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-TG-004
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	Sente
Product Description	Powdered 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.
Basic UDI-DI	868302002LPVJ
Size	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	SELPP01-S, SELPP02-M, SELPP03-L, SELPP04-XL
Conformity Assessment Route (MDR):	Annex I and Annex II and Annex IV
Classification & Rule (MDR)	Class I, Rule 5 transient use
Applicable Standards	

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	EN 455-1:2020	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.
2	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.
3	EN 455-3:2015	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation.
4	EN 455-4:2009	Medical gloves for single use. Part 4: Requirements and testing for shelf life determination.

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	5	EN ISO 14971:2019	Medical device - Application of risk management to medical device.
	6	ISO 2859-1:2011	Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
	7	ISO 10993-1:2018	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process
	8	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
	9	EN ISO 10993-10:2013	Biological evaluation of medical devices- Tests for irritation and skin sensitization.
	10	EN ISO 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity
	11	ISO 10993-12:2021	Biological evaluation for medical devices- Sample preparation and reference materials
	12	ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
	13	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
	14	MDR 2017/745 (Annex I: Chapter 2)	Requirements Regarding Design and Manufacture
	15	MDR 2017/745 (Chapter I: Article 2)	Scope and Definitions
	16	MDR 2017/745 (Annex VIII)	Classification rules
	17	MDR 2017/745 (Annex II)	Technical Documentation
	18	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation
	19	MEDDEV 2.7/1	2.7/1 Clinical Evaluation
	20	MEDDEV 2.12-1 rev 8	Medical Device Vigilance System
	21	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System
	22	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance

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	23	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies
	24	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies
	25	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex lll	Post Marketing Surveillance (PMS)
	26	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production
	27	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	28	EN 62366-1:2015	Medical Devices-Part 1: Application of usability engineering to medical devices
	29	MDR 2017/745	Medical Device Regulation
	30	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	31	ISO 9001: 2015	Quality management systems – requirements

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 documentation is retained under the premise of the manufacturer.
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System:
- 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 :

Approval Date : 07 Dec 2023

Place of Approval : Istanbul, Turkey