

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDİKAL-SRT-001							
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	Powderfree 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	868227994LPFX3							
Country of Origin	Thailand							
Size	XS, S, M, L, XL							
EAN Code	8683020022966, 8681695367016, 8681695367023, 8681695367030, 8682279940830							
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)							
Global Medical Device Nomenclature (GMDN)	47172 (Hevea-latex Examination/treatment glove, non-powdered, non-antimicrobial)							
Product Catalogue/Reference Number	ML01-XS, ML02-S, ML03-M, ML04-L, ML05-XL							
Product Group Reference Number	LO01							
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745							
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5							
Device Classification (PPER)	Category III							
EU Type-Examination Certificate (PPER)	2777/10467-05/E15-01							
Notified Body (PPER)	EU-Type Examination and Ongoing Conformity by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [CE 2777]							
Applicable Standards	<table border="1"> <thead> <tr> <th>No.</th> <th>Regulation/ Standard Number</th> <th>Regulation/ Standard Name</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>MDR (EU) 2017/745</td> <td>Medical Device Regulation</td> </tr> </tbody> </table>		No.	Regulation/ Standard Number	Regulation/ Standard Name	1	MDR (EU) 2017/745	Medical Device Regulation
	No.	Regulation/ Standard Number	Regulation/ Standard Name					
1	MDR (EU) 2017/745	Medical Device Regulation						



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MY TICARET VE MEDİKAL A.S.

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Tel: +902124382064 Fax: +902124382065

Website: www.mymedikal.com.tr.

2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
4	ISO 9001: 2015	Quality management systems – requirements
5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
6	EN 455-1: 2020	Requirements and testing for freedom from holes
7	EN 455-2: 2015	Requirements and testing for physical properties
8	EN 455-3: 2015	Requirements and testing for biological evaluation
9	EN 455-4: 2009	Requirements and testing for shelf-life determination
10	ISO 10993-1: 2018	Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process
11	ISO 10993-5: 2009	Biological evaluation of medical devices –Part 5: Test for in vitro cytotoxicity
12	ISO 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
13	ASTM F1671: 2013	Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using phi-x174 bacteriophage penetration as a test system
14	ASTM D3578: 2019	Standard specification for rubber examination gloves
15	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
16	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer
17	ASTM D7160: 2016	Determination of expiration dating for medical gloves
18	ASTM D7161: 2016	Determination of real time expiration dating of mature medical gloves stored under typical warehouse conditions



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Website: www.mymedikal.com.tr.

19	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
20	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
21	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
22	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
23	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
24	EN ISO 21420: 2020	Protective gloves - General requirements and test methods

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.
- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2777 by SATRA Technology Europe Ltd.
- Is in conformity to type based on quality assurance of the production process under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ
Title : General Manager/CEO
Signature :
Approval Date : 23 Sep 2024
Place of Approval : Istanbul, Turkey

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad
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Website: www.mymedikal.com.tr

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDİKAL-SRT-003												
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	B-good												
Product Description	Latex Powderfree 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	868227994LPFX3												
Size	XS, S, M, L, XL												
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)												
Global Medical Device Nomenclature (GMDN)	47172 (Hevea-latex Examination/treatment glove, non-powdered, non-antimicrobial)												
Product Catalogue/Reference Number	BGLP01-XS, BGLP02-S, BGLP03-M, BGLP04-L, BGLP05-XL												
Product Group Reference Number	LO01												
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745												
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5												
Device Classification (PPER)	Category III												
EU Type-Examination Certificate (PPER)	2777/10467-05/E15-01												
Notified Body (PPER)	EU-Type Examination and Ongoing Conformity by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [CE 2777]												
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1	MDR (EU) 2017/745	Medical Device Regulation											
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3	ISO 13485: 2016	Medical devices - Quality management											



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Website: www.mymedikal.com.tr.

		systems - Requirements for regulatory purposes
4	ISO 9001: 2015	Quality management systems – requirements
5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
6	EN 455-1: 2020	Requirements and testing for freedom from holes
7	EN 455-2: 2015	Requirements and testing for physical properties
8	EN 455-3: 2015	Requirements and testing for biological evaluation
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10	ISO 10993-1: 2018	Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process
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13	ASTM F1671: 2013	Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using phi-x174 bacteriophage penetration as a test system
14	ASTM D3578: 2019	Standard specification for rubber examination gloves
15	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
16	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer
17	ASTM D7160: 2016	Determination of expiration dating for medical gloves
18	ASTM D7161: 2016	Determination of real time expiration dating of mature medical gloves stored under typical warehouse conditions
19	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks



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Website: www.mymedikal.com.tr.

20	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
21	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
22	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
23	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
24	EN ISO 21420: 2020	Protective gloves - General requirements and test methods

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.
- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2777 by SATRA Technology Europe Ltd.
- Is in conformity to type based on quality assurance of the production process under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ
Title : General Manager/CEO
Signature : 
Approval Date : 15 Feb 2024
Place of Approval : Istanbul, Turkey

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
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EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDİKAL-SRT-005												
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	Douromed												
Product Description	Powderfree 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	868227994LPFX3												
Size	XS, S, M, L, XL												
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)												
Global Medical Device Nomenclature (GMDN)	47172 (Hevea-latex Examination/treatment glove, non-powdered, non-antimicrobial)												
Product Catalogue Number	ML01-XS, ML02-S, ML03-M, ML04-L												
Reference Number	63369, 78564, 125634, 233635												
Product Group Reference Number	LO01												
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745												
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5												
Device Classification (PPER)	Category III												
EU Type-Examination Certificate (PPER)	2777/10467-05/E15-01												
Notified Body (PPER)	EU-Type Examination and Ongoing Conformity by Notified Body SATRA TECHNOLOGY EUROPE LTD Bracetown Business Park, Clonee, D15YN2P, Ireland [CE 2777]												
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Website: www.mymedikal.com.tr.

		systems - Requirements for regulatory purposes
4	ISO 9001: 2015	Quality management systems – requirements
5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
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18	ASTM D7161: 2016	Determination of real time expiration dating of mature medical gloves stored under typical warehouse conditions
19	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks



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Website: www.mymedikal.com.tr.

20	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
21	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
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23	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
24	EN ISO 21420: 2020	Protective gloves - General requirements and test methods

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.
- Is following the EU-Type Examination with the provisions of new PPE Regulations (EU) 2016/425 Category III of the notified body number 2777 by SATRA Technology Europe Ltd.
- Is in conformity to type based on quality assurance of the production process under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.
- This EU Declaration of Conformity is prepared in accordance with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature

Approval Date : 15 Feb 2024

Place of Approval : Istanbul, Turkey

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
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Tel: +902124382064 Fax: +902124382065

Website: www.mymedikal.com.tr

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDİKAL-SRT-006																									
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	E-care																									
Product Description	Powderfree 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.																									
Size	XS, S, M, L, XL																									
Global Medical Device Nomenclature (GMDN)	47172 (Hevea-latex Examination/treatment glove, non-powdered, non-antimicrobial)																									
Product Catalogue Number	ENBXS00, ENBS01, ENBM02, ENBL03, ENBXL04																									
Conformity Assessment Route (MDR):	Annex II and Annex III																									
Classification & Rule (MDR)	Class I, Rule 1 & Rule 5																									
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Website: www.mymedikal.com.tr.

8	ISO 10993-1: 2018	Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process
9	ISO 10993-5: 2009	Biological evaluation of medical devices –Part 5: Test for in vitro cytotoxicity
10	ISO 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
11	ISO 20417:2021	Medical devices- Information to be supplied by the manufacturer of medical devices
12	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer

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

- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature

Approval Date

Place of Approval

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad
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: 08 Dec 2023

: Istanbul, Turkey



MY Medikal

MY TICARET VE MEDİKAL A.S.

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EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDİKAL-TG-001																														
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	Powderfree Latex Gloves																														
Intended Purpose	A glove is a personal protective equipment that is designed to be worn for minimum risk only.																														
Size	XS, S, M, L, XL																														
Product Catalogue Number	MLPF02																														
Conformity Assessment Procedure (MDD)	Annex VII																														
Classification (MDD)	Class I, Non-sterile																														
Device Classification (PPER)	Category I with minimum risk only																														
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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.

	10	ISO 10993-10: 2010	Biological evaluation of medical devices –Part 10: Test for irritation and skin sensitization
	11	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	12	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer

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

- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.
- Is following the EU-Type Examination and conforming with the provisions of new PPE Regulations (EU) 2016/425 Category I with minimum risk only.
- Is fully compliance with the Essential Requirement of the EC Council Directive 93/42/EEC 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature

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

Approval Date : 07-Dec 2023

Place of Approval : Istanbul, Turkey

CE



MY Medikal

MY TICARET VE MEDİKAL A.S.

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Tel: +902124382064 Fax: +902124382065

Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDİKAL-TG-003															
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	Sente															
Product Description	Powderfree 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	868302002LPFLR															
Size	S, M, L, XL															
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)															
Global Medical Device Nomenclature (GMDN)	47172 (Hevea-latex Examination/treatment glove, non-powdered, non-antimicrobial)															
Product Catalogue Number	SELPF01-S, SELPF02-M, SELPF03-L, SELPF04-XL															
Conformity Assessment Route (MDR):	Annex I and Annex II and Annex IV															
Classification & Rule (MDR)	Class I, Rule 5 transient use															
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Website: www.mymedikal.com.tr.

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 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 with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ

Title : General Manager/CEO

Signature : 
MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad
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Tel:0212 438 20 64 Fax:0212 438 20 65
www.mymedikal.com

Approval Date : 07 Dec 2023

Place of Approval : Istanbul, Turkey

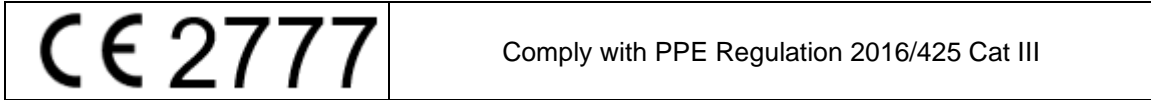




As of 04 Mar 2024



USER INFORMATION



These products are classed as Category III Personal Protective Equipment (PPE) by the European PPE REGULATION 2016/425 and have been shown to comply with this Regulation through the Harmonised European Standard(s): EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016

Product references:

Mumu, Douromed, Elastron Latex Powderfree Gloves, Chlorinated, Non-sterile
ML01-XS, ML02-S, ML03-M, ML04-L, ML05-XL

B-good Latex Powderfree Gloves, Chlorinated, Non-sterile
BGLP01-XS, BGLP02-S, BGLP03-M, BGLP04-L, BGLP05-XL

Sizes available: XS, S, M, L, XL

Colour: Natural/ Pale Yellow, the color may vary due to storage time and conditions

Intended Use:

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.

Performance and limitation of use –This product has been tested and achieved the following performance levels:

Classification:

EN ISO 374-1:2016+A1:2018 /Type B	Level	EN ISO 374-4:2019 Degradation%
40% Sodium Hydroxide (K)	4	-72.4%
96% Sulphuric Acid (L)	1	92.9%
65% Nitric Acid (M)	1	20.9%
37% Formaldehyde (T)	6	-81.7%
30% Hydrogen Peroxide (P)	6	-64.1%

EN ISO 374-5:2016

Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

EN ISO 374-1:2016+A1:2018 /Type B



KTP



Virus





EN ISO 374-1:2016+A1:2018 Permeation levels are based on breakthrough times as follows:

Permeation performance level	1	2	3	4	5	6
Measured breakthrough time (min)	>10	>30	>60	>120	>240	>480

EN ISO 374-4:2019 Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.

“The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture.”

“It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation.”

“When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves”

“Before usage, inspect the gloves for any defect or imperfections.”

Storage and transport: When not in use, store the product in a well-ventilated area away from extremes of temperature

Glove performance quoted is based on laboratory data and may not reflect the actual duration of protection in the workplace due to other factors influencing the performance such as temperature, abrasion, degradation etc.)

The glove does not contain any substances that are known to cause allergies.

The Gloves have no mechanical protection offered.

For single use only, do not littering.

Check for damage before use, do not use damaged gloves





Donning:

1. Remove all hand and wrist jewelry, and wash the hands before donning.
2. Place the gloves on the prepared work surface.
3. The user puts a glove on his/her dominant hand by grabbing it with the other hand, remembering to only touch the inside of the gloves, and slipping it over the dominant hand until it reaches the final level.
4. The wearer uses the gloved dominant hand to slip the other glove onto the non-dominant hand.
5. Once both gloves are on, the users can touch the outside of the gloves to ensure a proper fit

Doffing:

1. Using the dominant hand, users start by grabbing the outside of the glove on the non-dominant hand on the palm side near the cuff.
2. Pull the glove off the non-dominant hand and place it in the gloved hand, balling it up.
3. Slip two fingers under the cuff of the other hand glove and carefully peel it off the hand without touching the wrist, turning the remaining glove inside out as it is removed and in turn encasing the first glove.
4. The gloves can be disposed.

The DOC (declaration of conformity) will be shown on website: www.mymedikal.com.tr/documents

Notified Body responsible for certification and ongoing conformity:

SATRA Technology Europe Ltd

Bracetown Business Park

Clonee, Dublin

D15 YN2P, Ireland (NB2777)

Product manufactured by: MY TICARET VE MEDİKAL A.Ş.





These products also comply with Medical Device Regulation (EU) 2017/745 under the Class I category.

CAUTIONS AND RESTRICTION

1. Keep in dry conditions and avoid sunlight or other ozone sources.
2. For single-use only.
3. For latex gloves: This product contains natural latex which may cause allergic reactions.

DISPOSAL METHOD

Throw it away in the special rubbish can after using it.

INSTRUCTIONS FOR USE

1. Always wash hands before putting on gloves and each time you change to a new pair.
2. Take the gloves out from their original box.
3. Select a glove appropriate for the task and in your size. Inform yourself prior to the application.
4. Touch only a restricted surface of the glove corresponding to the wrist (at the top edge of the cuff)
5. Don the first glove by inserting your hand into the opening and pulling it over by applying a soft pull with the second hand.
6. Take the second glove with a bare hand and touch only a restricted surface of the glove corresponding to the wrist.
7. To avoid touching the skin of the forearm with the gloved hand, turn the external surface of the glove to be donned on the folded fingers of the gloved hand so there is a good hold on it. Thus, permitting to glove the second hand by pulling softly with the first gloved hand.
8. Once gloved, hands should not touch anything else that is not defined by indications and conditions for glove use.
9. Change gloves before beginning a different task to avoid cross-contamination.
10. Pinch one glove at the wrist level to remove it, without touching the skin of the forearm, and peel it away from the hand, thus, allowing the glove to turn inside out.
11. Hold the removed glove in the gloved hand and slide the fingers of the ungloved hand inside between the glove and the wrist of the gloved hand. Remove the second glove by rolling it down the hand and fold the first glove into the outside palm area of the second glove. If done correctly, the user holds a pack of the outer glove turned inside and out and the contaminated surface of both gloves is within the package.
12. Discharge the removed gloves and wash hands thoroughly according to the respective hygiene standards.
13. Not intended to be used as a chemical barrier. The shelf life is normally advised to be













MY Medikal

five years. Check the original dispenser instructions for details.

Other Common Graphical Symbols:

SYMBOLS	TITLE
	Manufacturer
	Date of Manufacture
	Use-by date/ Expiration Date
	Batch Code/ Lot Number
	Keep away from sunlight
	Keep dry
	Do not re-use
	Non-sterile

**MY TİCARET VE
MEDİKAL ANONİM ŞİRKETİ**
Ömerli Mh.General Şükrü Koraltı Cad
No:33 Arnavutköy/İSTANBUL
B.ÇEKMECE V.D.6260404505
İl:0212 436 20 64 Fax:0212 436 20 65
www.mymedikal.com






As of 02 Jan 2025



USER INFORMATION

	<p>Comply with PPE Regulation 2016/425 Cat I-For Minimal Risk Only</p> <p><i>Note: Please refer to the Declaration of Conformity for more details</i></p>
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Product references:

Mumu Powderfree Latex Gloves

MLPF02

Sizes available: XS, S, M, L, XL

Intended Use:

The Latex Examination Gloves is a disposable device intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

“Before usage, inspect the gloves for any defect or imperfections.”

Storage and transport: When not in use, store the product in a well-ventilated area away from extremes of temperature

For single use only, do not littering.

Check for damage before use, do not use damaged gloves

Donning:

1. Remove all hand and wrist jewelry, and wash the hands before donning.
2. Place the gloves on the prepared work surface.
3. The user puts a glove on his/her dominant hand by grabbing it with the other hand, remembering to only touch the inside of the gloves, and slipping it over the dominant hand until it reaches the final level.
4. The wearer uses the gloved dominant hand to slip the other glove onto the non-dominant hand.
5. Once both gloves are on, the users can touch the outside of the gloves to ensure a proper fit





Doffing:

1. Using the dominant hand, users start by grabbing the outside of the glove on the non-dominant hand on the palm side near the cuff.
2. Pull the glove off the non-dominant hand and place it in the gloved hand, balling it up.
3. Slip two fingers under the cuff of the other hand glove and carefully peel it off the hand without touching the wrist, turning the remaining glove inside out as it is removed and in turn encasing the first glove.
4. The gloves can be disposed.

The DOC (declaration of conformity) will be shown on website: www.mymedikal.com.tr

Product manufactured by: MY TICARET VE MEDİKAL A.Ş.



	This product also complies with Medical Device Regulation (EU) 2017/745 under the Class I category.
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Other Common Graphical Symbols:

SYMBOLS	TITLE
	Manufacturer
	Date of Manufacture
	Use-by date/ Expiration Date
	Batch Code/ Lot Number





MY Medikal

	Keep away from sunlight
	Keep dry
	Do not re-use
	Non-sterile
EN455	European Standard

MY TİCARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koralı Cad
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www.mymedikal.com





As of 22 May 2024



USER INFORMATION

	<p>Comply to PPE Regulation 2016/425 Cat I (For Minimal Risk Only)</p> <p><i>Note: Please refer to the Declaration of Conformity for more details</i></p>
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Product: Simplistic Powderfree Latex Gloves

Catalog No./ Product reference: SLPF01-XS, SLPF02-S, SLPF03-M, SLPF04-L, SLPF05-XL

Sizes available: XS, S, M, L, XL

Colour: White

Intended Use:

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.

Before usage, inspect the gloves for any defects or imperfections.

Storage and transport: When not in use, store the product in a well-ventilated area away from extremes of temperature

For single use only, do not littering.

Check for damage before use, do not use damaged gloves

Donning:

1. Remove all hand and wrist jewelry, and wash the hands before donning.
2. Place the gloves on the prepared work surface.
3. The user puts a glove on his/her dominant hand by grabbing it with the other hand, remembering to only touch the inside of the gloves, and slipping it over the dominant hand until it reaches the final level.
4. The wearer uses the gloved dominant hand to slip the other glove onto the non-dominant hand.
5. Once both gloves are on, the users can touch the outside of the gloves to ensure a proper fit





Doffing:







1. Using the dominant hand, users start by grabbing the outside of the glove on the non-dominant hand on the palm side near the cuff.
2. Pull the glove off the non-dominant hand and place it in the gloved hand, balling it up.
3. Slip two fingers under the cuff of the other hand glove and carefully peel it off the hand without touching the wrist, turning the remaining glove inside out as it is removed and in turn encasing the first glove.
4. The gloves can be disposed.

The DOC (Declaration of Conformity) will be shown on the website: www.mymedikal.com.tr/documents

Product manufactured by: MY TICARET VE MEDİKAL A.Ş.



Other Common Graphical Symbols:

SYMBOLS	TITLE
	Manufacturer
	Date of Manufacture
	Use-by date/ Expiration Date
	Batch Code/ Lot Number
	Keep away from sunlight
	Keep dry





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	Do not re-use
	Non-sterile

MY TİCARET VE
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Tel: +902124382064 Fax: +902124382065

Website: www.mymedikal.com.tr.

EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDİKAL-CDS-001																										
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	Simplistic																										
Product Description	Powder-Free Latex Gloves																										
Intended Purpose	This is a personal protective equipment that is designed to be worn for minimum risk only.																										
Size	XS, S, M, L, XL																										
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)																										
Global Medical Device Nomenclature (GMDN)	47172 (Hevea-latex Examination/treatment glove, non-powdered, non-antimicrobial)																										
Product Catalogue Number	SLPF01-XS, SLPF02-S, SLPF03-M, SLPF04-L, SLPF05-XL																										
Conformity Assessment Route (MDD)	Annex VII																										
Classification & Rule (MDD)	Class I, Rule 5																										
Device Classification (PPER)	Category I (For minimal risk only)																										
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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.

8	EN 455-4: 2009	Requirements and testing for shelf-life determination
9	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
10	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer

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

- Is fully compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC.
- Is following the PPE Regulations (EU) 2016/425 Category I (For minimal risk only).
- The gloves are manufactured according to EN ISO 9001:2015 and EN ISO 13485:2016 Quality Management System.

Authorized Signatory:

Approver : MURAT YILDIZ
Title : General Manager/CEO
Signature : 
Approval Date : 08 Dec 2023
Place of Approval : Istanbul, Turkey

MY TICARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koraltı Cad
No:33 Arnavutköy/İSTANBUL
Büyükdere Şişli V.D.526 040 4605
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EU DECLARATION OF CONFORMITY

DOC No.	DOC-MYMEDİKAL-ITCM-001		
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	Powderfree Latex Gloves		
Intended Purpose	The Latex Examination Gloves is a disposable device intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.		
Basic UDI-DI	868227994LPFX3		
Size	XS, S, M, L, XL		
European Medical Device Nomenclature (EMDN)	T010201 (Examination/Treatment Gloves, Latex)		
Global Medical Device Nomenclature (GMDN)	47172 (Latex examination/treatment glove, non-powdered)		
Product Catalogue/Reference Number	MLPF02		
Conformity Assessment Route (MDR):	Annex II and Annex III according to EU 2017/745		
Classification & Rule (MDR)	Class 1, as per rule 5 of annex VIII of Regulation (EU) 2017/745 on Medical Device (MDR), All invasive devices with respect to body orifices, which are not intended for connection to an active device or which are intended for connection to a class 1 active device are classified as class 1, if they are intended for transient use.		
Device Classification (PPER)	Category I-For Minimal Risk Only		
Applicable Standards	No.	Regulation/ Standard Number	Regulation/ Standard Name
	1	MDR (EU) 2017/745	Medical Device Regulation
	2	PPE (EU) 2016/425	Category I-For Minimal Risk Only
	3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	4	ISO 9001: 2015	Quality management systems – requirements
	5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
	6	EN 455-1: 2020	Requirements and testing for freedom from holes



MY Medikal

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	7	EN 455-2: 2015	Requirements and testing for physical properties
	8	EN 455-3: 2015	Requirements and testing for biological evaluation
	9	EN 455-4: 2009	Requirements and testing for shelf-life determination
	10	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	11	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer

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.
- Is following the PPE Regulations (EU) 2016/425 Category I-For Minimal Risk Only.
- This EU Declaration of Conformity is prepared in accordance with Annex IV of Medical Device Regulation (EU) 2017/745.

Authorized Signatory:

Approver : MURAT YILDIZ
Title : General Manager/CEO
Signature :
Approval Date : 02Jan2025
Place of Approval : Istanbul, Turkey

MY TICARET VE
MEDİKAL ANDRİM ŞİRKETİ
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