk only).
- 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 : 08 Dec 2023

Place of Approval : Istanbul, Turkey