EC DECLARATION OF CONFORMITY

Manufacturer's Name and Address	:	MY TİCARET VE MEDİKAL A.Ş. Ömerli Mah. General Şükrü Koraltı Cad. No :33 Arnavutköy-İstanbul/TURKEY
Name Of Device	:	Latex Examination Gloves Nitrile Examination Gloves
Type and Registiration/Catalog No	:	Powdered Latex Examination Gloves - [redacted] Powder Free Latex Examination Gloves - [redacted] Powder Free Nitrile Examination Gloves - [redacted]
Brand	:	Mumu – Mumu Plus
Classification	:	Class I
Conformity Assessment Procedure	:	Annex VII
Conformity Route	:	Self Declaration

We herewith declare with our own responsibility that above mentioned product(s) with CE mark is fully compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC.

Verification Certificates	:	Quality Management System EN ISO13485:2016 Certificate No: ISO 02 836 1179 Quality Management System EN ISO9001:2015 Certificate No: ISO 01 940 117

MY Medikal

Standards : EN 374-2 Protective gloves against dangerous chemicals and microorganisms-Part 2: Determination of resistance to penetration.

EN 16523-1+A1 Determination of material resistance to permeation by chemicals-Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (EN 374-3 standard has been revised as EN 16523-1+A1)

EN 374-4 Protective gloves against dangerous chemicals and microorganisms-Part 4: Determination of resistance to degradation by chemicals.

EN 374-5 Protective gloves against dangerous chemicals and microorganisms-Part 2: Terms and performance rules for microorganism risks.

EN 455-1 Medical gloves for single use Part 1: Requirements and testing for freedom from holes.

EN 455-2 Medical gloves for single use Part 2: Requirements and testing for physical properties.

EN 455-3 Medical gloves for single use Part 3: Requirements and testing for biological evaluation.

EN 455-4 Medical gloves for single use Part 4: Requirements and testing for shelf life determination.

EN ISO 10993-1 Biological evaluation of medical devices-Part-1: Evaluation and testing within a risk management process.

Authorised Signatory

Name-Surname : MURAT YILDIZ

Position : CEO

Signed : [redacted]

Date : 22.03.2020

CE

[redacted]

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 ELDiVENi, NiTRiL PUDRASIZ MUAYENE ELDiVENi, STERiL / NON-STERiL CERRAHi ELDiVEN, STERiL / NON-STERiL SPANÇ GAZ KOMPRES, STERiL / NON-STERiL BATIN KOMPRES, STERiL / NON-STERiL PAMUKLU PED, GAZLI BEZ,
STERiL / NON-STERiL CERRAHi MASKE ÜRETİMİ VE SATIŞI

ISO 01 940 1179	Jun. 5, 2020	Jun. 4, 2021
Certificate No.	*Date of this Certificate*	*Certification Expiry Date*
May. 28, 2020	Jun. 5, 2020	[redacted]
Date of Audit	*Date of Registration*	*Managing Director / Director*

[redacted]

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

* You can query the validity of this certificate by sending an e-mail to info@medicert.com.tr.

EUROLAB®
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TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

UNITED ACCREDITATION FOUNDATION
UAF

[redacted]

Report No: [redacted]
Applicant: MY TİCARET VE MEDİKAL A.Ş
Ömerli Mah. General Şükrü Karaltı Caddesi No:33 Arnavutköy/İSTANBUL
Contact Person: Z.Melek ÖZ BOLAT
Contact Telephone: [redacted]
Contact e-mail: kalite@mymedikal.com.tr
Sample Accepted on: 03.07.2020
Report Date: 27.07.2020
Total number of pages: 7 (pg)

Sample ID: NİTRİLE EXAMİNATİON GLOVE / LATEX EXAMİNATİON GLOVE

	TEST	METHOD	Specimen	RESULT
	[redacted]			
*	CHEMI[redacted]			

[redacted]

Seal

[redacted]

Customer Representative
Hasan KUTLU

[redacted]

Laboratory Manager
Hava SARIAYDIN

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL
Tel: [redacted]
Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EUROLAB ® (TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.)

Environment

The requirements and standards apply to equipment intended for use in

X	Residential (domestic) environment
X	Commercial and light-industrial environment
X	Industrial environment
X	Medical environment

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

Tel: [redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

TS EN ISO 374-2 Protective Gloves Against Dangerous Chemicals And Micro-Organisms - Part 2: Determination Of Resistance To Penetration

Scope

T[redacted]
d

Air Leak Test Method

- The glove is fastened to the circular mandrel and is inflated after [redacted]
wi
m
- T
bu

Table 1

Nominal glove thickness (e) mm As provided by the manufacturer	Air pressure (X) kPa
[redacted]	

Product	**Medical Glove**
Brand	**Mumu – Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number: [redacted]**
	Latex Examination Glove Catalog Number: [redacted]
Color	**Blue, White**

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[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Test Results

Specimen	Total Air Pressure (kPa)	Observation	Result
[redacted]			

Water Leak Test Method

[redacted]

Test Results

Specimen	Observation	Result
[redacted]		

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Tel: [redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

TS EN ISO 16523-1 Determination Of Material Resistance To Permeation By Chemicals - Part 1: Permeation By Potentially Hazardous Liquid Chemicals Under Conditions Of Continuous Contact

Scope

[redacted]

Test Method

[redacted]

Gloves Type	Requirement
[redacted]	[redacted]

Product	**Medical Glove**
Brand	**Mumu – Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number:** [redacted]
	Latex Examination Glove Catalog Number: [redacted]
Color	**Blue, White**

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Tel: [redacted]
Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Table 2 EN ISO 374-1 glove permeation test list

Code Letter	Chemical	Cas Number	Class
A	[redacted]		
B			
C			
D			
E			nic
F			
G			
H			
I			
J			
K			
L			
M			g
N			
O			
P			
S			
T	Formaldehyde %37	50-00-0	Aldehyde

Test Results

Specimen	Chemical	Observation	Gloves Type
Nitrile Examination Glove	[redacted]		
Nitrile Examination Glove			
Nitrile Examination Glove			
Nitrile Examination Glove			

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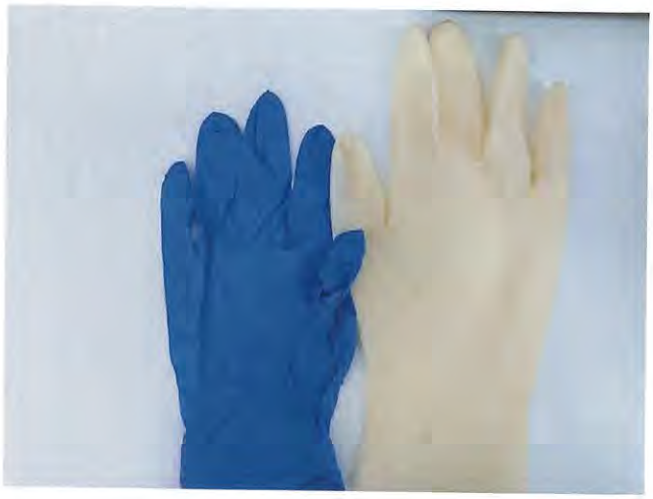
[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Specimen	Chemical	Observation	Gloves Type
Latex Examination Glove	Methanol	Not permeable	[redacted] 2016

Image



END OF REPORT

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

[redacted]

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TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

UNITED ACCREDITATION FOUNDATION UAF

[redacted]

Report No: 2[redacted]
Applicant: **MY TİCARET VE MEDİKAL A.Ş**
Ömerli Mah. General Şükrü Koraltı Cd. No:33 Arnavutköy/İstanbul
Contact Person: Z. Melek Öz Bolat
Contact Telephone: [redacted]
Contact e-mail: kalite@mymedikal.com.tr
Sample Accepted on: 03.07.2020
Report Date: 19.08.2020
Total number of pages: 11 (Pg)

Sample ID: **Nitrile Examination Glove – Latex Examination Glove**

Nitril Muayene Eldiveni - Lateks Muayene Eldiveni

	TEST	METHOD	Specimen	RESULT
*	Prot che Part deg	[redacted]		
*	TS E agai micr perf risks.			

Seal

[redacted]
Customer Representative
Hasan KUTLU

[redacted]
Laboratory Manager
Hava SARIAYDIN

Merkez Mh, Gencosman Cd. No 11 / A GÜNGÖREN / İSTANBUL
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[redacted]

Environment

The requirements and standards apply to equipment intended for use in

X	Residential (domestic) environment
X	Commercial and light-industrial environment
X	Industrial environment
X	Medical environment

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[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EN 374-4 Protective gloves against dangerous chemicals and microorganisms - Part 4: Determination of resistance to degradation by chemicals

SCOPE

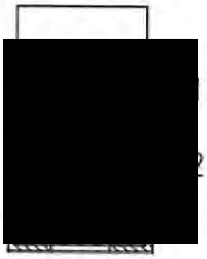
[redacted]

Principle

[redacted]

Procedure

[redacted]



Key

[redacted]

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[redacted]

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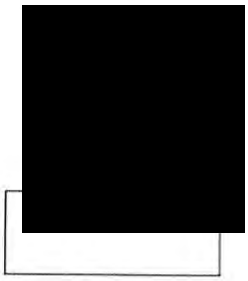
Puncture testing

[redacted] vial [redacted] d (see [redacted] n that [redacted]



Key

1 [redacted]

2 [redacted]

[redacted] t

Product	**Medical Glove**
Brand	**Mumu – Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number:** [redacted] **Latex Examination Glove Catalog Number:** [redacted]
Color	**Blue/White**

Result

The following degradation data (see Table A.1) have been obtained in laboratory.

Table A.1 — Results in % of correlation trial with other gloves materials

Laboratory	Acetone		Sulfuric Acid	
	Mean value for Nitrile glove	Mean value Latex glove	Mean value for Nitrile glove	Mean value Latex glove
1	[redacted]			
2				
3				
4				
5				
6				

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T [redacted]

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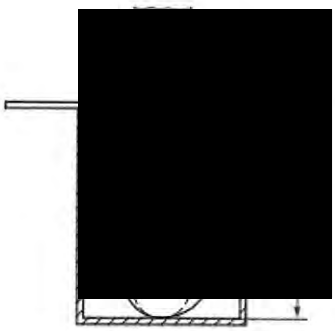
Weight Charge Test

Test Conditions

[redacted]

Procedure

[redacted]



[redacted]

Result

[redacted]

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[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

TS EN ISO 374-5:2016 Protective gloves against dangerous chemicals and microorganisms - Part 5: Terms and performance rules for microorganism risks

Scope

[redacted]

Test Conditions

[redacted]

Procedure

[redacted]

Result

Specimen: Nitrile Examination Glove Catalog Number: [redacted]

Tested Specimen Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Observation	Result	Marking
[redacted]						

a [redacted]

b

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[redacted]

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Specimen: Latex Examination Glove Catalog Number: [redacted]

Tested Specimen Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Observation	Result	Marking
[redacted]						

a [redacted]

b [redacted]

SCOPE

[redacted]

Air Leak Test Method

[redacted]

Table 1

Nominal glove thickness (e) mm As provided by the manufacturer	Air pressure (X) kPa
[redacted]	

Product	**Medical Glove**
Brand	**Mumu – Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number:** [redacted] **Latex Examination Glove Catalog Number:** [redacted]
Color	**Blue, White**

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[redacted]

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Test Result

Specimen	Total Air Pressure (kPa)	Observation	Result
Nitrile Examination	[redacted]	[redacted]	[redacted]

Water Leak Test Method

-The glove is attached to an open-ended plastic tube by bringing the cuff to the 40 mm mark and fastening it w[redacted]
-
n
-
r
d

Test Results

Specimen	Observation	Result
[redacted]	[redacted]	[redacted]

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[redacted]

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EN 16523-1 Determination Of Material Resistance To Permeation By Chemicals - Part 1: Permeation By Potentially Hazardous Liquid Chemicals Under Conditions Of Continuous Contact

Test Method

[redacted] the

Gloves Type	Requirement
[redacted]	t
	t
	t

EN ISO 374-1 glove permeation test list

Code Letter	Chemical	Cas Number	Class
A	[redacted]		
B			
C			
D			
E			ganic
F			
G			
H			
I			
J			n
K			
L			
M			ing
N			
O			
P			
S			
T	Formaldehyde %37	50-00-0	Aldehyde

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[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Test Results

Specimen	Chemical	Observation	Gloves Type
Nitrile Examination Glove	Methanol	Not permeable	
[redacted]			

Test Results

Specimen	Chemical	Observation	Gloves Type
Latex Examination Glove	Methanol	Not permeable	
[redacted]			

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

T[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Image

***** End Of Report*****

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[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EUROLAB® Laboratory Services

TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

UNITED ACCREDITATION FOUNDATION UAF

[redacted]

Report No: [redacted]
Applicant: **MY TİCARET VE MEDİKAL A.Ş**
Ömerli Mah. General Şükrü Karaltı Caddesi No:33 Arnavutköy/İSTANBUL
Contact Person: Z.Melek ÖZ BOLAT
Contact Telephone: [redacted]
Contact e-mail: kalite@mymedikal.com.tr
Sample Accepted on: 03.07.2020
Report Date: 24.07.2020
Total number of pages: 6(Pg)

Sample ID: **NITRILE EXAMINATION GLOVE / LATEX EXAMINATION GLOVE**

	TEST	METHOD	Specimen	RESULT
*	[redacted]		Nitrile	
*				
			Glove	

Seal

Customer Representative
Hasan KUTLU

Laboratory Manager
Hava SARIAYDIN

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL
T[redacted]
Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EUROLAB ® (TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.)

[redacted]

Environment

The requirements and standards apply to equipment intended for use in

X	Residential (domestic) environment
X	Commercial and light-industrial environment
X	Industrial environment
X	Medical environment

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

T[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EN 455-1

Medical Gloves For Single Use Part 1: Requirments And Testing For Freedom From Holes

Scope;

[redacted]

Test Method;

[redacted]

Product	**Medical Glove**
Brand	**Mumu – Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number:** [redacted] **Latex Examination Glove Catalog Number:** [redacted]
Color	**Blue, White**

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T[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

TEST RESULTS

	Test	Result	Overal Rating
[redacted]			

Conclusion: There is no water leakage in the Glove, the test is successful.

EN 455-2

Medical Gloves For Single Use Part 2: Requirements And Testing For Physical Properties

Scope;

[redacted]

Product	**Medical Glove**
Brand	**Mumu - Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number:** [redacted] **Latex Examination Glove Catalog Number:** [redacted]
Color	**Blue, White**

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL [redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

TEST RESULTS

	Result	Overal Rating
	[redacted]	

Conclusion: Meet EN 455-2 reqirements Glove, the test is successful.

EN 455-4

Medical gloves for single use Part 4: Requirements and testing for shelf life determination

This part of EN 455 specifies requirements for shelf life for medical gloves for single use. It also specifies therequirements for labelling and the disclosure of information relevant to the test methods used

Product	**Medical Glove**
Brand	**Mumu – Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number:** [redacted] **Latex Examination Glove Catalog Number:** [redacted]
Color	**Blue, White**

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

T[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Image

END OF REPORT

Merkez Mh. Gencosman Cd. No 11 / A GÜNGÖREN / İSTANBUL [redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EUROLAB Laboratory Services

TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

UNITED ACCREDITATION FOUNDATION UAF

[redacted]

Report No: [redacted]
Applicant: **MY TİCARET VE MEDİKAL A.Ş**
Ömerli Mah. General Şükrü Karaltı Caddesi No:33 Arnavutköy/İSTANBUL
Contact Person: Z.Melek ÖZ BOLAT
Contact Telephone: +[redacted]
Contact e-mail: kalite@mymedikal.com.tr
Sample Accepted on: 03.07.2020
Report Date: 19.08.2020
Total number of pages: 24 (Pg)

Sample ID: **NITRILE EXAMINATION GLOVE/ LATEX EXAMINATION GLOVE**

	TEST	METHOD	Specimen	RESULT
*	[redacted]		Nitrile	
*				
*				
			Glove	

[redacted]

Seal

[redacted]

Customer Representative
Hasan KUTLU

[redacted]

Laboratory Manager
Hava SARIAYDIN

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL
[redacted]
Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EUROLAB ® (TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.)

[redacted]

Environment

The requirements and standards apply to equipment intended for use in

X	Residential (domestic) environment
X	Commercial and light-industrial environment
X	Industrial environment
X	Medical environment

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

Te[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EN 455-3 Medical Gloves For Single Use - Part 3: Requirements And Testing For Biological Evaluation

Scope:

[redacted]

TEST METHODS

Endotoxins

[redacted]

Powder

[redacted]

Procedure:

[redacted]

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Proteins, Leachable

[redacted]

Procedure:

[redacted]

Product	**Medical Glove**
Brand	**Mumu – Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number:** [redacted] **Latex Examination Glove Catalog Number:** [redacted]
Color	**Blue / White**

TEST RESULTS

Endotoxins

Specimen	Endotoxin Requirement (EU)	Result
[redacted]		

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL [redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Powder

Specimen	Powder Value (mg)	Result
[redacted]		

Proteins, Leachable

Specimen	Protein value (µg)	Result
[redacted]		

EN 455-4 Medical Gloves For Single Use - Part 4: Requirements And Testing For Shelf Life Determination

Scope:

[redacted]nts

Real time shelf life determination

G[redacted]the

i

U s

a

Merkez Mh. Gencosman Cd. No 11 / A GÜNGÖREN / İSTANBUL [redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Accelerated shelf life determination

[redacted]

Product	**Medical Glove**
Brand	**Mumu – Mumu Plus**
Type/Models	**Nitrile Examination Glove Catalog Number:** [redacted] **Latex Examination Glove Catalog Number:**
Color	**Blue / White**

TEST RESULTS

Real time shelf life determination

[redacted]

Test Condition:

Exposure cycle

[redacted]

Test	UVA Exposure Time	Gray Scale	Customer Requirement	Result
[redacted]				

Observation ;

[redacted]

UV AGING

[redacted]

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

UV AGING

[redacted]

Conclusion: [redacted]

Measurement Device	Rates	Date of Calibration
[redacted]		

[redacted]

Accelerated shelf life determination

[redacted]

Test	UVA Exposure Time	Gray Scale	Customer Requirement	Result
[redacted]				

Observation :

[redacted]

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

T[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

UV AGING

[redacted]

Measurement Device	Rates	Date of Calibration
[redacted]		

[redacted]

TS EN ISO 10993-1

[redacted]

Cytotoxicity

[redacted]

Delayed-type hypersensitivity

[redacted]

Irritation (including intracutaneous reactivity)

[redacted]

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

Tel: [redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

[redacted]

Systemic toxicity (acute)

[redacted]

Subacute and subchronic toxicity

[redacted]

Genotoxicity

[redacted]

Implantation

[redacted]

Haemocompatibility

[redacted]

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

T[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

[redacted]

Chronic toxicity

[redacted]

Carcinogenicity

[redacted]

Reproductive and developmental toxicity

[redacted]

Biodegradation

[redacted]

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

[redacted]

Toxicokinetic studies

[redacted]

Merkez Mh. Gencosman Cd. No 11 / A GÜNGÖREN / İSTANBUL [redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Immunotoxicology

[redacted]

Evaluation tests for consideration

Medical device categorization by	Biological effect
[redacted]	

[redacted]

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

[redacted]

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EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
3	G		
3.1	T in pi		
3.2	Ir m fo pi to m		
3.3	T to		
	a)		
	b) re		
	c)		
	d)		
	e) pr		
	f) pr		
3.4	Te in in m na th th fa 4) to		
3.5	A fo im ne		
3.6	A ap fo pe		

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

T

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
3.7	Tl bi		
3.8	Tl w co in de cli ov		
4			
4.1			
4.2			
4.2.1			
4.2.2			
4.2.3			

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

Te

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EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	[redacted]		
4.2.4			
4.3			

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	[redacted]		
5	T[redacted]		
5.1	C[redacted]		
5.2	I[redacted]		
5.2.1	C[redacted]		
5.2.2	C[redacted]		
	W d c n C		
5.2.3	S[redacted]		
	T p e a a s S		
5.2.4	I[redacted]		
	T d a a p e d p 1		
5.2.5	I[redacted]		
	T m w te a u I 10993-10		

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
5.2.6	[redacted]		
5.2.7			
5.2.8			
5.2.9			

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	[redacted]		
5.2.10			
5.3			
5.3.1			
5.3.2			
5.3.3			

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

T[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	[redacted]		
5.3.4			
5.3.5			
6			

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL [redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	[redacted]		
7	[redacted]		
7.1			
7.2			

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[redacted]

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EN ISO 10993-1			
Clause	Requirement - Test	Result - Remark	Verdict

Table 1 — Initial evaluation tests for consideration

Medical device categorization by		Biological effect
Nature of body contact (see 5.2)		[redacted]
Category	Contact	
Surface device	Skin	
	Mucosal membrane	
	Breached or Compromised surface	
External communicating device	Blood path, indirect	

EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	Tis[redacted]		
	Ci[redacted]		
Implant device	Tis[redacted]		
	Bl[redacted]		

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[redacted]

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Table 2 — Supplementary evaluation tests for consideration			
Medical device categorization by		Biological effect	
Nature of body contact (see 5.2)		[redacted]	
Category	Contact		
Surface device	Skin		
	Mucosal membrane		
	Breached or compromised surface		
External communicating device	Blood path, indirect		
	Tissue/bone/dentin		
	Circulating blood		
Implant device	Tissue/bone		

EN ISO 10993-1			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	[redacted]		
Blood			

Result:

[redacted]

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T[redacted]

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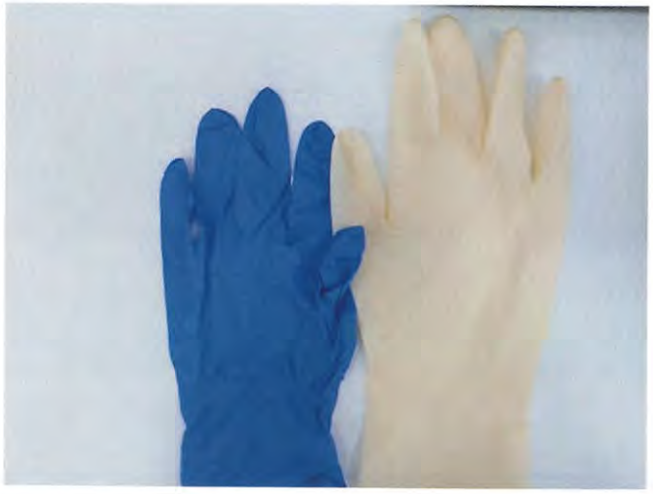
IMAGE



END OF REPORT

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL

[redacted]

Web: www.laboratuvar.com E-mail: info@laboratuvar.com

MY TİCARET VE MEDİKAL A.Ş.
OVERALL MIGRATION TESTING (OMT) REPORT

Type of Glove : Nitrile Powder Free Online Single Chlorinated, Blue, Textured

[redacted]

Type of Stimulant	Size	Testing Condition	Overall migration content requirement	Overall migration result (mg/dm^2)	Disposition
[redacted]					

Prepared by,
Z. Melek Öz Bolat
QA/ QC Officer

Verified by,
Vedat ÇETİN
QA Manager

MY TİCARET VE MEDİKAL A.Ş.

Test Report

Brand [redacted]

Size	Quantity (Carton)	Quantity (Pieces)	Lot No.	Manufacturing Date	Expiry Date
S	[redacted]				
	[redacted]				
	[redacted]				
	[redacted]				

[redacted]

MY TİCARET VE MEDİKAL A.Ş.

Test Report

Characteristics	Size	Unit	Sample Size	Median Value	Result
[redacted]					

Characteristics	Size	Unit	Sample Size	Median Value	Result
F[redacted]					

MY TİCARET VE MEDİKAL A.Ş.

Test Report

EN 455-2:2015 Requirement:

Before Aging: After Aging:

[redacted]

Characteristics	Size	Unit	Sample Size	Mean Value	Result
[redacted]					

Conclusion

[redacted].

Prepared By
Z. MELEK ÖZ BOLAT
Chemist, QC

Approved By
VEDAT ÇETİN
Manager, QA

This is a computer generated test report, no signature is required.

WINMED SDN BHD

CERTIFICATE OF ANALYSIS

[redacted]

Name: SITI
Date: 24/4/20
Time: 10AM

47400 Pet
Tel/Fax: 03-8

Certificate of Compliance

CE

We hereby declare that the technical file of product complied with the requirement of Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: CE-[redacted]

Manufacturer

Name : **E Glove Sdn Bhd**

Address : **No-15-2, Jalan 65C, Off Jalan Pahang Barat, Pekeliling Business Centre, 53000 Kuala Lumpur Wilayah Persekutuan Kuala Lumpur, Malaysia**

Products : **Latex and Nitrile Examination Glove (Powdered and Powder Free)**

Varients : **As Per appendix-I**

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	07th August 2020
1st Surveillance Audit Due	06th August 2021
2nd Surveillance Audit Due	06th August 2022
Certificate Expiry (subject to the company maintaining its system to the required standard)	06th August 2023

[redacted]

Authorised Signatory

Certificate of Compliance Appendix-I

Appendix to Certificate no.:- CE-[redacted]

Manufacturer :- E Glove Sdn Bhd

Address : No-15-2, Jalan 65C, Off Jalan Pahang Barat, Pekeliling Business Centre, 53000 Kuala Lumpur Wilayah Persekutuan Kuala Lumpur, Malaysia

CE

This certificate referred to above covers the following products like:

Varients:

- Latex Examination Powdered Glove, non-sterile
- Latex Examination Powder Free, non-sterile
- Nitirile Examination Powder Free, non-sterile
- Latex Long length glove 300mm, 400mm
- Nitrile Long length glove 300mm, 400mm
- Dental Dam Latex, Non-latex

[redacted]

Authorised Signatory

CERTIFICATE

This is to Certify that the
Quality Management System
of

E Glove Sdn Bhd

No-15-2, Jalan 65C, Off Jalan Pahang Barat, Pekeliling Business Centre, 53000 Kuala Lumpur Wilayah Persekutuan Kuala Lumpur, Malaysia

has been assessed and approved
in accordance with the guidelines of:

ISO 9001: 2015

For the following scope of activities:

Latex and Nitrile Examination Glove (Powdered and Powder Free)

Certificate Number: Q-[redacted]

Date of initial registration:	**07th August 2020**
Date of this Certificate:	**07th August 2020**
Surveillance Audit on or before:	**06th August 2021**
Recertification Due / Certificate Expiry:	**06th August 2023**

This Certificate is property of DBS Certifications and remains valid subject to satisfactory surveillance audits

[redacted]

Head of Certification

ACCREDITED
Management Systems Certification Body.
MSCB-157

The certificate remains the property of DBS Certifications Private Limited, to whom it must be returned upon request.

DBS CERTIFICATIONS PVT. LTD.
142, IInd Floor, Avtar Enclave, Paschim Vihar, Delhi-110063, (INDIA) info@dbscertification.com, www.dbscertification.com

ACCREDITED BY :
International Accreditation Service (IAS) 3060, Saturn Street Suite 100, Brea, Ca 92821-1732, United States of America

CERTIFICATE

E Glove Sdn Bhd

No-15-2, Jalan 65C, Off Jalan Pahang Barat, Pekeliling Business Centre, 53000 Kuala Lumpur Wilayah Persekutuan Kuala Lumpur, Malaysia

has been independently assessed and is compliant
with the requirement of:

ISO 13485:2016

Quality Management System for Medical Devices

For the following scope of activities:

Latex and Nitrile Examination Glove (Powdered and Powder Free)

Date of Certification: 07th August 2020
1st Surveillance Audit Due: 06th August 2021
2nd Surveillance Audit Due: 06th August 2022
Certificate Expiry: 06th August 2023

Certificate Number: UO-[redacted]

[redacted]

Head of Certification

The certificate remains the property of DBS Certifications Private Limited, to whom it must be returned upon request.

DBS CERTIFICATIONS PVT. LTD.
142, IInd Floor, Avtar Enclave, Paschim Vihar, Delhi-110063, (INDIA) info@dbscertification.com, www.dbscertification.com

ACCREDITED BY :
UK Akkreditering Forum Limited, UK (www.ukaf.org.uk)
5 Jupiter House, Calleva Park, Aldermaston, Reading Berkshire RG78NN UK

Príloha č. 2 - Návrh na plnenie kritéria na vyhodnotenie ponúk a identifikačné údaje uchádzača

Obchodné meno uchádzača:	MPV Group, s.r.o.
Sídlo uchádzača:	Cesta pod Hradovou 22, 040 01 Košice
IČO:	46 667 407
Meno a priezvisko štatutárneho zástupcu	Mgr. Mária Puškárová
IČ DPH:	SK2023519927
Názov banky:	Všeobecná úverová banka a.s.
Číslo účtu (IBAN):	S[redacted]
Telefónne číslo:	+4[redacted]
E-mailová adresa:	obchod@zdravotnetesty.sk

Predmet zákazky: „Ochranné jednorazové latexové rukavice“

Kritérium na vyhodnotenie ponúk: najnižšia cena za celý predmet zákazky v EUR s DPH.

Celková cena za predmet zákazky v EUR bez DPH	**Výška DPH**	**Celková cena za predmet zákazky** v EUR s DPH
14 603,00 €	**20%, 2 920,60 €**	**17 523,60 €**

Z toho:	**Cena v EUR bez DPH**	**Výška DPH**	**Cena v EUR s DPH**
Jednorazové latexové rukavice v množstve 47 200ks (veľkosť S)	**4 054,48 €**	**810,896 €**	**4 865,376 €**
Jednorazové latexové rukavice v množstve 85 000ks (veľkosť M)	**7 301,50 €**	**1 460,30 €**	**8 761,80 €**
Jednorazové latexové rukavice v množstve 37 200ks (veľkosť L)	**3 195,48 €**	**639,096 €**	**3 834,576 €**
Jednorazové latexové rukavice v množstve 600ks (veľkosť XL)	**51,54 €**	**10,308 €**	**61,848 €**

Cena uvedená uchádzačom obsahuje všetky náklady, ktoré uchádzačovi vzniknú v súvislosti s plnením predmetnej zákazky.

Som – Nie som platiteľom DPH (nehodiace sa preškrtnite)

Ak uchádzač nie je platiteľom DPH, na túto skutočnosť upozorní verejného obstarávateľa. Ak uchádzač nie je platcom DPH, ním uvedená cena bude považovaná za konečnú aj v prípade, ak by sa počas plnenia predmetu zákazky stal platiteľom DPH. V prípade, ak uchádzač je platiteľom DPH, avšak jeho sídlo je v inom členskom štáte EÚ alebo sídli mimo EÚ, uvedie v ponuke cenu, ktorá bude rozdelená na ním navrhovanú cenu bez DPH, výšku DPH a aj cenu s DPH podľa slovenských právnych predpisov (20%), aj keď samotnú DPH nebude fakturovať.

V Košiciach, dňa 8.12.2020

Mgr. Mária Pušk[redacted]

konateľ

mumu

Lateks Pudralı Muayene Eldiveni
Powdered Latex Examination Gloves

M
MEDIUM

NON STERILE

LATEX

EN 455

AQL 1.5

***100 Adet** / Pieces*
by count

Príloha č. 3 – Produktový list

Obchodné meno uchádzača:	MPV Group, s.r.o.
Sídlo uchádzača:	Cesta pod Hradovou 22, 040 01 Košice
IČO:	46 667 407
Meno a priezvisko štatutárneho zástupcu	Mgr. Mária Puškárová
IČ DPH:	SK2023519927
Názov banky:	Všeobecná úverová banka a.s.
Číslo účtu (IBAN):	[redacted]
Telefónne číslo:	+421[redacted]
E-mailová adresa:	obchod@zdravotnetesty.sk

Predmet zákazky: „Ochranné jednorazové latexové rukavice“

Latexové rukavice púdrované, certifikované zn. **3R resp. Mumu**