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

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 examiners hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except 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	EN 1041:2008 + A1 2013	Information supplied by the manufacturer of medical device
	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 documentations are retained under the premise of manufacturer.

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

- This EU Declaration of Conformity is prepared in accordance to Annex IV of Medical Device Regulation (EU) 2017/745.

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Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature :

Approval Date : 26.10.2022

Place of Approval : Istanbul, Turkey