



MADEIT GROUP Srl

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Phone: +39 392 643 330
Email: direction@dariozanco.com

Country of Origin: Malaysia

Product imported by: Nundinae Group d.o.o.

PRODUCT SPECIFICATION:

Type: Disposable Medical Latex examination glove, Powdered, Non-sterile

Material: Natural Rubber Latex

Color: White

Design and features: Ambidextrous, finger/palm-textured surface, beaded cuff

Storage: Allows for properties maintenance when stored in dry conditions. Do not expose product to direct sunlight.

Shelf-life: 5 years from the date of manufacturing

AQL: 1,5

REGULATION AND QUALITY STANDARD REFERENCE:

Manufactured under: EN ISO 13485:2016 and EN ISO 9001:2015 Quality Management System

Standard conformity: Category I ; EN 374/1-5:2016; EN 455/1-4; EN ISO 10993-1

GLOVE SIZES:

Small, Medium, Large

Size of gloves shall be marked on the shipping carton and the packaging

FUNCTIONALITY AND SUGGESTED USE:

- Protection from unwanted or dangerous substances
- Enhanced durability, tearing resistance and protective properties
- Thinner gauges provide improved tactile sensitivity
- Suitable for use in the medical sector – hospital and laboratory environment. Intended for medical use for cross-contamination protection of the patient and user.

CONFECTION AND PACKAGING:

Primary confection:

Box of 100 gloves. Product specification and size marked on packaging.

Secondary confection:

Carton of 20 boxes or 2.000 gloves. Product specification and size marked on packaging.



mumu

Latex Powdered Disposable Gloves

FEATURES

- Easy Donning
- Outstanding Softness & Comfort
- AQL 1.5
- Smooth Surface
- Made of Natural Rubber Latex



SPECIFICATION

Glove Details	Specification
Material	Natural Rubber Latex
Powder	> 2mg /glove
Surface	Smooth
Shape	Ambidextrous
Colour	Natural
Sterilization	Non Sterile
Shelf Life	5 Years
Cuff Finished	Beaded

PHYSICAL PROPERTIES

Glove Details	Properties
Weight (Size M)	4.8g (+/- 0.2g)
Freedom from Holes	AQL 1.5
Length (mm)	240 mm
Finger Thickness	Min. 0.08 (+/- 0.02 mm)
Palm Thickness	Min. 0.08 (+/- 0.02 mm)
Cuff Thickness	Min. 0.06 (+/- 0.02 mm)

SIZING

Size	Extra Small	Small	Medium	Large	Extra Large
Palm Width	76 +/- 3 mm	84 +/- 3 mm	94 +/- 3 mm	105 +/- 3 mm	113 +/- 3 mm

QUANTITIES

Packaging	Dimension	20 FT	40 HC	Packing
Outer carton	495 x 365 x 210 mm	750	1,800	20 Inner boxes / 2,000 pieces per carton
Inner Box	200 x 120 x 70 mm	15,000	36,000	100 pieces per inner box

For any inquiry:

My Ticaret ve Medikal A.Ş.
Ömerli Mahallesi General Şükrü Koralı Cad. No:33 Arnavutköy / İstanbul / Türkiye
T: + 90 212 438 20 64 Email: info@mymedikal.com.tr



Disclaimer : Artwork or product specification are subject to change without earlier notice. Please consult with your sales


MY Medikal

Rev.01- 012022



Certificate

ISO 13485 : 2016

**TİO MEDİKAL TIBBİ ÜRÜNLER TURİZM
İNŞ. SAN. VE TİC. LTD. ŞTİ.**

Buca OSB Mah. 2/20 Sk. Sepe Blok No: 53 Buca/İzmir/ TURKEY

This certificate shows that the medical devices - quality management system (EN ISO 13485:2016) of the above company was approved by PCA Certification for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria

SCOPE

Manufacturing and sales of non sterile disposable patient and visitor dressing, disposable surgical gowns, sterile disposable surgical drapes, sterile surgical ped, sterile microscope cover, sterile cartooned camera cover, sterile disposable drape packs

GROUP CODE

A - D

Certificate No	: TC-75156
Registration Date	: 22.07.2019
Reissue Date	: 11.08.2021
Expiry Date	: 21.07.2022
Certificate Period	: 3 Years (Form the date of registration)
Exclusion	: 7.3 / 7.5.3 / 7.5.4 / 7.5.9.2 / 8.3.4



PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi
Orta Mah. Ordu Sk. İzpark C Blok No:26/23 Kartal/ İSTANBUL
Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49
www.pca-tr.com info@pca-tr.com





MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-002-MS

Certificate of Registration

This is to certify that

Quality Management System

of

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ

ÖMERLİ MAHALLESİ GENERAL ŞÜKRÜ KORALTI CAD. NO: 33
ARNAVUTKÖY - İSTANBUL / TÜRKİYE

complies with requirements of

ISO 9001:2015

This certificate is valid concerning all activities related to;

PRODUCTION AND SALE OF POWDERED/POWDER-FREE LATEX EXAMINATION GLOVES, POWDER-FREE NITRILE EXAMINATION AND PROTECTIVE GLOVES, POWDERED/POWDER-FREE STERILE SURGICAL GLOVES, POWDERED/POWDER-FREE VINYL EXAMINATION GLOVES, SURGICAL MASK, FILTERING HALF/PROTECTIVE FACE MASK, STERILE & NON-STERILE GAUZE SWABS/ LAP SPONGES/ COTTON PADS/ GAUZE, STERILE SYRINGE/NEEDLE

PUDRALI/PUDRASIZ LATEKS MUAYENE ELDİVENİ, NİTRİL PUDRASIZ MUAYENE VE KORUYUCU ELDİVEN, PUDRALI VE PUDRASIZ STERİL CERRAHİ ELDİVEN, VİNİL PUDRALI/PUDRASIZ MUAYENE ELDİVENİ, CERRAHİ MASKE, FİLTRELİ KORUYUCU YÜZ MASKESİ, STERİL & NON-STERİL GAZ KOMPRES/BATIN KOMPRES/PAMUKLU PED/GAZLI BEZ, STERİL ŞİRINGA/İĞNE ÜRETİMİ VE SATIŞI

ISO 01 940 1179

Certificate No.

May. 25, 2022

Date of this Certificate

Jun. 04, 2023

Certification Expiry Date

May. 09, 2022

Date of Audit

Jun. 05, 2020

Date of Registration

Managing Director / Director



Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir
Tel: 0232 327 33 44 www.medicert.com.tr info@medicert.com.tr

This certificate is only valid if it is available / valid on Medicert website at www.medicert.com.tr

This certificate of Registration remains the property of Medicert Certificate Ltd and shall be returned immediately upon request
*In Case if Surveillance Audit is not allowed to be conducted on or before the specified date; the Certificate shall be Suspended/Withdrawn.



EC DECLARATION OF CONFORMITY

Manufacturer : My Ticaret ve Medikal A.Ş
Manufacturer's Address : Ömerli Mahallesi General Şükrü Koraltı
Caddesi No: 33 Arnavutköy/İstanbul/Turkey

This declaration of conformity covers the Class 1 medical device products mentioned below.

Device Description:

Device Name / Product Code	Brand	Size	Intended Purpose
Latex Powder Free Examination Gloves	MUMU	XS, S, M, L, XL	Non-sterile, single use, powder free and Powdered examination 100pcs,200pcs,300pcs. Sizes; X-Small, Small, Medium, Large, X-Large,
Latex Powdered Examination Gloves /	MUMU		

Device Classification : Class I, according to Annex VIII of Regulation (EU) 2017/745.

Rule(s) : 1 and 5

Conformity Assesment Procedure : Annex II and Annex III

Table of Basic UDI-DI: :

Device Name	Basic UDI Code
Latex Powdered Examination Gloves	868227994LP5H
Latex Powder Free Examination Gloves	868227994LPFX3

We, My Ticaret ve Medikal A.Ş. herewith declared thar above mentioned device:

- İs in conformity with the Regulation (eu) 2017/745 of The European Parliament and of The Council of medical devices.

This EU declaration of conformity is issued under the sole responsibility of the manufacturer,
My Ticaret ve Medikal A.Ş

Applicable Standards (MDR):

No	Standard	Descriptions
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.
5	EN 1041:2008 + AI 2013	Information supplied by the manufacturer of medical devices
6	EN ISO 14971:2019	Medical device - Application of risk management to medical device.
7	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
8	ISO 10993-1:2018	Biological evaluation for medical device — Part 1: Evaluation and testing within a risk management process
9	ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
10	EN ISO 10993-10:2013	Biological evaluation of medical devices - Tests for irritation and skin sensitization.
11	EN ISO 10993-11:2018	Biological evaluation of medical devices, Tests for systemic toxicity
12	ISO 10993-12:2012	Biological evaluation for medical devices - Sample preparation and reference materials
13	EN ISO 15223-1:2016	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 (Chapter II: Article 11&12)	Guideline for Authorized Representative

19	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation
20	MEDDEV 2.7/1	2.7/1 Clinical Evaluation
21	MEDDEV 2.12-1 rev 8	Medical Device Vigilance System
22	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System
23	MDR 2017/745 (Chapter VI': Section 2: Article	Vigilance
24	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies
25	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies
26	MDR 2017/745 (Chapter VI': Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)
27	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production
28	MDR 2017/745	Medical Device Regulation

EU DoC Issuance Date

: 02.02.2022

Signed for and Behalf of My Ticaret ve Medikal A.Ş

Name: MURAT YILDIZ

Designation: General Manager

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
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Tel:0212 438 20 64 Fax:0212 438 20 65
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TEST REPORT: 7191281871-CHM22-01-TSL

Date: 02 JUN 2022

Tel: +65 6973 6154

Client's Ref:

Email: Sihai.Li@tuv sud.com

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.



PSB Singapore

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SUBJECT

Overall Migration for "Mumu Latex Powdered Examination Gloves" Sample

CLIENT

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad. No:33
34555 Arnavutköy / İSTANBUL, TURKEY

Attn : Ms Lera Ajero

SAMPLE SUBMISSION DATE

29 Apr 2022

DESCRIPTION OF SAMPLE

One packet of glove sample labelled as follows was received.



Picture 1: "Mumu Latex Powdered Examination Gloves" Sample as received

The test was confirmed to be analysed on 09 May 2022.

DATE OF ANALYSIS

10 May 2022 – 01 Jun 2022



Laboratory:
TÜV SÜD PSB Pte. Ltd.
15 International Business Park
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Singapore 609937

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Regional Head Office:
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15 International Business Park
TÜV SÜD @ IBP
Singapore 609937
TUV®

METHOD OF TEST

The sample was analysed for the following tests according to EU ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs.

1. Preparation of Test Specimen

Only the exterior of the glove sample was performed for the test.

2. Overall Migration Tests:

a) Aqueous Food Simulant (3% Acetic Acid, 10% Ethanol, 20% Ethanol & 50% Ethanol)

According to BS EN 1186-9:2002 – Test Methods for overall migration into aqueous food simulants by article filling.

b) Fatty Food Simulant (Olive Oil):

According to BS EN 1186-8:2002 – Test Methods for overall migration into olive oil by article filling.

RESULTS

Table 1 : Overall Migration Content with Food Simulants for the “Mumu Latex Powdered Examination Gloves” Sample

Type of Simulant	Testing Condition* ¹	Surface Area (dm ²)	Volume of Extractant (ml)	Overall Migration (mg/dm ²) * ²	Resolution ResAP(2004)4 Requirement for Overall Migration Content (mg/dm ²)
1. 10% Ethanol	40 °C, 2 hours	4.40	225	2.0	<10
2. 3% Acetic Acid	40 °C, 2 hours	4.39	225	60.0	<10
3. 20% Ethanol	40 °C, 2 hours	4.40	225	2.7	<10
4. 50% Ethanol	40 °C, 2 hours	4.41	225	3.7	<10
5. Vegetable Oil (Olive Oil)	40 °C, 2 hours	4.40	225	<1.0	<10

*¹ The testing conditions were specified by client.

*² Analytical tolerance is 2 mg/dm² or 12 mg/kg for aqueous simulants and 3 mg/dm² or 20 mg/kg for fatty food simulants.

Based on the above result, the “Mumu Latex Powdered Examination Gloves” sample met the overall migration requirement under Resolution ResAP(2004)4 – “Rubbers products intended to come into contact with foodstuffs” shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams of total constituents released per dm² of food contact surface (mg/dm²) (overall migration limit)”, except for 3% Acetic Acid.



MS TAN SER LING
TECHNICAL EXECUTIVE



DR LI SIHAI
AVP / SENIOR CHEMIST
MICROCONTAMINATION DIAGNOSIS
CHEMICAL & MATERIALS

TEST REPORT: 7191281871-CHM22-01-TSL
02 JUN 2022



PSB Singapore

Please note that this Report is issued under the following terms :

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Effective 26 January 2021

