



MY Medikal

MY TICARET VE MEDİKAL 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 MEDİKAL A.S.			
Manufacturer Address	Ömerli mah General Şükrü Koraltı Cd no:33, 34555 Arnavutkoy/Istanbul, Turkey			
Single Registration Number (SRN)	TR-MF-000018372			
Brand	Mumu			
Product Description, Packaging, Product Catalogue No.	Non-sterile 3Ply Adult/Kids Surgical Mask Type IIR			
	Product Description	Packaging	Color	Product Catalogue No.
	Non-sterile 3Ply Adult Surgical Mask Type IIR	50pcs	Blue	MM.NS.LM.01
	Non-sterile 3Ply Kids Surgical Mask Type IIR	10pcs	Pattern/Designed	MM.NS.LM.32
	Non-sterile 3Ply Kids Surgical Mask Type IIR	50pcs	Pattern/Designed	MM.NS.LM.29
	Non-sterile 3Ply Adult Surgical Mask Type IIR	10pcs/pack.	Blue	MM.NS.LM.24
	Non-sterile 3Ply Adult Surgical Mask Type IIR	10pcs	Blue	MM.NS.LM.20
	Non-sterile 3Ply Tie Adult Surgical Mask Type IIR	50pcs	Blue	MM.NS.BM.01
	Non-sterile 3Ply Tie Adult Surgical Mask Type IIR	100pcs	Blue	MM.NS.BM.02
	Non-sterile 3Ply Adult Surgical Mask Type IIR	1 pc. (Single Pack)	Blue	MM.NS.LM.22
	Non-sterile 3Ply Adult Surgical Mask Type IIR	5pcs/pack	Blue	MM.NS.LM.23
	Non-sterile 3Ply Adult Surgical Mask Type IIR	50pcs	Black	MM.NS.LM.502
Non-sterile 3Ply Kids Surgical Mask Type IIR	10pcs	Green	MM.NS.LM.507	



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	Non-sterile 3Ply Kids Surgical Mask Type IIR	10pcs	Red	MM.NS.LM.506
	Non-sterile 3Ply Kids Surgical Mask Type IIR	10pcs	Pink	MM.NS.LM.505
	Non-sterile 3Ply Kids Surgical Mask Type IIR	50pcs	Blue	MM.NS.LM.509
	Non-sterile 3Ply Kids Surgical Mask Type IIR	10pcs	Blue	MM.NS.LM.508
	Non-sterile 3Ply Kids Surgical Mask Type IIR	10pcs	Black	MM.NS.LM.504
	Non-sterile 3Ply Adult Surgical Mask Type IIR	10pcs	Red	MM.NS.LM.503
	Non-sterile 3Ply Adult Surgical Mask Type IIR	10pcs	Black	MM.NS.LM.549
	Non-sterile 3Ply Adult Surgical Mask Type IIR	10pcs	Green	MM.NS.LM.501
	Non-sterile 3Ply Adult Surgical Mask Type IIR	10pcs	Pink	MM.NS.LM.500
Intended Purpose	A surgical mask, also known as a medical face mask, worn by healthcare professionals during medical procedures. It is a medical device that when properly fitted, prevents the transmission of airborne infections between patients and/or treatment personnel by preventing pathogens (primarily bacteria and viruses) emitted in respiratory droplets and aerosols from entering the user's mouth and nose. According to EN 14683:2019+AC:2019 standard; Type IIR and BFE is >98%.			
Basic UDI-DI	868227994MSKXT			
Packaging	50 pcs, 10 pcs, 5 pcs, 1 pc.(Single pack)			
European Medical Device Nomenclature (EMDN)	T020604- Medical Use Face Masks, Type II and IIR			
GMDN Code	35177			
Classification & Rule (MDR)	Class I, Rule 1			
Conformity Assessment Procedure (MDR)	Annex II & III according to Medical Device Regulation (EU) 2017/745			
Applicable Standards	EN 14683: 2019+AC: 2019 ; EN 14683:2019+AC-EQV			



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We, My Ticaret ve Medikal A.S. herewith declare that the above-mentioned device:

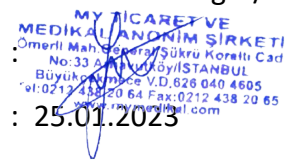
- Is in compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentations are retained under the premise of manufacturer.
- The surgical mask is manufactured according to EN ISO 13485:2016 Quality Management System:

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.

Authorized Signatory:

Approver : MURAT YILDIZ
Title : General Manager/CEO
Signature : 
Approval Date : 25.01.2023
Place of Approval : Istanbul, Turkey

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
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