

mumu

3-ply Surgical Kid's Mask With Earloop

EN 14683:2019+ AC:2019 Tip/Type IIR;BFE % \geq 98

PURPOSE OF USE

Surgical kid's mask can be used for hygienic applications. Suitable for use by kids.
Made of non-woven fabric.
Air permeable structure allows easy breathing.
Produced with food contact paints.
Does not contain allergic materials.
3-ply structure. Non irritating.

KIDS



Filtered and 3 - Ply



Compatible Tire





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 LATEX POWDERED / POWDER FREE EXAMINATION GLOVES, NITRILE
POWDER FREE EXAMINATION GLOVES, STERIL / NON-STERILE SURGICAL GLOVES, STERIL / NON-STERILE
SPONGE GAUZE COMPRESS, STERIL / NON-STERIL COMPRESSE ABDOMINALE, STERIL / NON-STERILE
COTTON PAD, GAUZE, STERILE / NON-STERILE SURGICAL MASK

LATEKS PUDRALI / PUDRASIZ MUAYENE ELDIVENİ, NİTRİL PUDRASIZ MUAYENE ELDIVENİ, STERİL / NON-
STERİL CERRAHI ELDIVEN, STERİL / NON-STERİL SPANÇ GAZ KOMPRES, STERİL / NON-STERİL BATIN
KOMPRES, STERİL / NON-STERİL PAMUKLU PED, GAZLI BEZ,
STERİL / NON-STERİL CERRAHI MASKE ÜRETİMİ VE SATIŞI

ISO 01 940 1179
Certificate No.

Jun. 5, 2020
Date of this Certificate

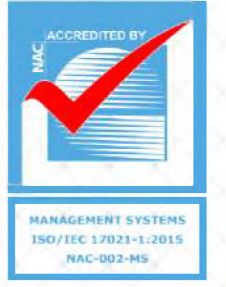
Jun. 4, 2021
Certification Expiry Date

May. 28, 2020
Date of Audit

Jun. 5, 2020
Date of Registration


Managing Director / Director





Certificate of Registration

This is to certify that

Quality Management System
for Medical Devices

of

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ

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

complies with requirements of

ISO 13485:2016

This certificate is valid concerning all activities related to;

SALES OF LATEX POWDERED / POWDER-FREE EXAMINATION GLOVES- NITRILE POWDER-FREE EXAMINATION GLOVES- POWDERED / POWDER-FREE STERILE SURGICAL GLOVES-VINYL POWDERED / POWDER-FREE EXAMINATION GLOVES. PRODUCTION AND SALE OF DISPOSABLE NON-STERILE MASKS.

LATEKS PUDRALI/PUDRASIZ MUAYENE ELDİVENİ- NİTRİL PUDRASIZ MUAYENE ELDİVENİ- PUDRALI/PUDRASIZ STERİL CERRAHİ ELDİVEN-VİNİL PUDRALI/PUDRASIZ MUAYENE ELDİVENİ SATIŞI. TEK KULLANIMLIK NON-STERİL MASKE ÜRETİMİ VE SATIŞI.

ISO 02 836 1179
Certificate No.

Feb. 26, 2020
Date of this Certificate

Feb. 25, 2021
Certification Expiry Date

Feb. 21, 2020
Date of Audit

Feb. 26, 2020
Date of Registration


Managing Director / Director





Certificate of Registration 2020

This is to certify that the registration of

MY TICARET VE MEDIKAL A.S
OMERLI MAH. GENERAL SUKRU KORALTI CAD. NO: 33 ARNAVUTKOY,
ISTANBUL, TURKEY - 34555

with U.S. Food and Drug Administration as required by 21 CFR Part 807 is successfully completed by Liberty Management Group Ltd with the information provided by My Ticaret Ve Medikal A.S

Owner/Operator Number	10075681
Date of Registration	June 23, 2020
Date of Expiration	December 31, 2020
US Agent	Liberty Management Group Ltd.
Device Listing Numbers	See Annex
Certificate Number	3006230220

This certificate does not make representations or warranties to any person or entity other than the named certificate holder; it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S. food and Drug Administration. Liberty management Group Ltd. assumes no liability to any person or entity in connection with the foregoing.

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Liberty Management Group Ltd. is not affiliated with the U.S. Food and Drug Administration.

LMG LIBERTY
MANAGEMENT
GROUP LTD.

75 Executive Drive, Aurora, Illinois, USA
www.fdahelp.us

A handwritten signature in black ink that reads "Manoj Zacharias".

Manoj Zacharias

President

Liberty Management Group LTD.

Dated: June 23, 2020



Certificate of Registration 2020

Annex - Device Listings

Listing Number	Code	Device Name - Proprietary Names
D409537	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance - Mumu Surgical Mask

EC DECLARATION OF CONFORMITY



Manufacturer's Name: MY TICARET VE MEDİKAL A.Ş.

Manufacturer Address: Ömerli Mah. General Şükrü Koralıtı Cad. No: 33 Amavutköy / Istanbul

Medical Devices: Surgical Mask. 3-ply with earloop Ref No: MM.NS.LM.01

Classification: Medical Device Directive-Annex IX. Rule I. Class-1 (Type IIR)

GMDN Code and Term: 57794 /Surgical Medical Respirator

Scope of Application: All batches supplied to which the Declaration of Conformity Procedure has been applied.

Declaration: Conformity of the products has been assessed in accordance with Annex VII of the Directive. A dossier of technical documentation, as required by the Directive is available. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier. We declare our products comply with EN 14683:2019+AC: 2019 as Type IIR

Verification Certificates: Quality Management System- Medical devices EN ISO-13485:2016 ' Certificate No: ISO 02 836 1179 Quality Management System EN ISO 9001:2015 Certificate No: ISO 01 940 117

Standards Applied: EN ISO 13485 Medical devices-Quality management systems - Requirements for regulatory purposes

EN ISO 9001:2015 Quality management systems

EN ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied

MDD 93/42/EEC Medical devices directive

EN ISO 1041 Information supplied by the manufacturer of medical devices

EN ISO 14683:2019+AC: 2019 Medical face masks - Requirements and test methods

EN ISO 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices

EN ISO 14971 Medical devices - Application of risk management to medical devices

Authorised Signatory

Name-Surname: Murat YILDIZ

Position : CEO

Signed:

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koralıtı Cad.
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Dated: 22.03.2020