



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 Registration/Catalog No : Powdered Latex Examination Gloves - [REDACTED] 2
Powder Free Latex Examination Gloves - [REDACTED]
Powder Free Nitrile Examination Gloves - [REDACTED]

Brand : [REDACTED]

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



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

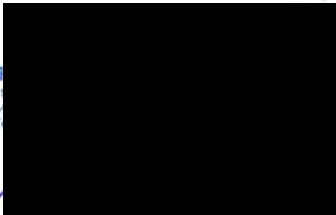
Position

: CEO

Signed

:

MY
İktisadi
Ticaret



Date

:

22.03.2020



Certificate of Registration



MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC: [REDACTED]

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 ELĐİVENİ, NİTRİL PUDRASIZ MUAYENE ELĐİVENİ, STERİL / NON-
STERİL CERRAHİ ELĐİVEN, STERİL / NON-STERİL SPANÇ GAZ KOMPRES, STERİL / NON-STERİL BATIN
KOMPRES, STERİL / NON-STERİL PAMUKLU PED, GAZLI BEZ,
STERİL / NON-STERİL CERRAHİ 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

[REDACTED]
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: [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.

**ÚRADNÝ PREKLAD Z ANGLIČTINY DO SLOVENČINY / OFFICIAL TRANSLATION FROM
ENGLISH INTO SLOVAK**

Predmet prekladu / Document description: ES VYHLÁSENIE O ZHODE / EC DECLARATION OF
CONFORMITY

Počet strán prekladanej listiny / Number of pages of the translated document: 02

Počet strán prekladu / Number of pages of the translation: 02

Počet odovzdaných vyhotovení / Number of copies handed over: 1

Miesto a dátum prekladu / Place and date of translation: Bratislava, 15/12/2020

Prekladateľ / Translator: Martin Krakovský, PhD., Mgr.

Palárikova 10, 811 05 Bratislava

Zadávateľ / Client: Skrivanek Slovensko, s.r.o. preklady@skrivanek.sk

Mlynská 22, 040 01 Košice

Číslo spisu (objednávky) / File (Order) number: -

Číslo v prekladateľskom denníku / Translator's register entry No.: 651/2020



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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

:

IV

IN

Date

:

22.03.2020



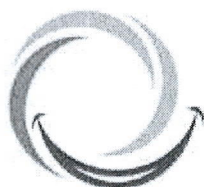


ES Vyhlásenie o zhode

Názov a adresa výrobcu	:	MY TİCARET VE MEDİKAL A.Ş. Ömerli Mah. General Şükrü Koraltı Cad. No :33 Arnavutköy-İstanbul/TURECKO
Názov pomôcky	:	Latexové vyšetrovacie rukavice Nitrilové vyšetrovacie rukavice
Typ a registračné/katalógové číslo	:	Pudrované latexové vyšetrovacie rukavice [REDACTED] Nepudrované latexové vyšetrovacie [REDACTED] Nepudrované nitrilové vyšetrovacie rukavice - [REDACTED]
Značka	:	[REDACTED]
Klasifikácia	:	Trieda I.
Postup posudzovania zhody	:	podľa Prílohy VII
Cesta k zhode	:	Vlastné vyhlásenie

Týmto prehlasujeme na vlastnú zodpovednosť, že vyššie uvedené výrobky s označením CE sú plne v súlade so základnými požiadavkami smernice Rady 93/42/EHS zo 14. júna 1993 o zdravotníckych pomôckach, zmenenej a doplnenej smernicou Rady 2007/47/ES.

Verifikačné certifikáty	:	Systém riadenia kvality EN ISO13485: 2016 Certifikát č .: ISO 02 836 1179 Systém manažérstva kvality EN ISO9001: 2015 Certifikát č .: ISO 01 940 117
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MY Medikal

ES Vyhlásenie o zhode

Príslušné normy

: EN 374-2 Ochranné rukavice proti nebezpečným chemikáliám a mikroorganizmom - Časť 2: Stanovenie odolnosti voči penetrácii.

EN 16523-1+A1 Stanovenie odolnosti materiálu voči priestupnosti chemikáliami - Časť 1: Priestupnosť potenciálne nebezpečných kvapalných chemikálií v podmienkach nepretržitého styku. (norma EN 374-3 bola revidovaná ako EN 16523-1+A1)

EN 374-4 Ochranné rukavice proti nebezpečným chemikáliám a mikroorganizmom - Časť 4: Stanovenie odolnosti voči degradácii vplyvom chemických látok.

EN 374-5 Ochranné rukavice proti nebezpečným chemikáliám a mikroorganizmom - Časť 2: Podmienky a pravidlá používania v styku s nebezpečnými mikroorganizmami.

EN 455-1 Lekárske rukavice na jednorazové použitie. Časť 1: Požiadavky a skúšanie na nepremokavosť.

EN 455-2 Lekárske rukavice na jednorazové použitie. Časť 2: Požiadavky a skúšanie fyzikálnych vlastností.

EN 455-3 Lekárske rukavice na jednorazové použitie. Časť 3: Požiadavky a skúšobné metódy na biologické hodnotenie.

EN 455-4 Lekárske rukavice na jednorazové použitie. Časť 4: Požiadavky a skúšanie na určenie doby skladovateľnosti.

EN ISO 10993-1 Biologické hodnotenie zdravotníckych pomôcok - Časť 1: Hodnotenie a skúšanie v rámci procesu riadenia rizík.

Podpis oprávnenej osoby

Meno Priezvisko

: MURAT YILDIZ

Pracovná pozícia

: výkonný riaditeľ

Podpis

: -nečitateľný podpis-

-pečiatka-

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ

İkitelli Organize San Bölge, Eskoop San Sii

A3 Blok No: 160 Başakşehir/İSTANBUL

Tel

İkitelli V D 626 040 4605

www.mymedikal.com.tr

Dátum

: 22.03.2020



Preklad/prekladateľský úkon som vypracoval ako prekladateľ zapísaný v zozname znalcov, tlmočníkov a prekladateľov, ktorý vedie Ministerstvo spravodlivosti Slovenskej republiky v odbore slovenský jazyk/anglický jazyk pod evidenčným číslom 971088.

Certified to be translated by a sworn translator of English and Slovak languages registered with the Ministry of Justice of the Slovak Republic in the List of Experts, Interpreters and Translators under number 971088.

Preklad je v denníku zapísaný pod číslom / Translator's register entry No.: 659/2020

Prekladané listiny súhlasia s priloženými listinami / Certified to be a true and faithful translation of the attached document.

Zároveň vyhlasujem, že som si vedomý následkov vedome nepravdivého prekladu/prekladateľského úkonu / I am aware of the consequences of wilfully untrue translation.

.....
Odtlačok úradnej pečate / Stamp

.....
Podpis prekladateľa / Translator's signature



From the Department of the Interior, Bureau of Land Management, Washington, D.C. 20250. The following information is being furnished to you for your information and use.

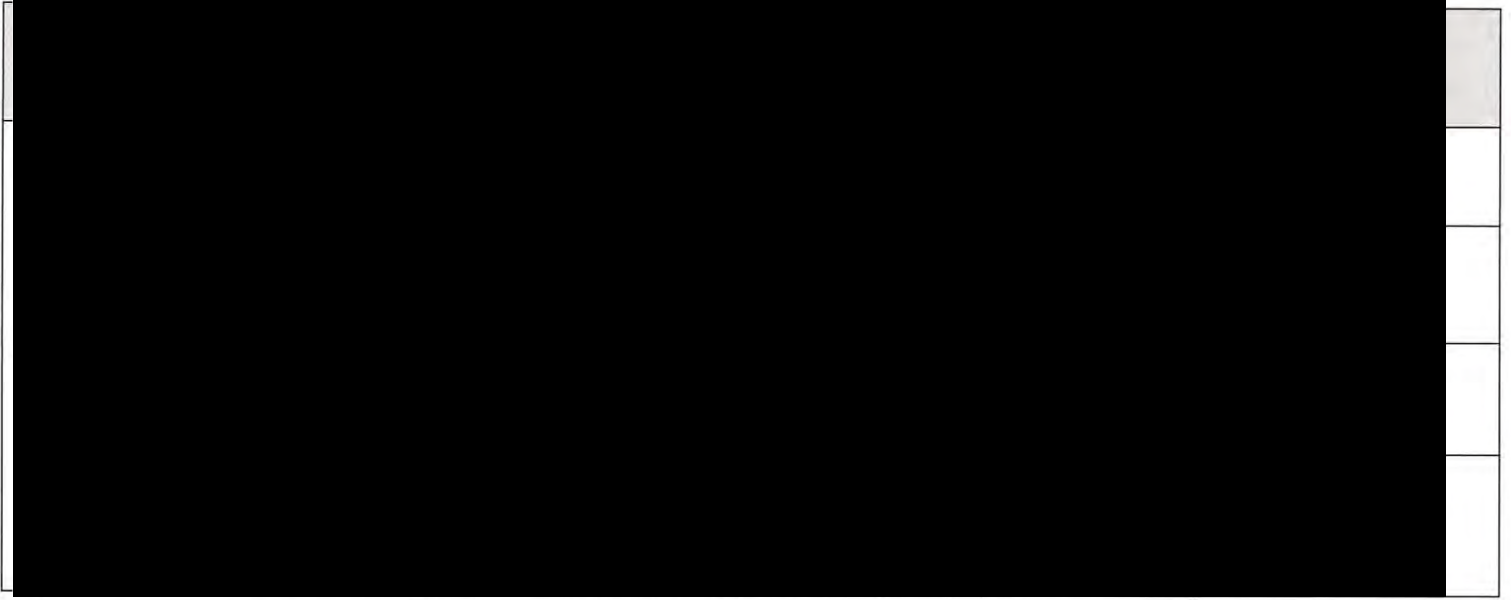
On the basis of the information received from the Bureau of Land Management, the following information is being furnished to you for your information and use.





Report No: [Redacted]
Applicant: MY TİCARET VE MEDİKAL A.Ş.
Ömerli Mah. General Şükrü Karaltı Caddesi No:33 Arnavutköy/İSTANBUL
Z.Melek ÖZ BOLAT
Contact Person: [Redacted]
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 EXAMINATION GLOVE / LATEX EXAMINATION GLOVE



Seal

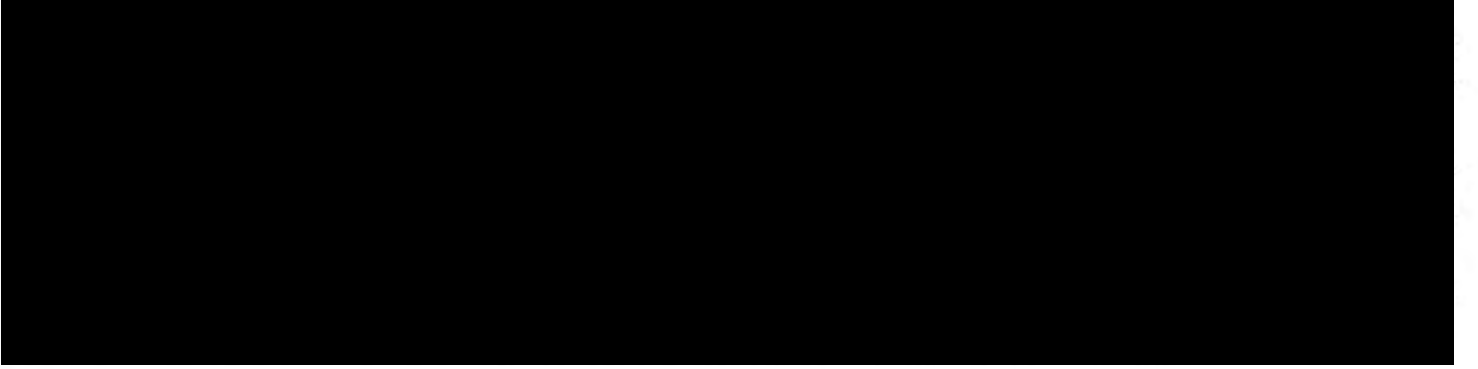


Customer Representative
Hasan KUTLU

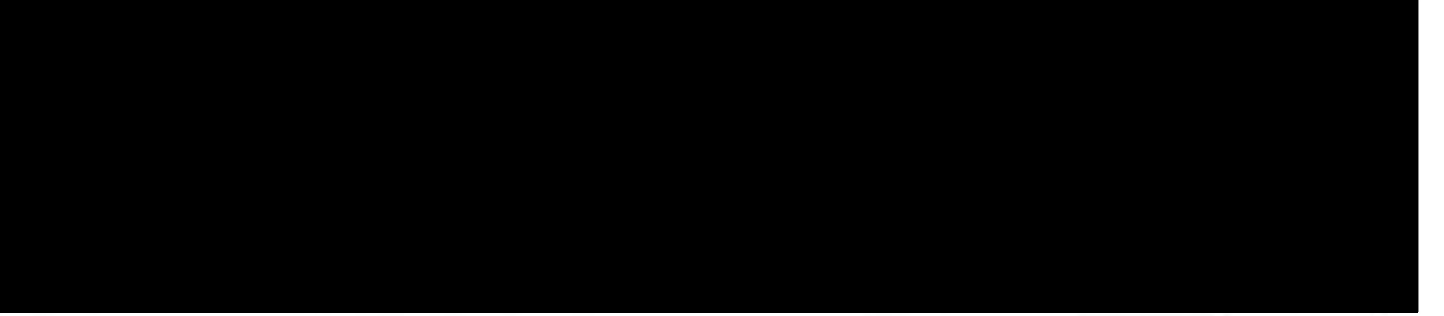


Laboratory Manager
Hava SARIAYDIN

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



Environment



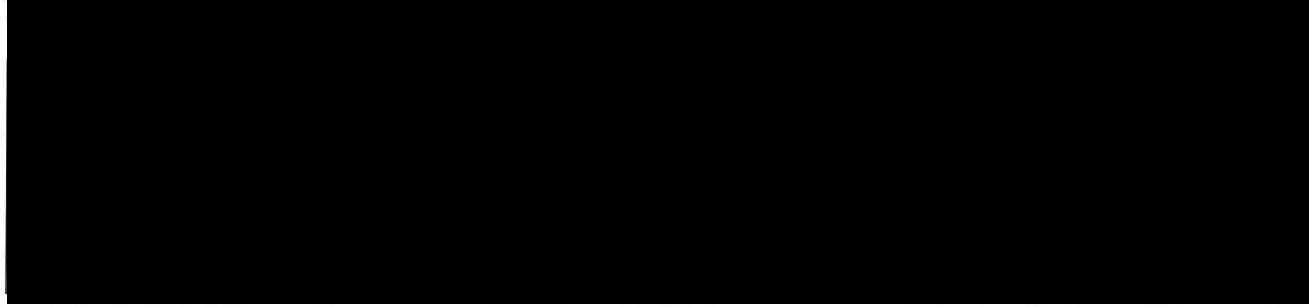
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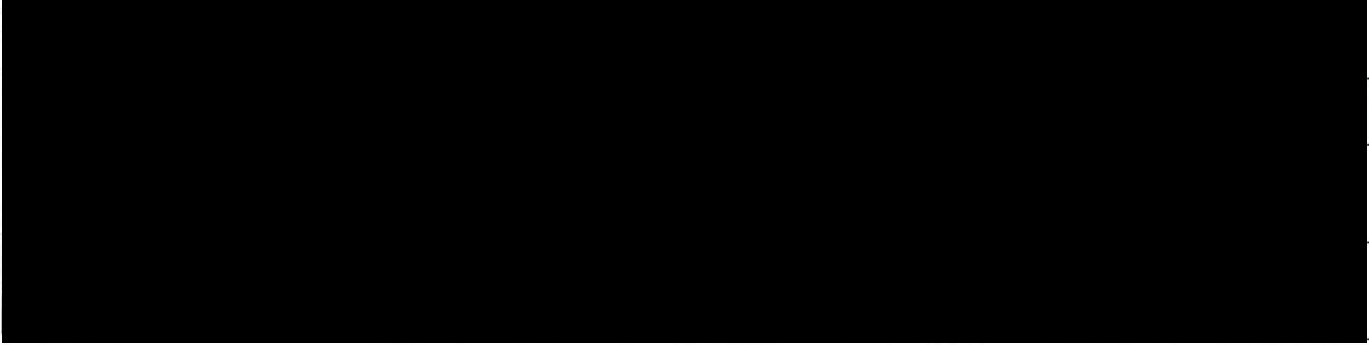
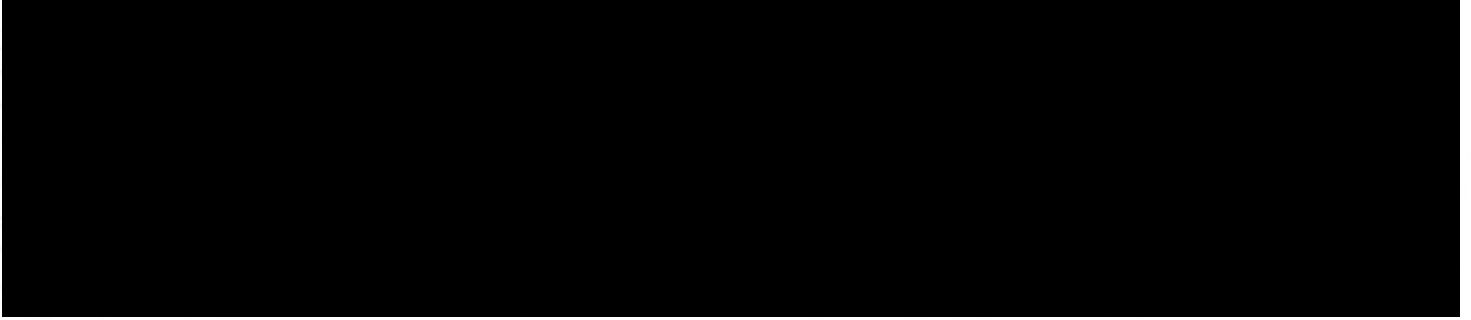
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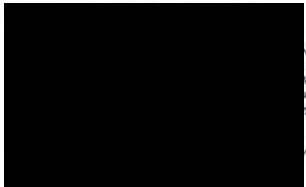
Table 1

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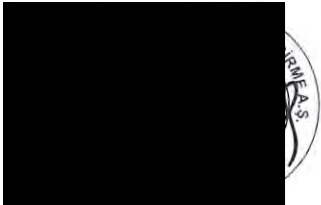
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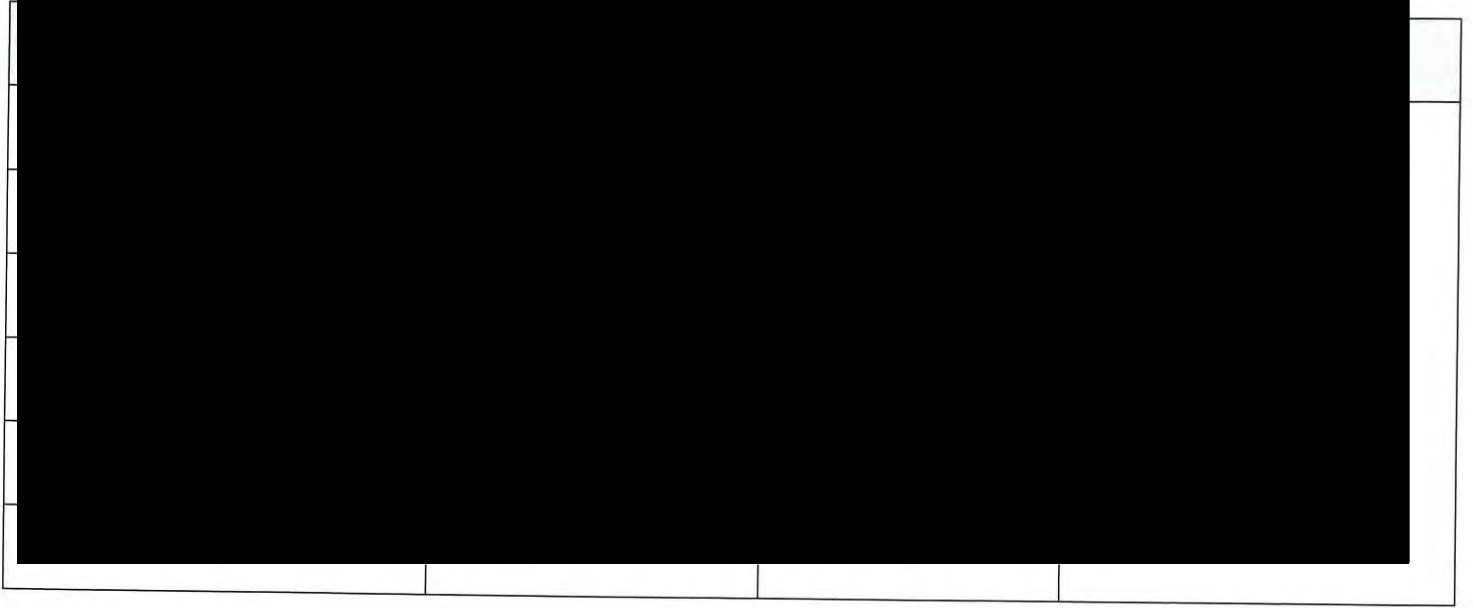
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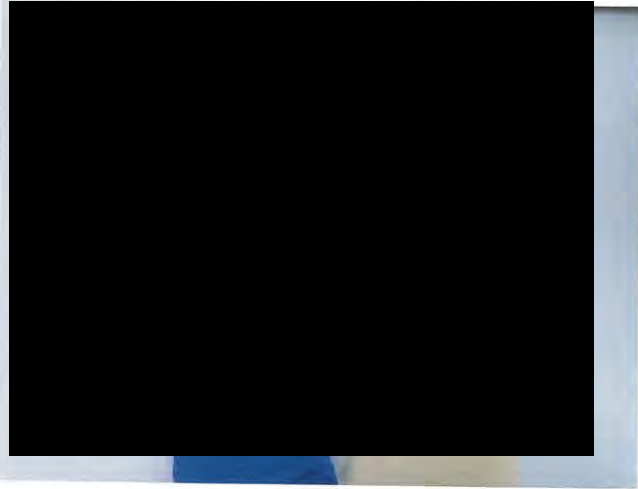
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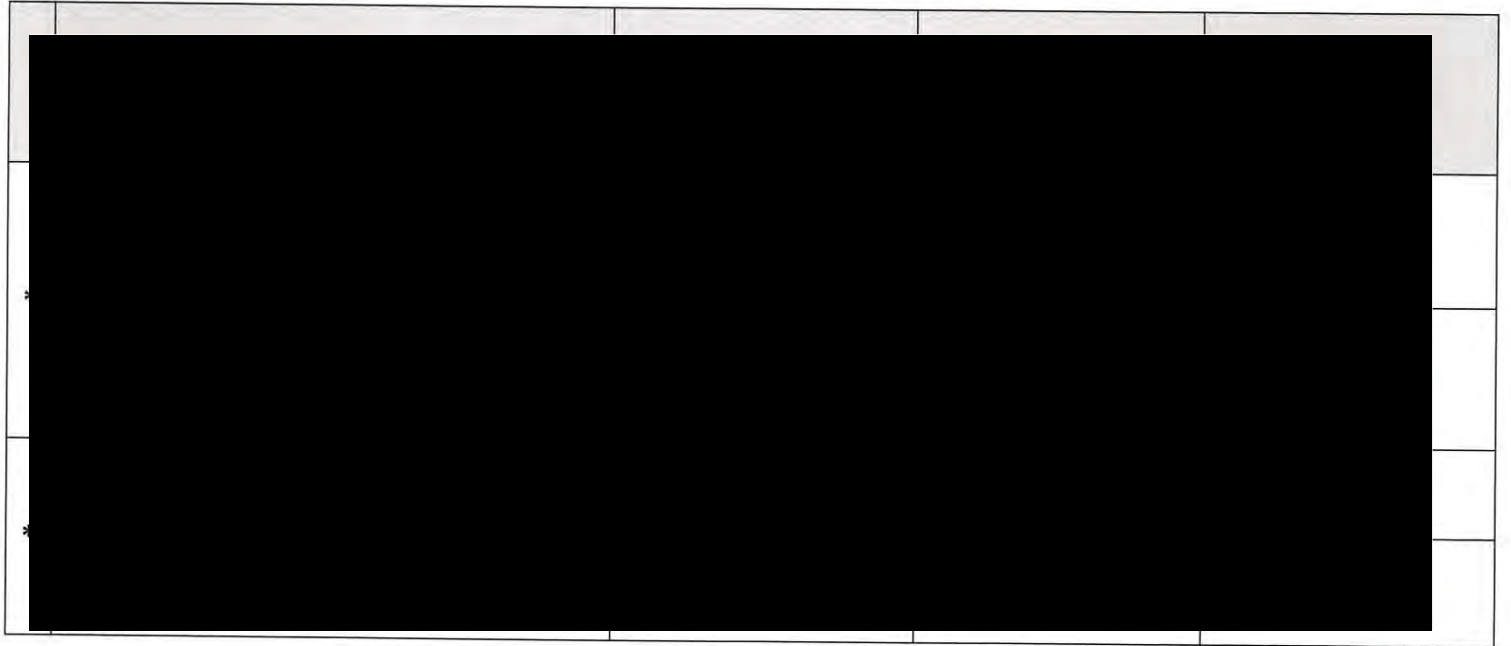
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*****END OF REPORT*****



Report No: [REDACTED]
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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: [REDACTED]



Seal

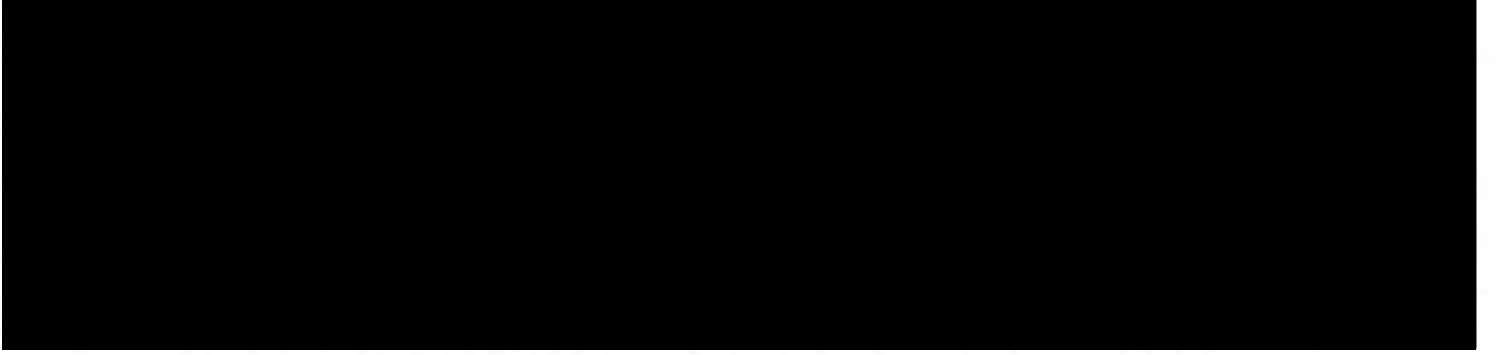


Customer Representative
Hasan KUTLU



Laboratory Manager
Hava SARIAYDIN

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



Environment





[Redacted]

[Redacted]

Principle

[Redacted]

Procedure

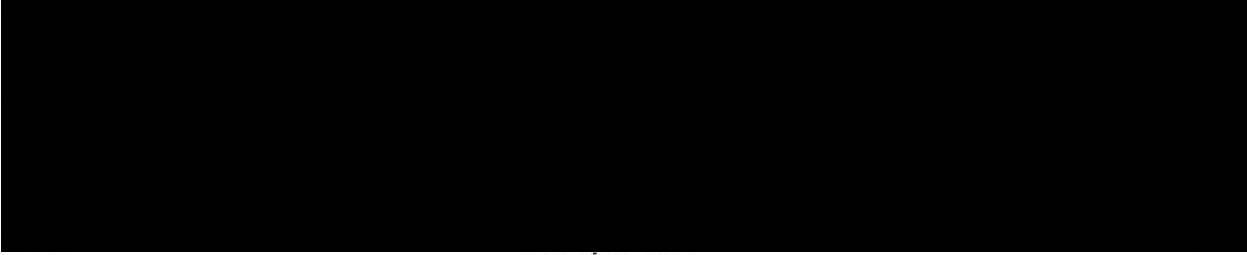
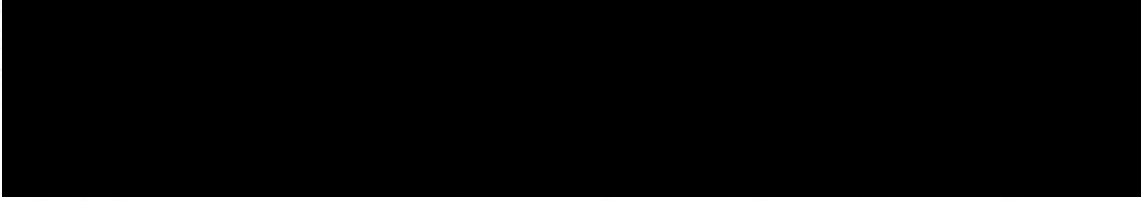
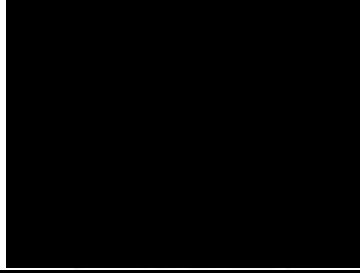
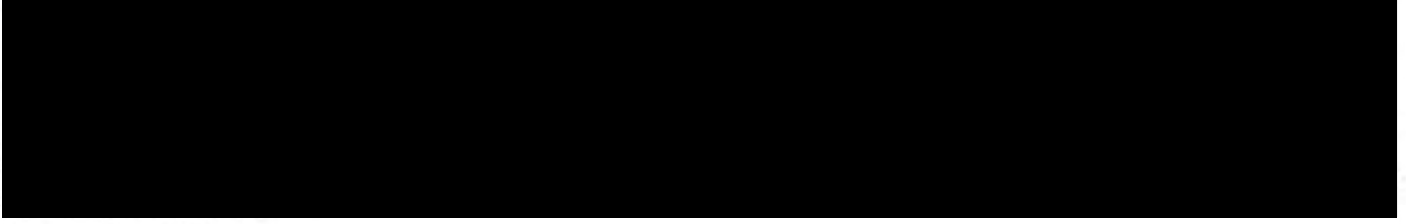
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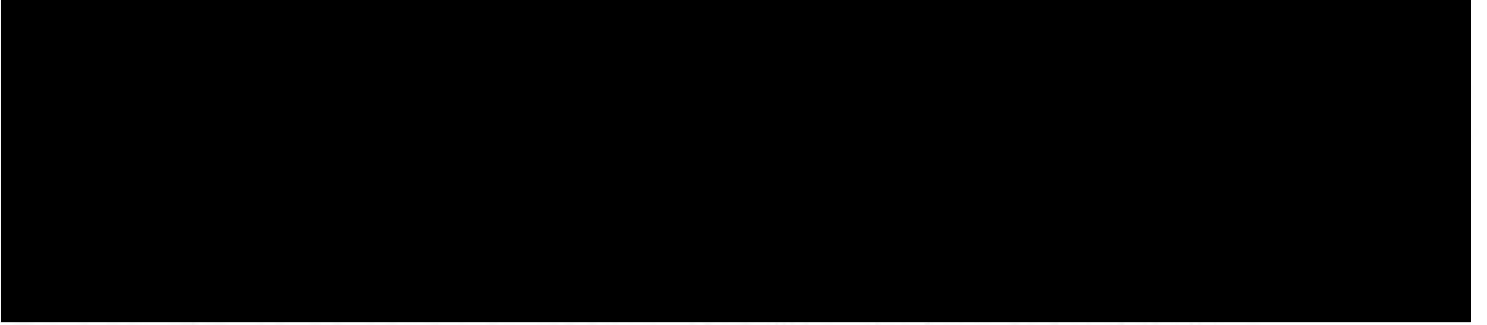
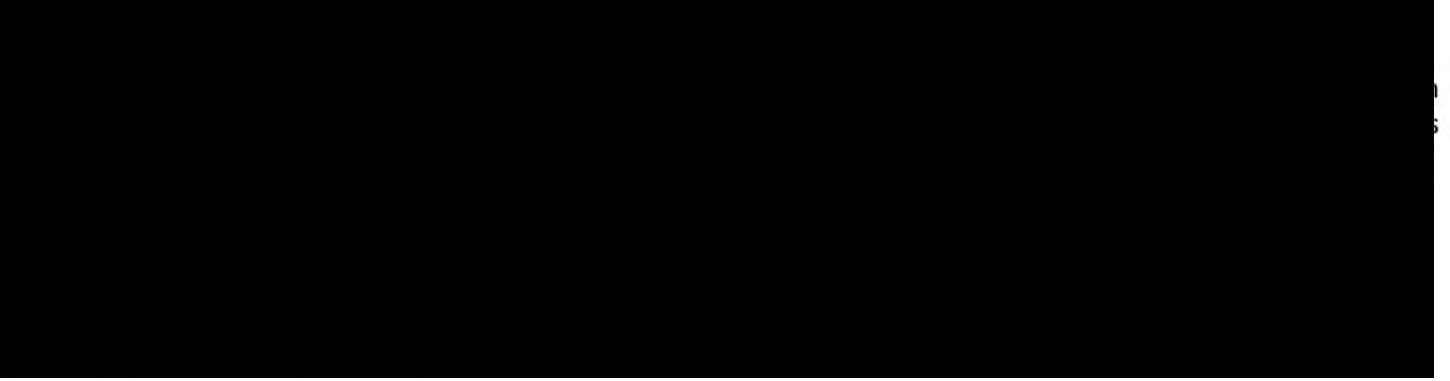
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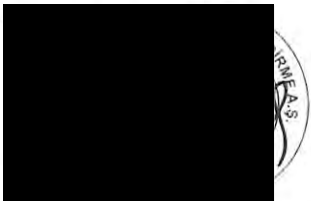
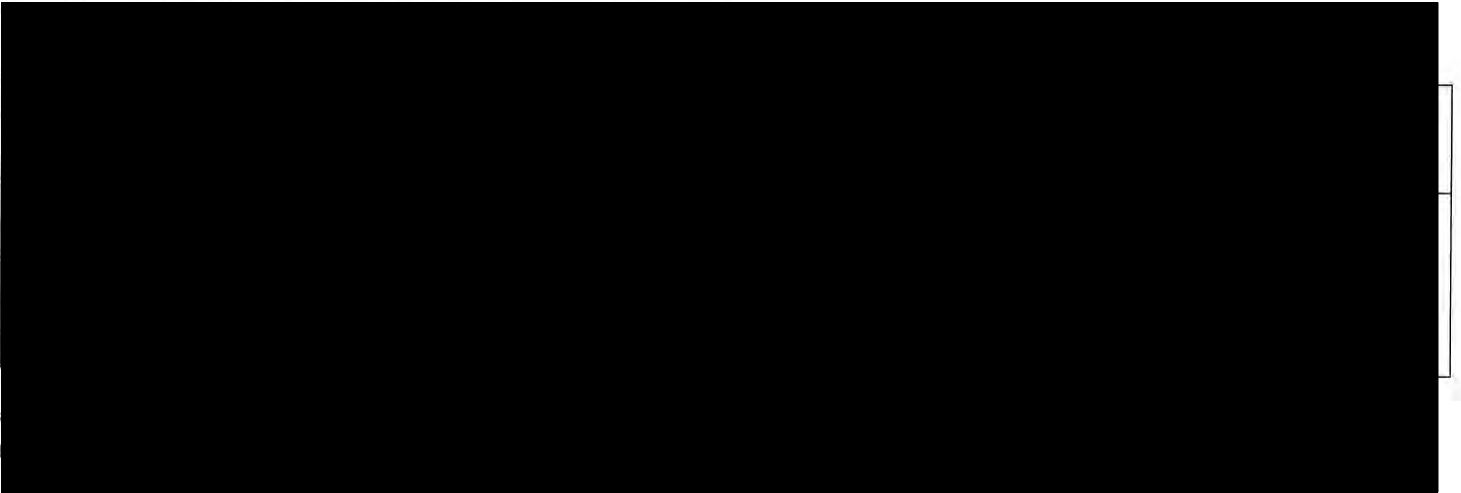
Procedure

the specimens.

Result



Result



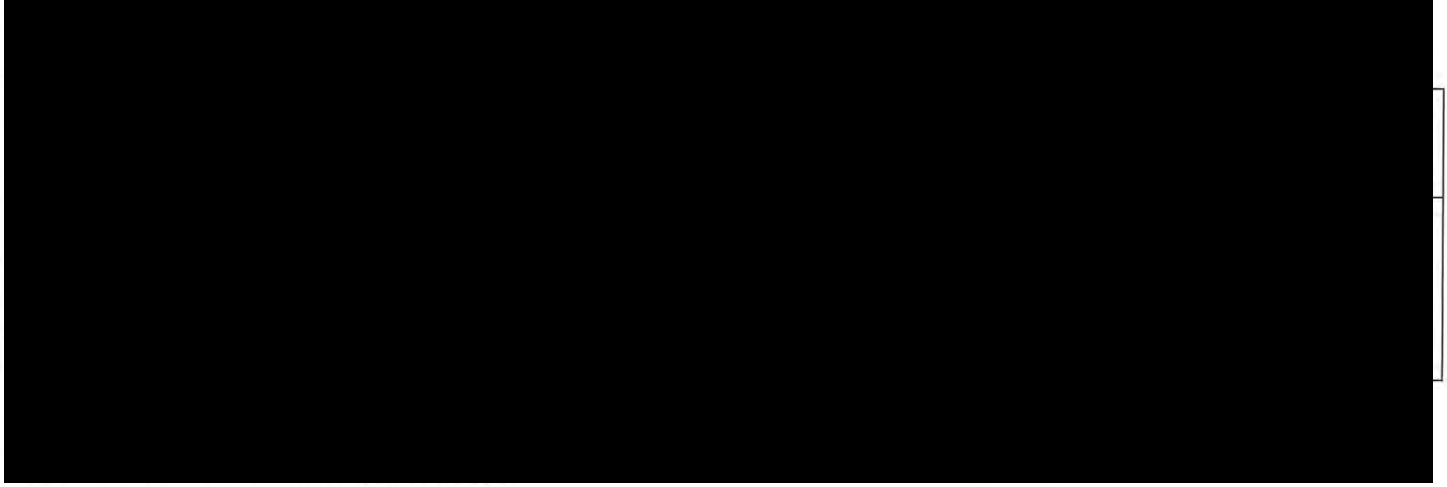
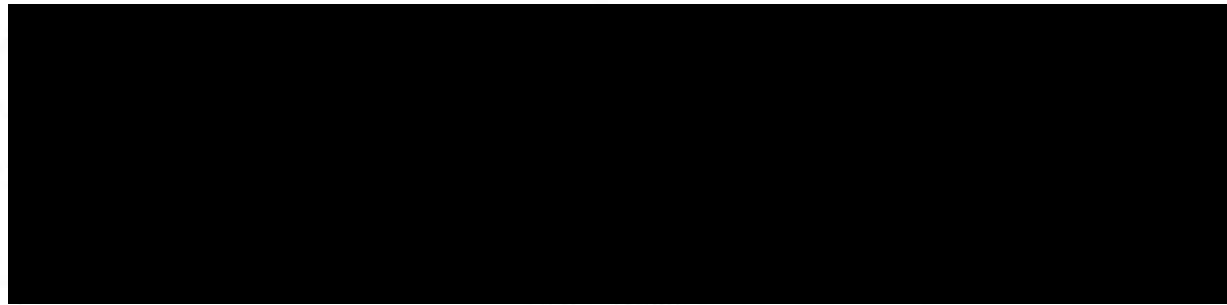


Table 1

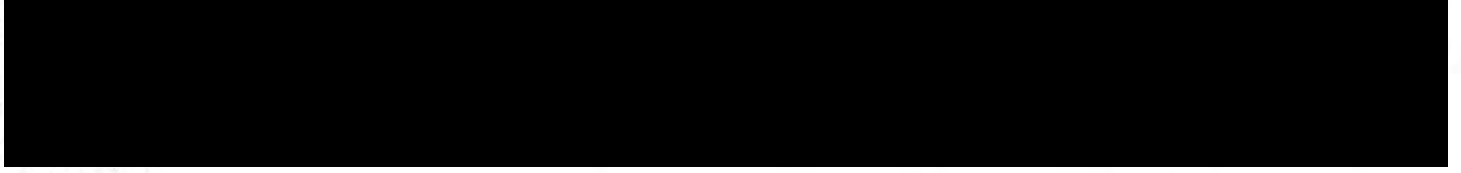


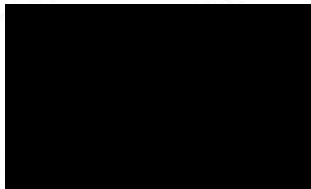
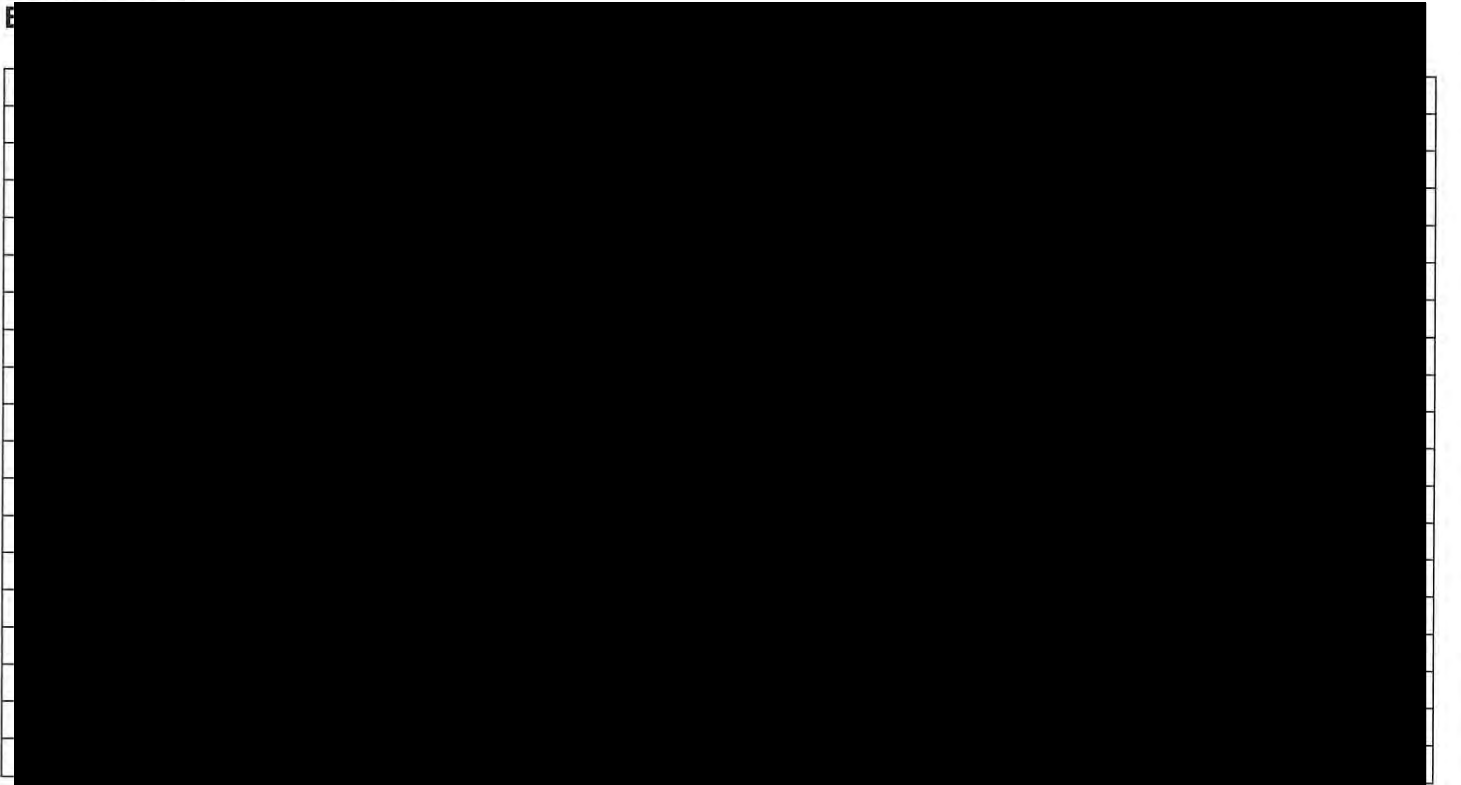
Test Result

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Test Results

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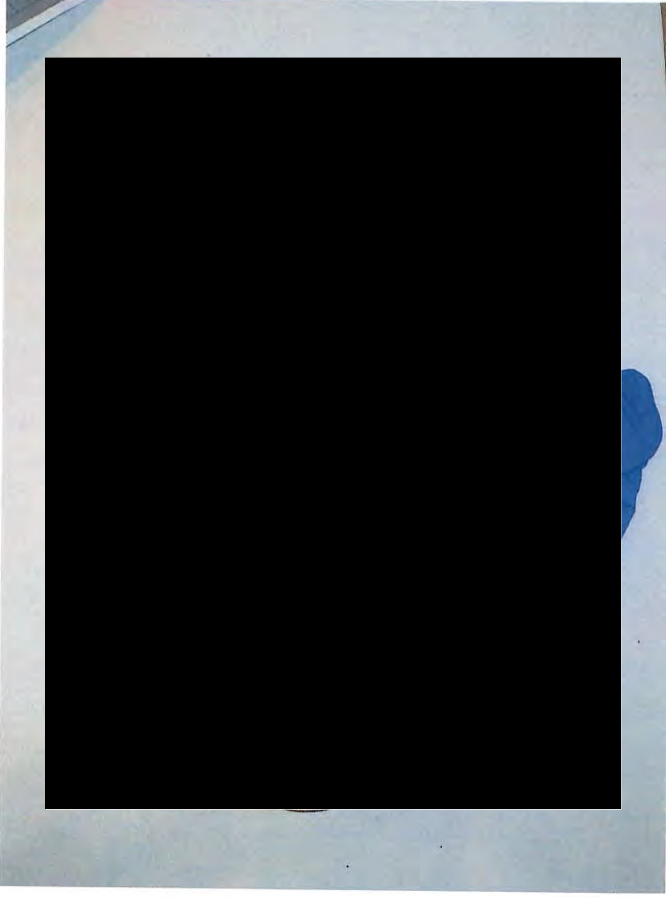
Test Results

[illegible]

Test Results

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Image



*** End Of Report***

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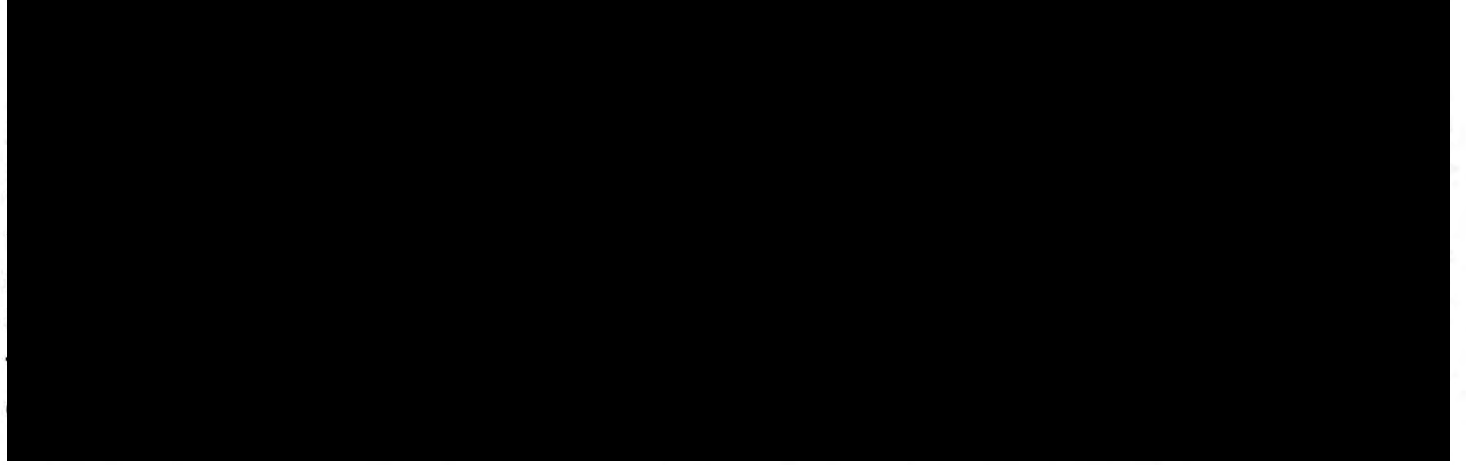
Seal



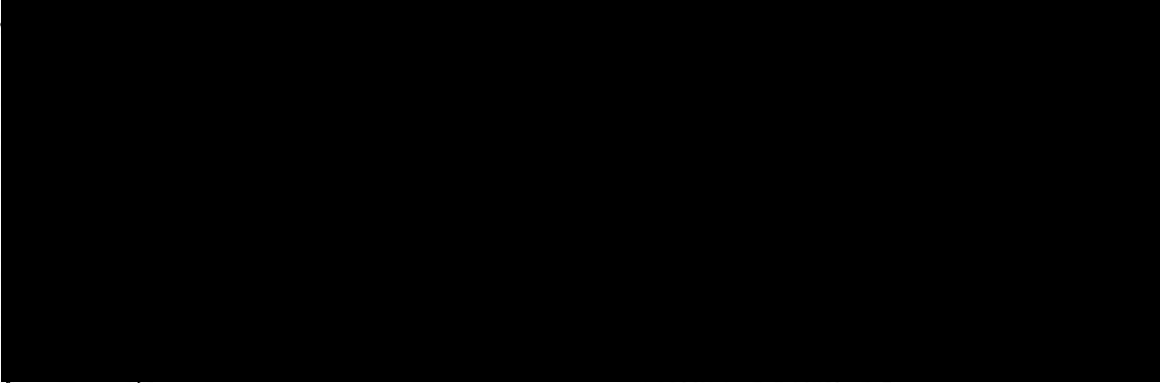
Customer Representative
Hasan KUTLU

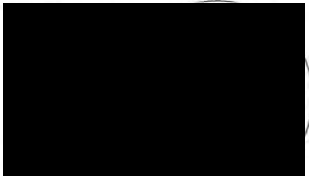


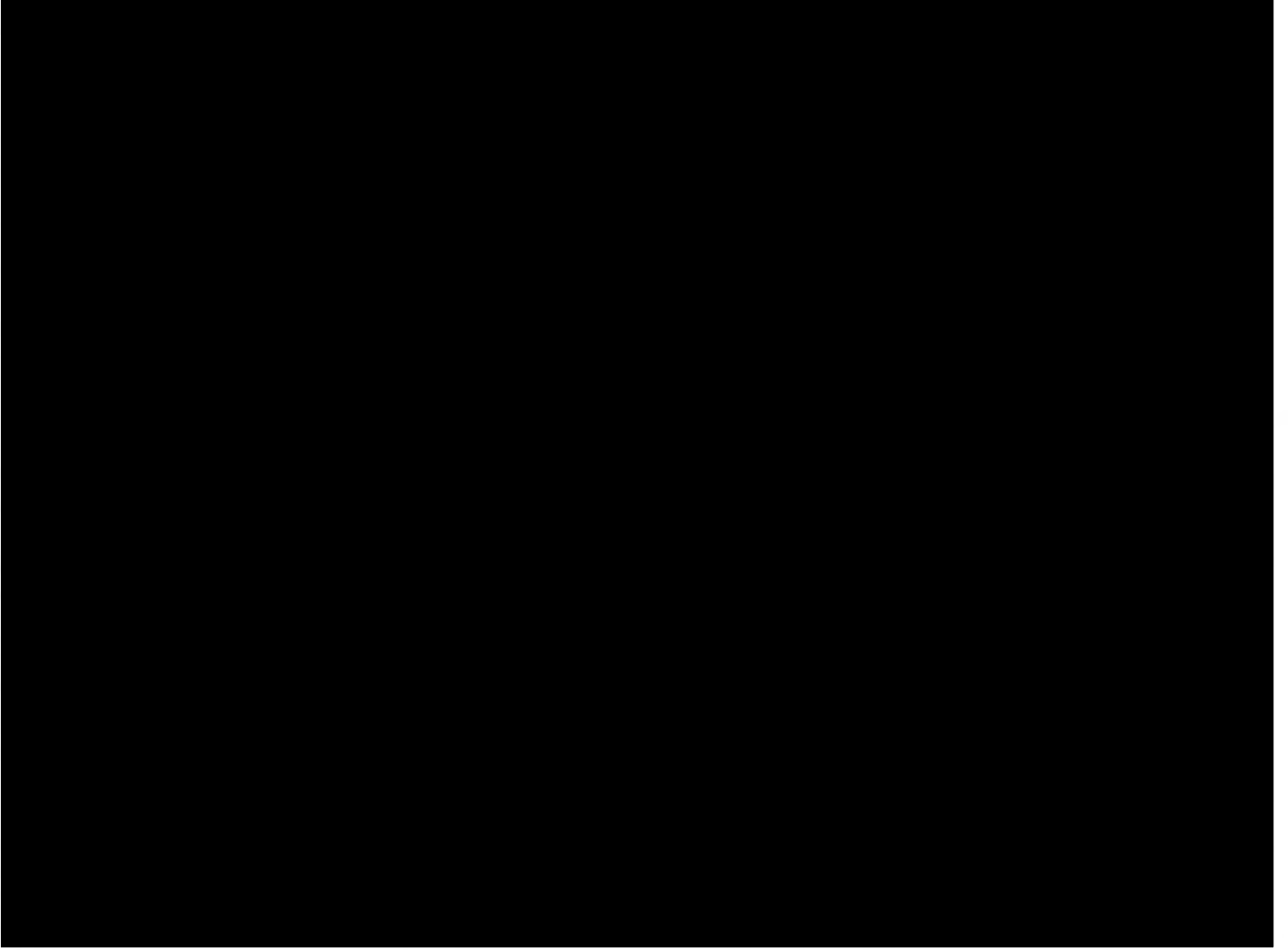
Laboratory Manager
Hava SARIAYDIN



Environment





TEST RESULTS

[illegible]

[REDACTED]

1. The first step is to identify the problem or question that needs to be addressed. This involves understanding the context and the specific requirements of the task.

2. The second step is to gather relevant information and resources. This may involve researching existing solutions, consulting with experts, or collecting data.

3. The third step is to develop a plan or strategy. This involves breaking down the problem into smaller, manageable tasks and determining the sequence of steps to be taken.

4. The fourth step is to implement the plan. This involves carrying out the tasks and making adjustments as needed based on feedback and progress.

5. The fifth step is to evaluate the results. This involves comparing the outcomes against the original goals and objectives to determine the effectiveness of the solution.

6. The sixth step is to document the process and findings. This involves creating a record of the steps taken, the resources used, and the results achieved.

7. The seventh step is to communicate the results. This involves sharing the findings with the relevant stakeholders and providing recommendations for future actions.

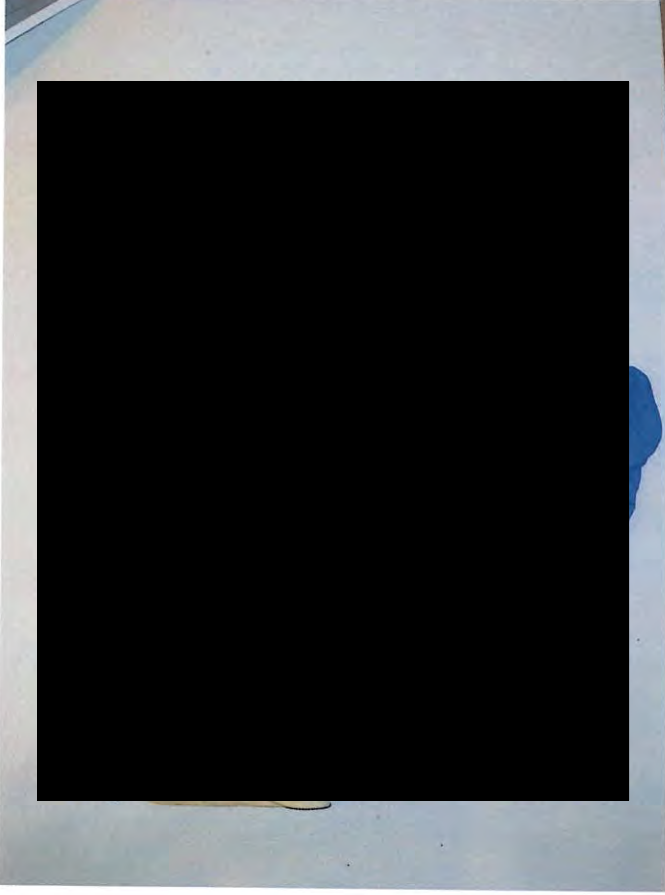
8. The eighth step is to reflect on the process. This involves considering what worked well, what challenges were encountered, and how the process can be improved for future tasks.

TEST RESULTS

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5

Image



*****END OF REPORT*****

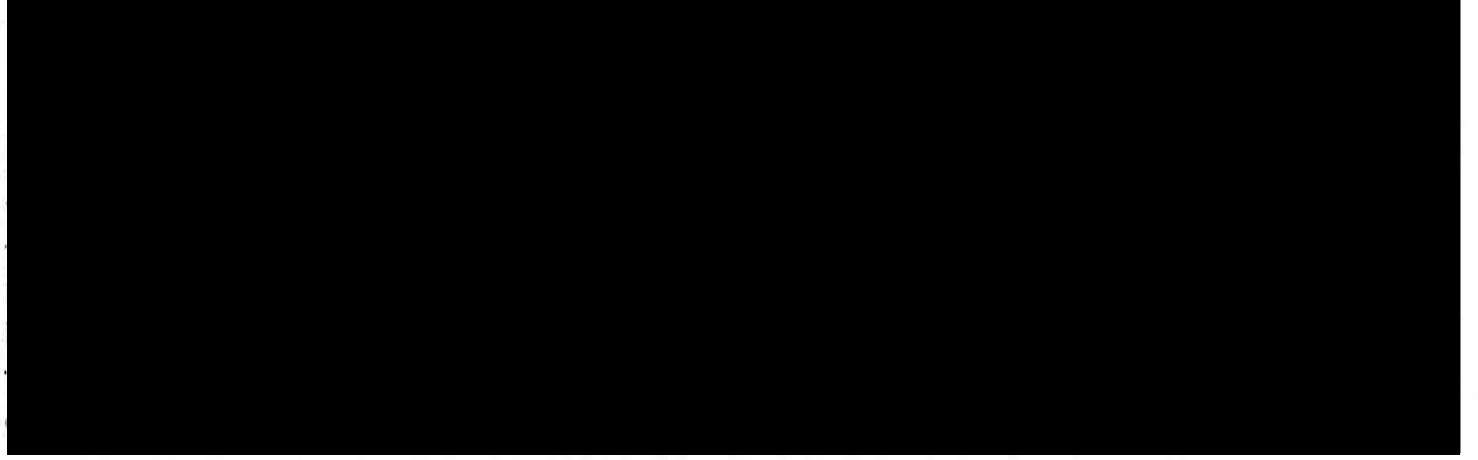
Report No:	[REDACTED]
Applicant:	MY TİCARET VE MEDİKAL A.Ş Ömerli Mah. General Şükrü Karaltı Caddesi No:33 Arnavutköy/İSTANBUL
Contact Person:	Z.Melek ÖZ BOLAT
Contact Telephone:	[REDACTED]
Contact e-mail:	kalite@mymedikal.com.tr
Sample Accepted on:	03.07.2020
Report Date:	19.08.2020
Total number of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

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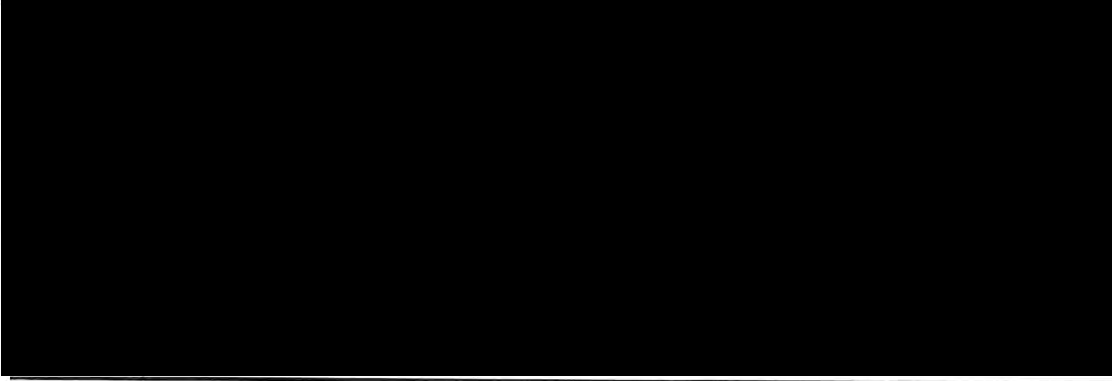
Seal

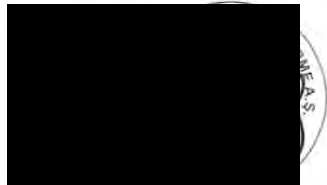
Customer Representative
Hasan KUTLU

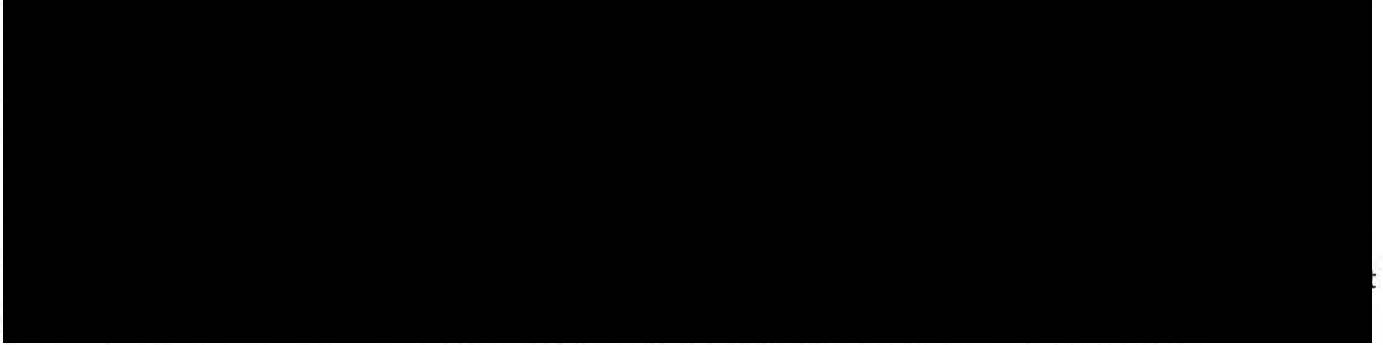
Laboratory Manager
Hava SARIAYDIN



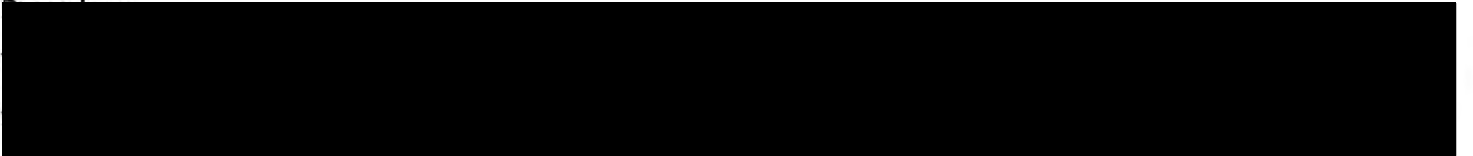
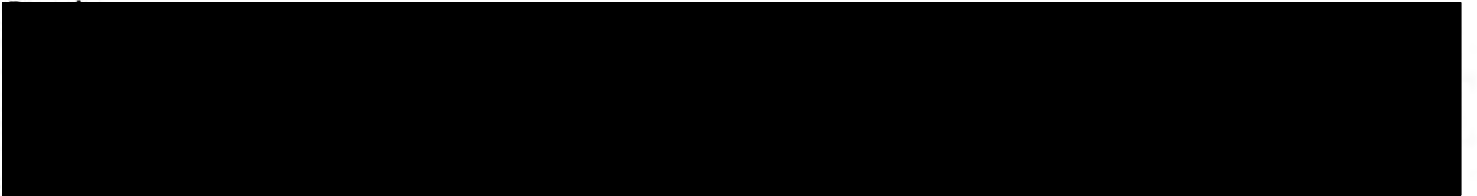
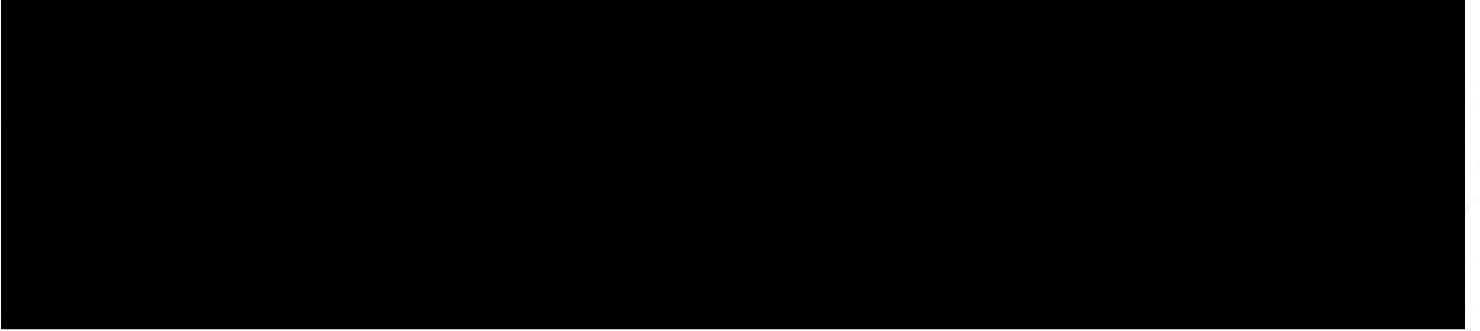
Environment



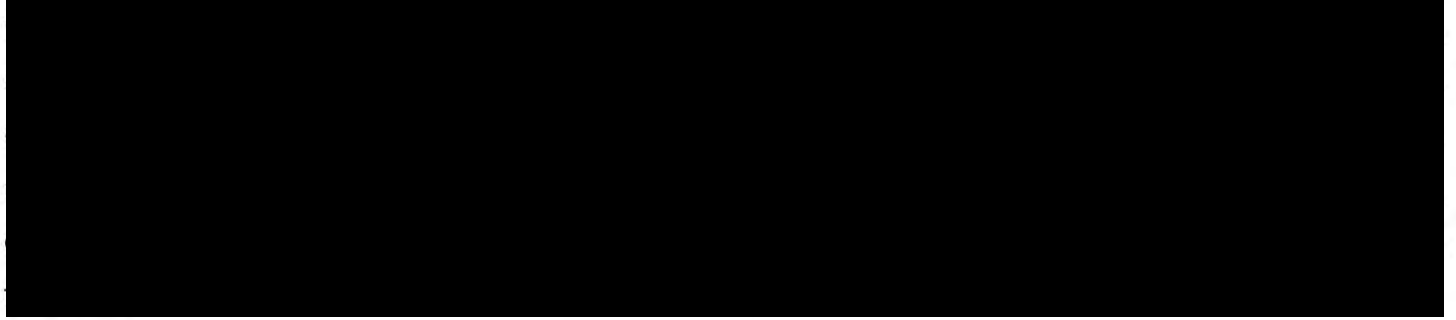




TEST METHODS



Procedure:



TEST RESULTS

Powder

Proteins, Leachable

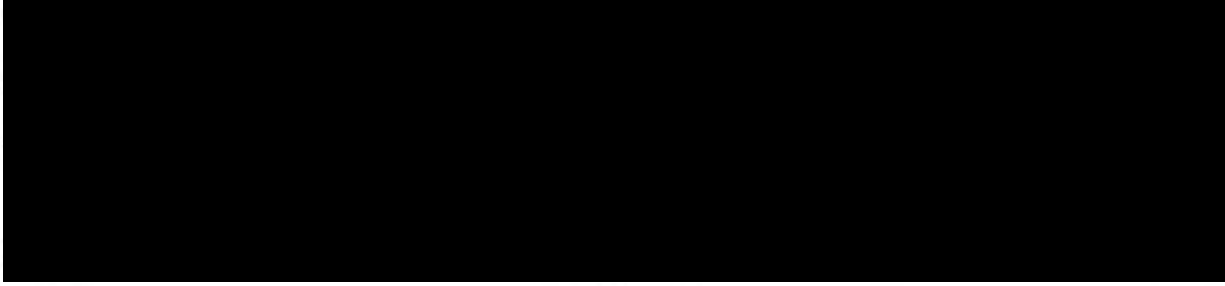
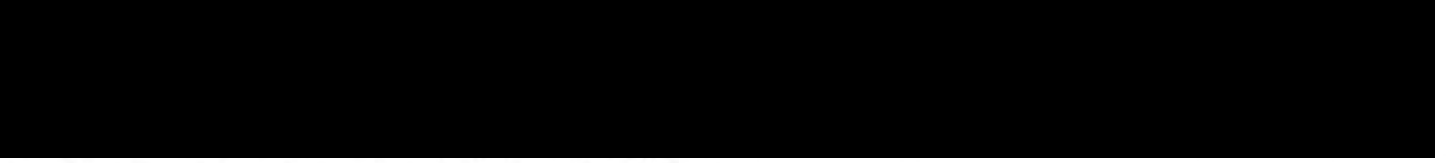
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Scope:

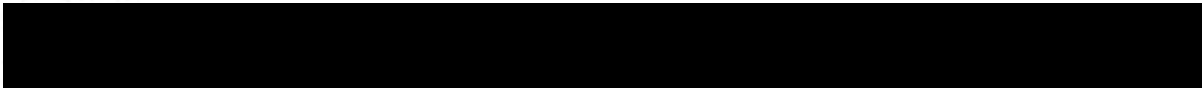
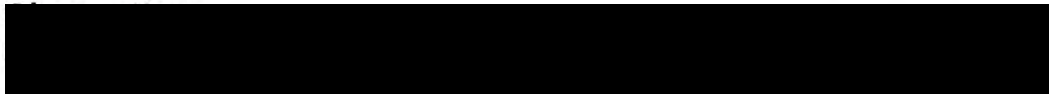
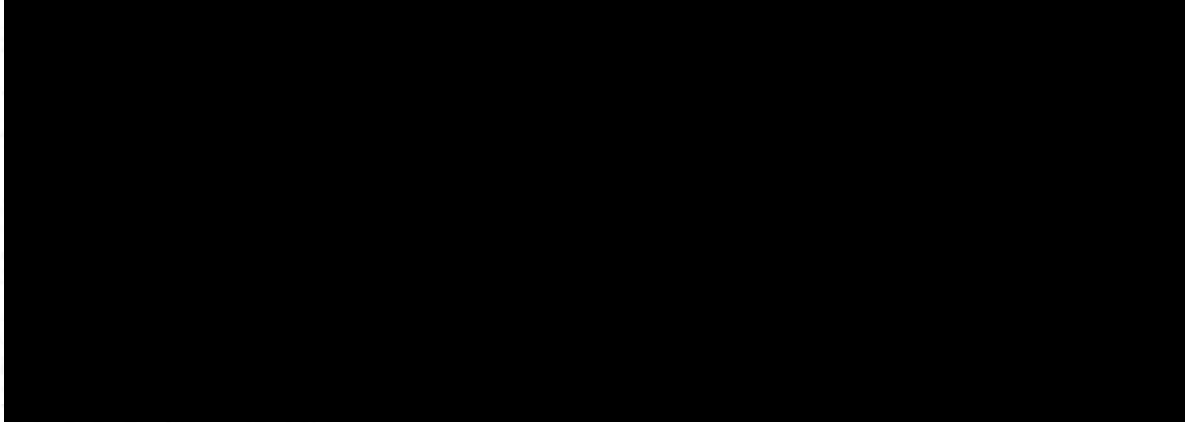
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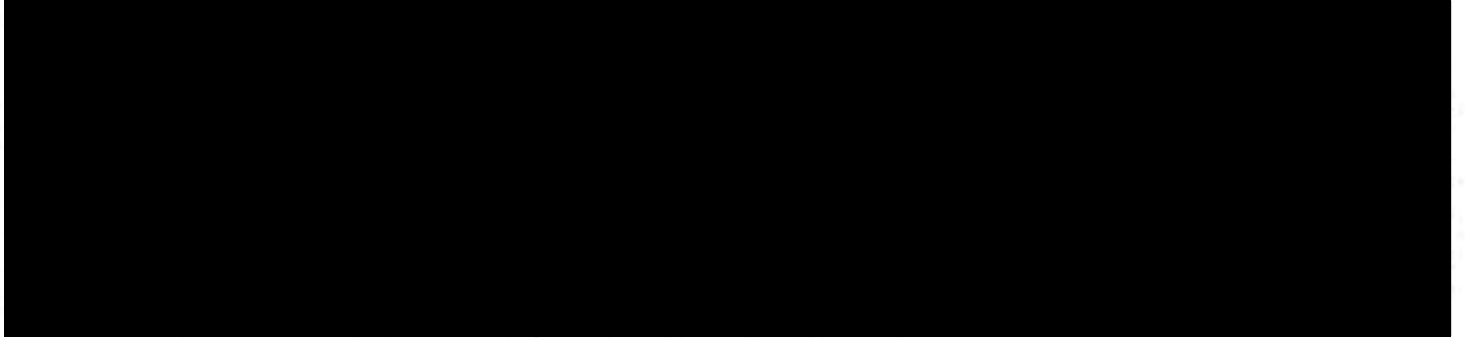
TEST RESULTS



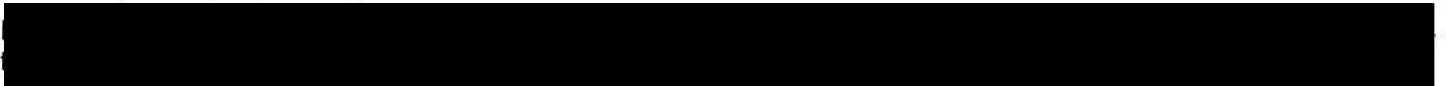
Accelerated shelf life determination

Test Condition:

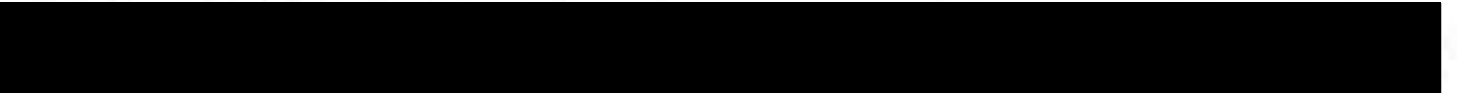




Delayed-type hypersensitivity



Irritation (including intracutaneous reactivity)



[Redacted]

Systemic toxicity (acute)

[Redacted]

Subacute and subchronic toxicity

[Redacted]

Genotoxicity

[Redacted]

Implantation

[Redacted]

[Redacted]

[Redacted]

[REDACTED]

[REDACTED]

Carcinogenicity

[REDACTED]

Reproductive and developmental toxicity

[REDACTED]

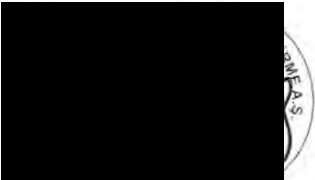
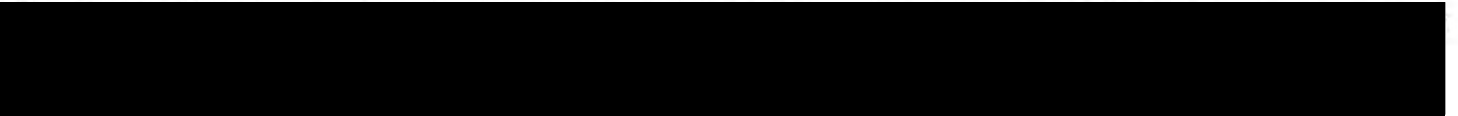
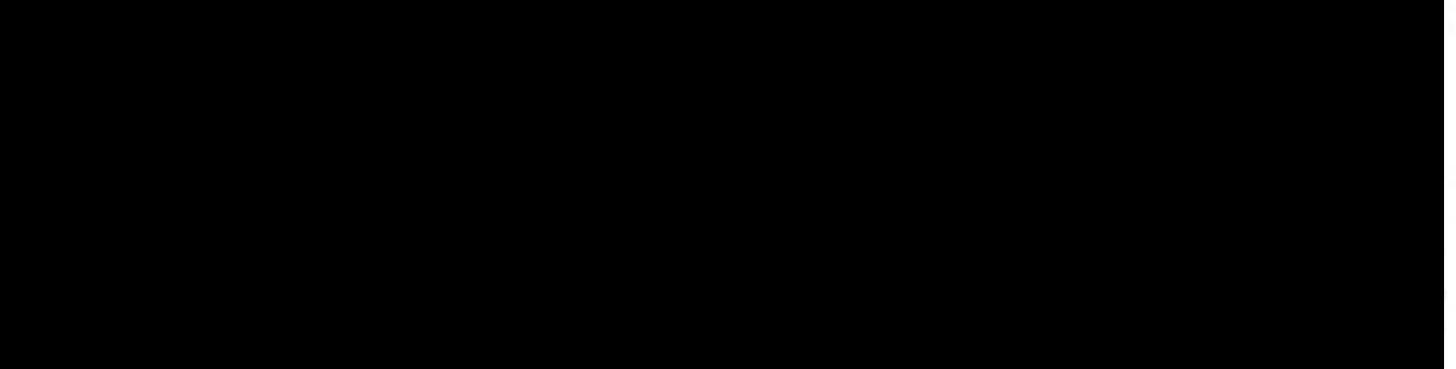
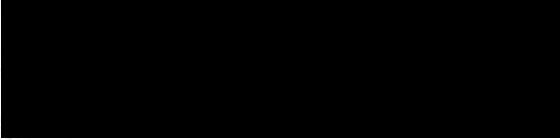
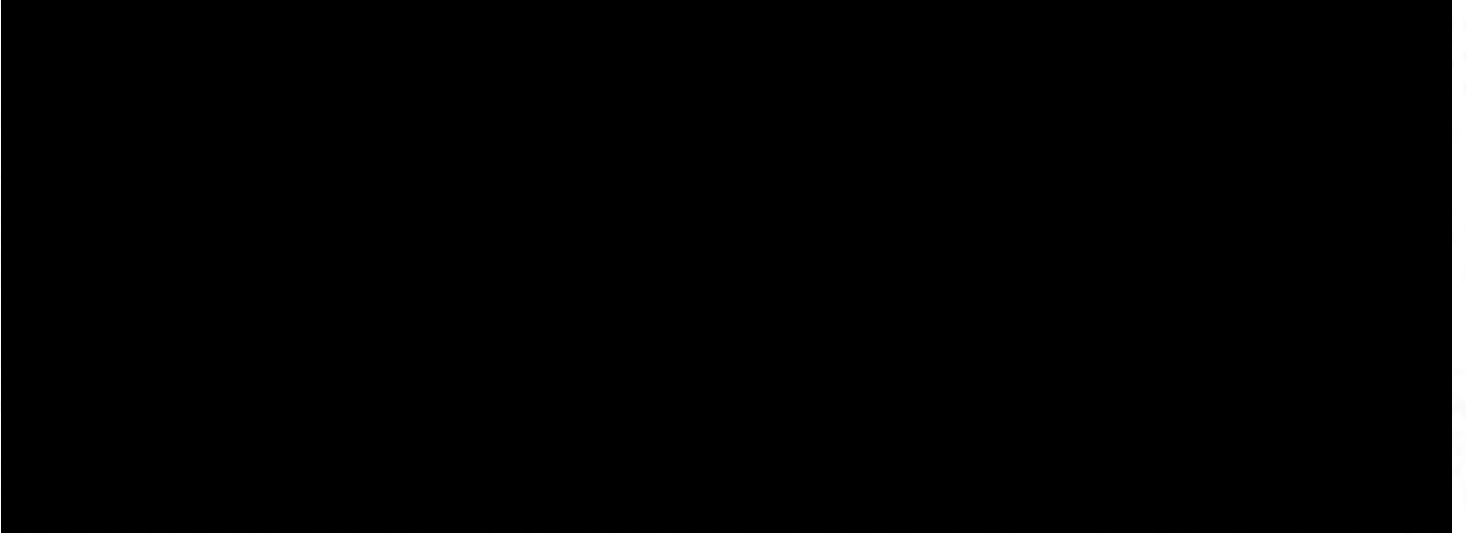
Biodegradation

[REDACTED]

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Evaluation tests for consideration

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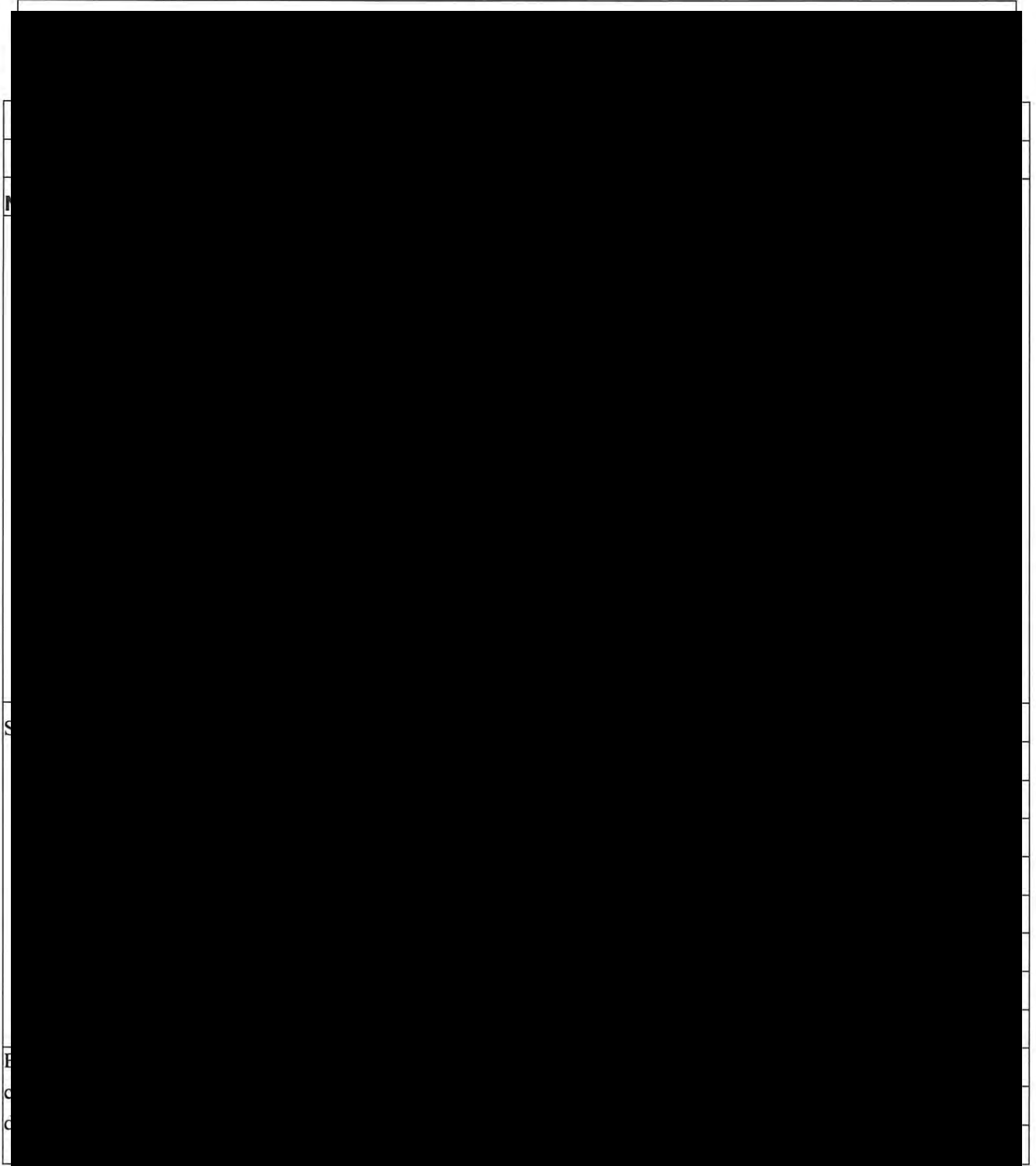
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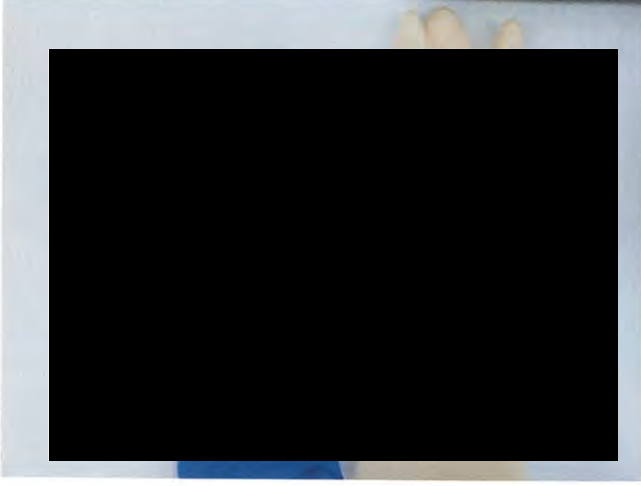


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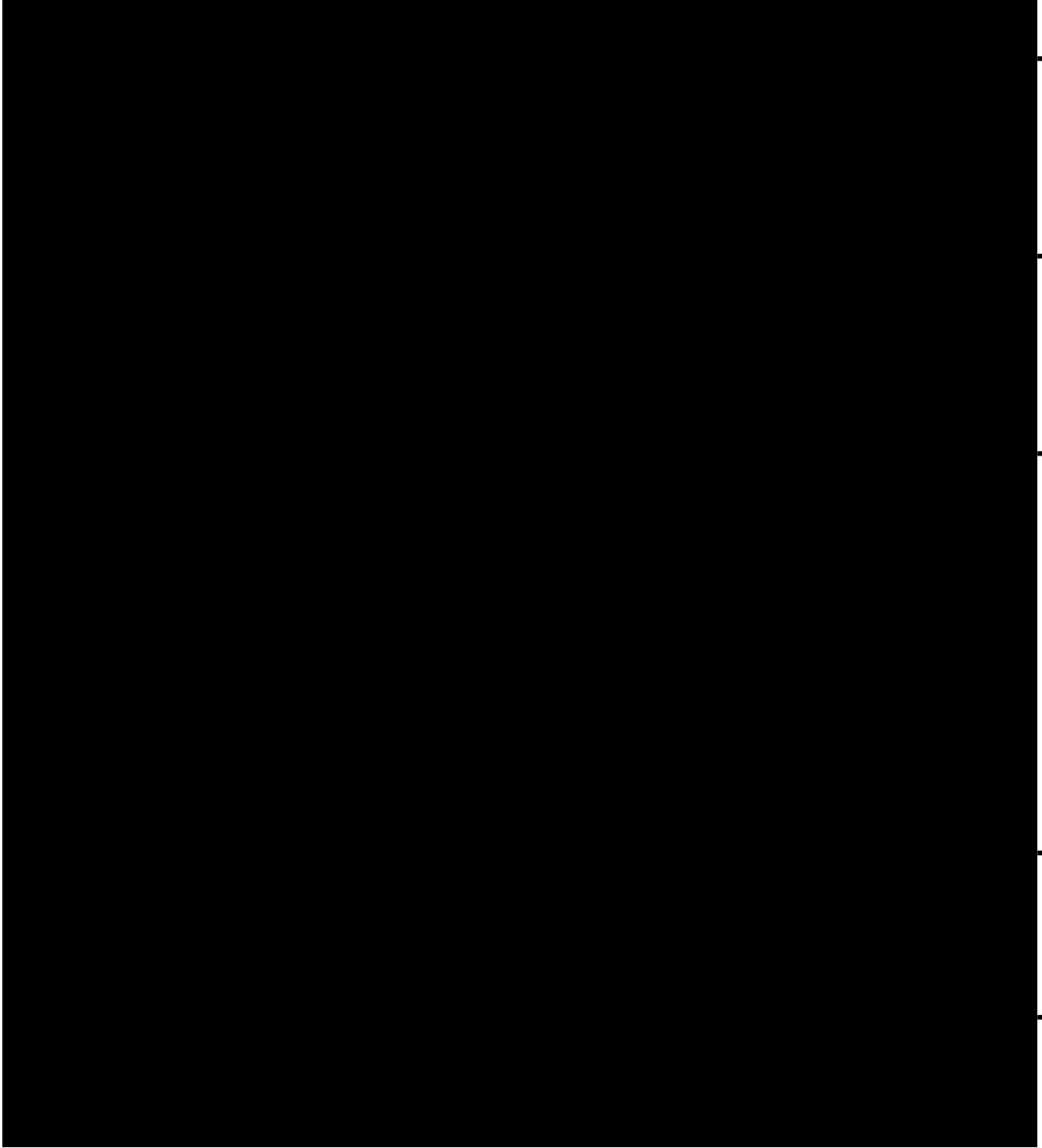
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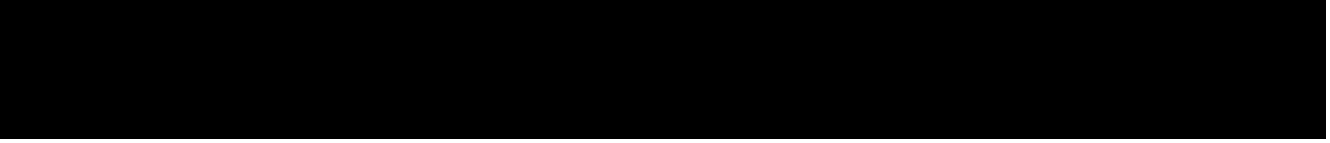
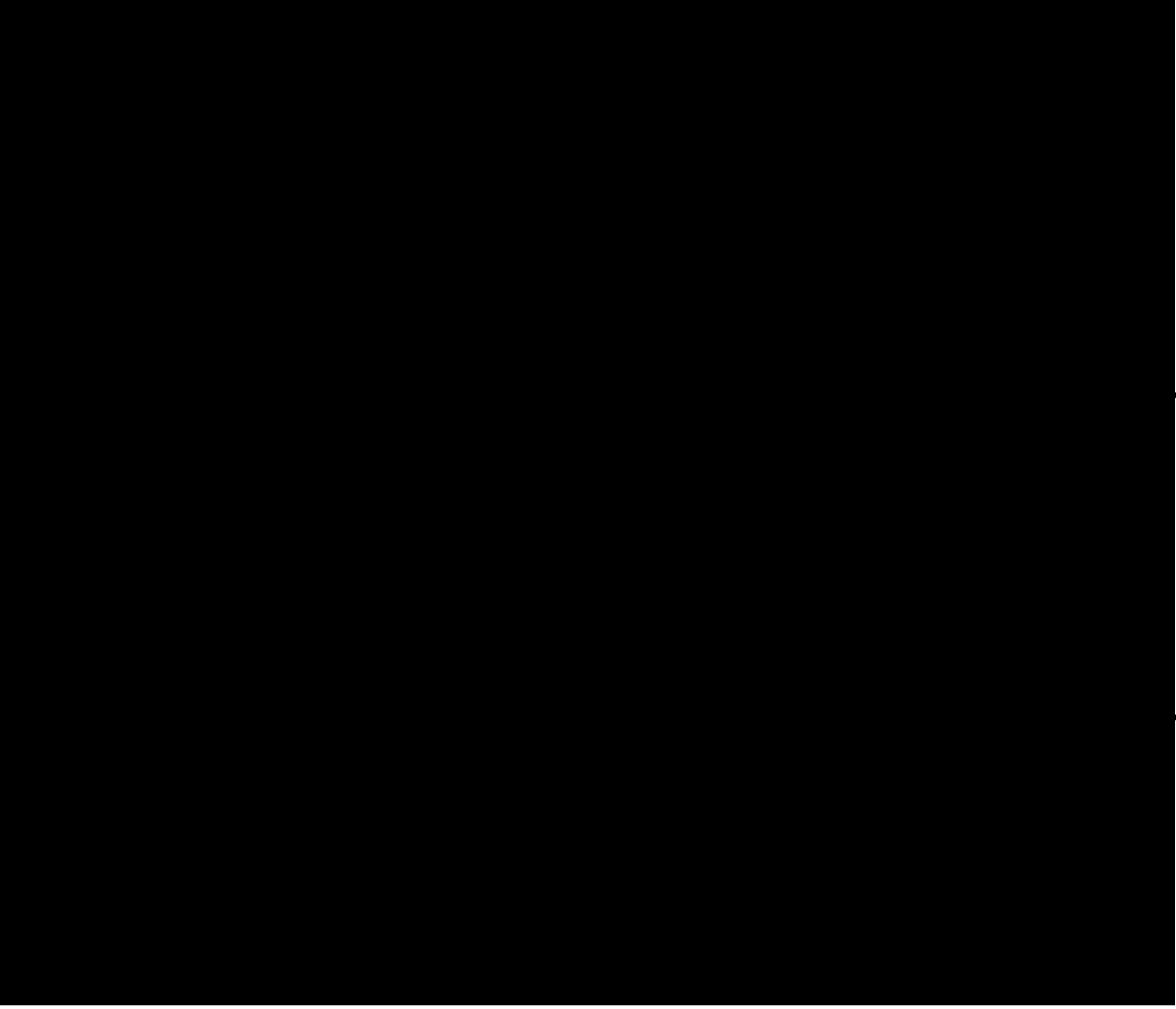
IMAGE



*****END OF REPORT*****

Verified by,
Vedat ÇETİN
QA Manager





Prepared By
Z. MELEK ÖZ BOLAT
Chemist, QC

Approved By
VEDAT ÇETİN
Manager, QA

|




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):
Telefónne číslo:
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
16 940,00	20% = 3 388,00	20 328,00

Z toho:	Cena v EUR bez DPH	Výška DPH	Cena v EUR s DPH
Jednorazové latexové rukavice v množstve 30 000ks (veľkosť S)	2 541,00	508,20	3 049,20
Jednorazové latexové rukavice v množstve 120 000ks (veľkosť M)	10 164,00	2 032,80	12 196,80
Jednorazové latexové rukavice v množstve 50 000ks (veľkosť L)	4 235,00	847,00	5 082,00

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 02.03.2021

Mgr. M



Hlavné mesto SR Bratislava
Primaciálne nám. 1
814 99 Bratislava

Dynamický nákupný systém
Výzva č. 24
„Ochranné jednorazové
latexové rukavice“

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):	
Telefónne číslo:	
E-mailová adresa:	obchod@zdravotnetesty.sk

Predmet zákazky: „Ochranné jednorazové latexové rukavice“

