

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 Manufacturer My Ticaret VE Medical Sukrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey Single Registration Number (SRN) Brand Product Description 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 Size S, M, L, XL European Medical Device Nomenclature (EMDN) Global Medical Device Nomenclature (GMDN) Product Catalogue Number Conformity Assessment Route (MDR): Classification & Rule (MDR) Applicable Standards No. Regulation/ Standard Regulation/ Standard Name Number Medical gloves for single use. Part | DOC No. | DOC- | MYMEDIKAL-TG-004 | | | |
|---|-----------------------------|---|--------------------------|-------------------------------------|--|--|
| Manufacturer Address | EC Certificate | Not applicable (Self- declared) | | | | |
| Arnavutkoy/Istanbul, Turkey Single Registration Number (SRN) 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) Global Medical Device (A7173 (Latex examination/Treatment Gloves, Latex) Nomenclature (GMDN) Product Catalogue Number SELPP01-S, SELPP02-M, SELPP03-L, SELPP04-XL Conformity Assessment Route (MDR): Class ification & Rule (MDR) Applicable Standards No. Regulation/ Standard Regulation/ Standard Number Medical gloves for single use. Part | Manufacturer | | | | | |
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| Nomenclature (EMDN) Global Medical Device Nomenclature (GMDN) Product Catalogue Number Conformity Assessment Route (MDR): Classification & Rule (MDR) Applicable Standards No. Regulation/Standard Number Medical gloves for single use. Part | Size | S, M, L, XL | | | | |
| Global Medical Device Nomenclature (GMDN) Product Catalogue Number Conformity Assessment Route (MDR): Classification & Rule (MDR) Applicable Standards No. Regulation/ Standard Number Medical gloves for single use. Part | European Medical Device | T010201 (Examination/Treatment Gloves, Latex) | | | | |
| Nomenclature (GMDN) Product Catalogue Number Conformity Assessment Route (MDR): Classification & Rule (MDR) Applicable Standards No. Regulation/ Standard Number Medical gloves for single use. Part | Nomenclature (EMDN) | | | | | |
| Product Catalogue Number Conformity Assessment Route (MDR): Classification & Rule (MDR) Applicable Standards No. Regulation/ Standard Number Medical gloves for single use. Part | Global Medical Device | 4717 | 3 (Latex examination/tr | eatment glove, powdered) | | |
| Conformity Assessment Route (MDR): Classification & Rule (MDR) Applicable Standards No. Regulation/ Standard Number Medical gloves for single use. Part | Nomenclature (GMDN) | | | | | |
| (MDR): Classification & Rule (MDR) Applicable Standards No. Regulation/ Standard Regulation/ Standard Name Number Medical gloves for single use. Part | Product Catalogue Number | | | | | |
| Classification & Rule (MDR) Applicable Standards No. Regulation/ Standard Regulation/ Standard Name Number Medical gloves for single use. Part | Conformity Assessment Route | Annex I and Annex IV | | | | |
| Applicable Standards No. Regulation/ Standard Regulation/ Standard Name Number Medical gloves for single use. Part | (MDR): | | | | | |
| No. Regulation/ Standard Regulation/ Standard Name Number Medical gloves for single use. Part | Classification & Rule (MDR) | Class I, Rule 5 transient use | | | | |
| Number Medical gloves for single use. Part | Applicable Standards | | | | | |
| Medical gloves for single use. Part | | No. | _ | Regulation/ Standard Name | | |
| | | | Number | | | |
| 1 EN 455 4:2020 4: Demiliarment 1: 1: 5 | | | | Medical gloves for single use. Part | | |
| | | 1 | EN 455-1:2020 | 1: Requirement and testing for | | |
| freedom from holes. | | | | | | |
| Medical gloves for single use. Part 2 EN 455-2:2015 2: Requirement and testing for | |) | EN 455 2:2015 | | | |
| physical properties. | | | EN 455-2.2015 | | | |
| Medical gloves for single use. Part | | | | | | |
| 3 EN 455-3:2015 3: Requirement and testing for | | 3 | EN 455-3:2015 | | | |
| biological evaluation. | | | | | | |
| Medical gloves for single use. Part 4 EN 455-4:2009 4: Requirements and testing for | | 1 | FN 455-4-2000 | | | |
| shelf life determination. | | " | LIN 400-4.2009 | | | |

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| | 5 | EN ISO 14971:2019 | Medical device - Application of risk management to medical device. |
|----------|----------|--------------------------|--|
| | | | Sampling procedures for inspection |
| | | | by attributes – Part 1: Sampling |
| | | | schemes indexed by acceptance |
| | 6 | ISO 2859-1:2011 | quality limit (AQL) for lot-by-lot |
| | | | inspection |
| | | | Biological evaluation for medical |
| | | | _ |
| | _ | 100 40002 4 2040 | device – |
| | 7 | ISO 10993-1:2018 | Part 1: Evaluation and testing |
| | | | within a risk management process |
| | | | Biological evaluation of medical |
| | 8 | ISO 10993-5:2009 | devices – Part 5: Tests for in vitro |
| | | | cytotoxicity |
| | | | Biological evaluation of medical |
| | 9 | EN ISO 10993-10:2013 | devices- Tests for irritation |
| | | | and skin sensitization. |
| | 10 | EN ISO 10993-11:2018 | Biological evaluation of medical |
| | 10 | FIN 120 T0322-T1.5010 | devices. Tests for systemic toxicity |
| | | | Biological evaluation for medical |
| | 11 | ISO 10993-12:2021 | devices- Sample preparation and |
| | | | reference materials |
| | 4.0 | 100 10000 00 0001 | Biological evaluation of medical |
| | 12 | ISO 10993-23:2021 | devices - Part 23: Tests for irritation |
| | | | Medical devices - Symbols to be |
| | | | used with medical device labels, |
| | 13 | EN ISO 15223-1:2021 | labelling and information to be |
| | | EN 130 13223-1.2021 | supplied General requirements. |
| | | | Supplied deficial requirements. |
| | | MDR 2017/745 | Requirements Regarding Design |
| | 14 | (Annex I: Chapter 2) | and Manufacture |
| | | MDR 2017/745 | מווע ועומוועומכנעוב |
| | 15 | | Scope and Definitions |
| | \vdash | (Chapter I: Article 2) | |
| | 16 | MDR 2017/745 (Annex | Classification rules |
| | \vdash | VIII) | |
| | 17 | MDR 2017/745 (Annex | Technical Documentation |
| | \vdash | II) | |
| | 18 | MDR 2017/745 | Clinical Evaluation |
| | | (Annex XIV: Part A) | |
| | 19 | MEDDEV 2.7/1 | 2.7/1 Clinical Evaluation |
| | 20 | MEDDEV 2.12-1 rev 8 | Medical Device Vigilance System |
| | | | 2.12/1 Medical Device Vigilance |
| | 21 | MEDDEV 2.12/1 | System |
| | | | |
| | | MDR 2017/745 | |
| | 22 | (Chapter VII: Section 2: | Vigilance |
| | 22 | Article 87-92) | vignatice |
| <u> </u> | | | |

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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 |
| | | MDR 2017/745 | |
| | 25 | (Chapter VII: Section 1: Article 83-86) Annex III | 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

MEDIKAL ANDRIM SIRKETI
Omerli Mah Separa/Sükrü Koraltı Cad
No:33 A VIII KADILI KAD

Approval Date : 07 Dec 2023

Place of Approval : Istanbul, Turkey

CE