**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 :

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad
No:33 Arnavutköy/İSTANBUL
Büyükçekmece V.D.626 040 4605
Tel:0212 438 20 64 Fax:0212 438 20 65
www.mymedikal.com

Approval Date : 26.10.2022

Place of Approval : Istanbul, Turkey

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