

# EU DECLARATION OF CONFORMITY

## MANUFACTURER

**İbişler Tekstil Sanayi ve Dış Tic. A.Ş.**

Orhan Gazi Mah Tunç Cad. B No:5 B Esenyurt İstanbul TURKEY

## PRODUCT DESCRIPTION

Brand Name: A&Z MED Model: OLI 2025

Filtering half mask

Classification: FFP2 NR

Particle Filtering Half Face Mask in Category III product according to (EU) 2016/425 Personal Protective Equipment Regulation

The Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product is a personal protective equipment that is intended for single use and solely in accordance with the Manufacturer's instructions.

### The Conformity is ensured with the following mechanism:

- Complies with EU 2016/425 Personal Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Essential Health and Safety Requirements of Technical harmonised standard EN 149:2001 +A1:2009
- All required tests referred in above standards are conducted,
- Complies with other relevant harmonized legislation and community standards
- For the assessment of conformity the EU Type Examination certificate (Serial No:2163-PPE-E306) is issued, after all technical evaluations for conformity to the regulation and harmonised standards conducted, by;
  - UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co, as Notified Body number 2163
- The product is under surveillance of same Notified Body, NB 2163 according to the Annex III (Module C2) of the PPE Regulation (EU) 2016/425, for quality assurance.

### MARKING, LABELLING

Marking, labelling and user information are prepared in accordance with EU 2016/425 Personal Protective Equipment Regulation and the harmonised product standards given above.

### MEASURES TO ENSURE CONFORMITY

The Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and technical requirements for this type of product.

General Manager  
19/08/2020

**CE**  
**2163**



UNIVERSAL

Verify the validity with the QR code



## EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1306

Respiratory protective devices, filtering half masks to protect against particles manufactured by

**İbişler Tekstil Sanayi ve Dış Tic. A.Ş.**

Orhan Gazi Mah Tunç Cad. B No:5 B Esenyurt İstanbul TURKEY  
are tested and evaluated according to

**EN 149:2001 + A1:2009 Respiratory Protective Devices -  
Filtering Half Masks to Protect Against Particles -  
Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

#### Product Definition

Brand Name: A&Z MED Model: OLI 2025  
Filtering half mask  
Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

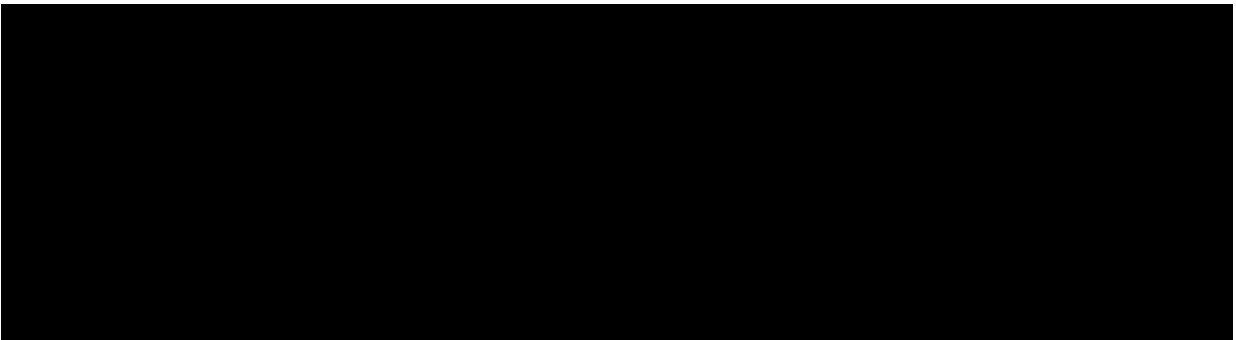
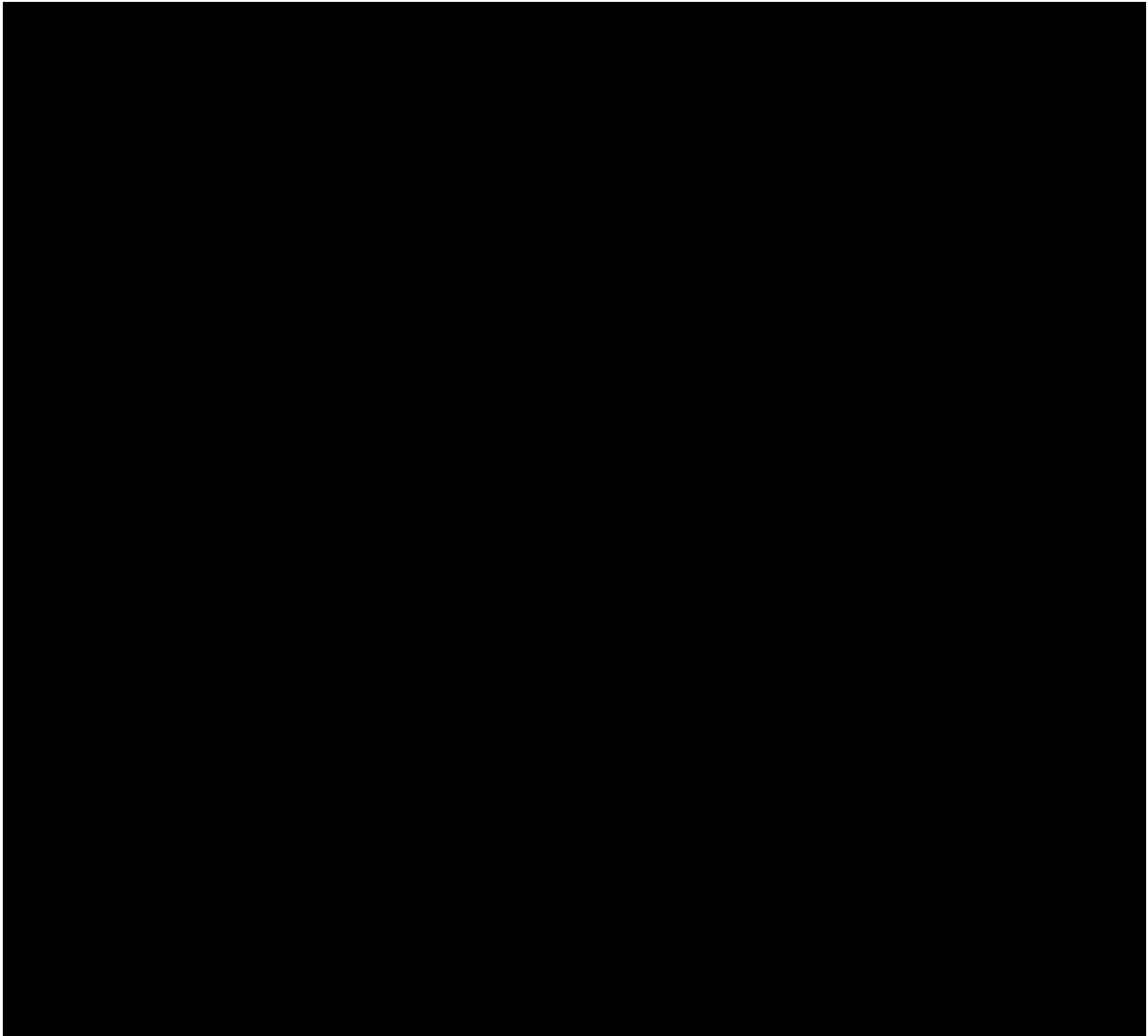
- Issuing an appropriate EU Declaration of Conformity according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective Equipment Regulation (EU) 2016/425 and harmonised standards, ensured by assessments based on Annex 7 (Module C2) or Annex 8 (Module D) of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on 18/08/2020 and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

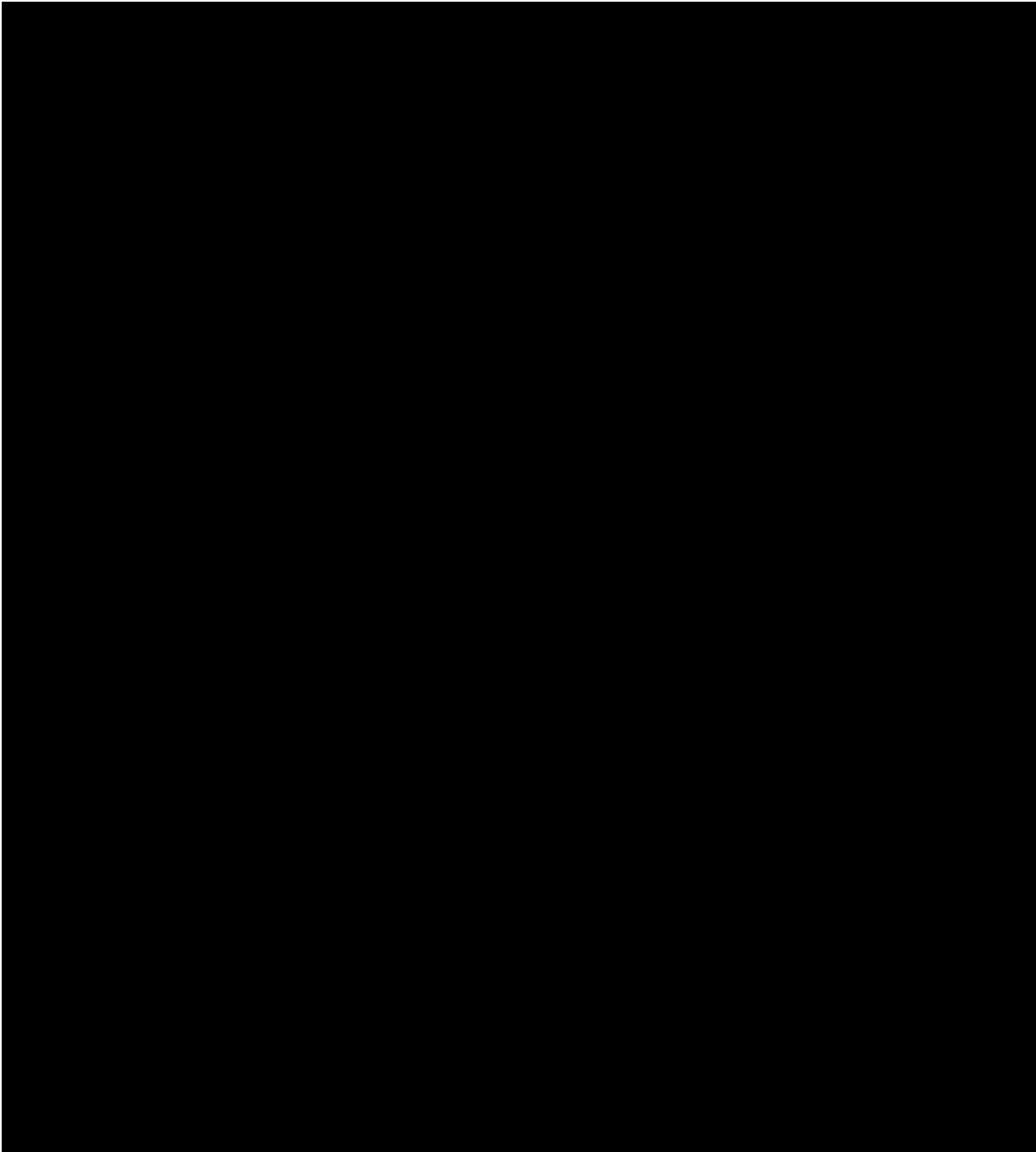
**CE**  
2163

Suat KACMAZ  
UNIVERSAL CERTIFICATION  
Director

**Správne nasadenie masky**



**Ošetrovanie FFP2**





## Príloha č. 2 - Návrh na plnenie kritérií

### Identifikačné údaje:

**Názov zákazky:** „Výzva č. 2 - Respirátor FFP2 bez výdychového ventilu“

**Uchádzač:** BDM group s.r.o

**Adresa sídla:** Kuzmányho 7, 974 01 Banská Bystrica

**IČO:** 47 383 232

**Číslo účtu (IBAN):** [REDACTED]

**Telefónne číslo:** [REDACTED]

**E-mailová adresa:** kancelaria@bdmgroup.sk

### Ponuková cena v súlade s opisom predmetu zákazky:

Názov	Celková cena v eur s DPH
Respirátor FFP2 bez výdychového ventilu v celkovom množstve 120 000 ks	21 600,00 €

Cena uvedená uchádzačom obsahuje všetky náklady, ktoré uchádzačovi vzniknú v súvislosti s plnením predmetnej zákazky. Verejný obstarávateľ upozorňuje, že novelou 67/2020 Z. z. účinnou od 12.02.2021 sa na respirátory FFP3 a FFP2 zaviedla 0 (nulová) DPH. Na základe uvedeného **bude celková cena s DPH totožná s celkovou cenou bez DPH a to bez ohľadu na to, či uchádzač je alebo nie platiteľom DPH.**

**Čestné vyhlásenie:** Predložením tejto ponuky zároveň **čestne vyhlasujem**, že postupujem v súlade s **etickým kódexom** uchádzača vydaným Úradom pre verejné obstarávanie:

<https://www.uvo.gov.sk/zaujemeauchadzac/eticky-kodex-zaujemcu-uchadzaca-54b.html>

V Banskej Bystrici dňa 25.5.2021




[REDACTED SIGNATURE]

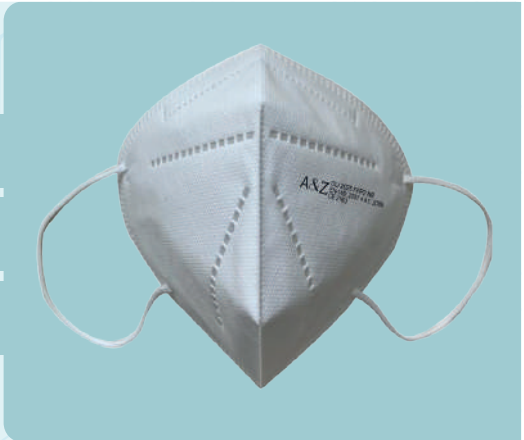
Radka Mikulčíková- konateľ



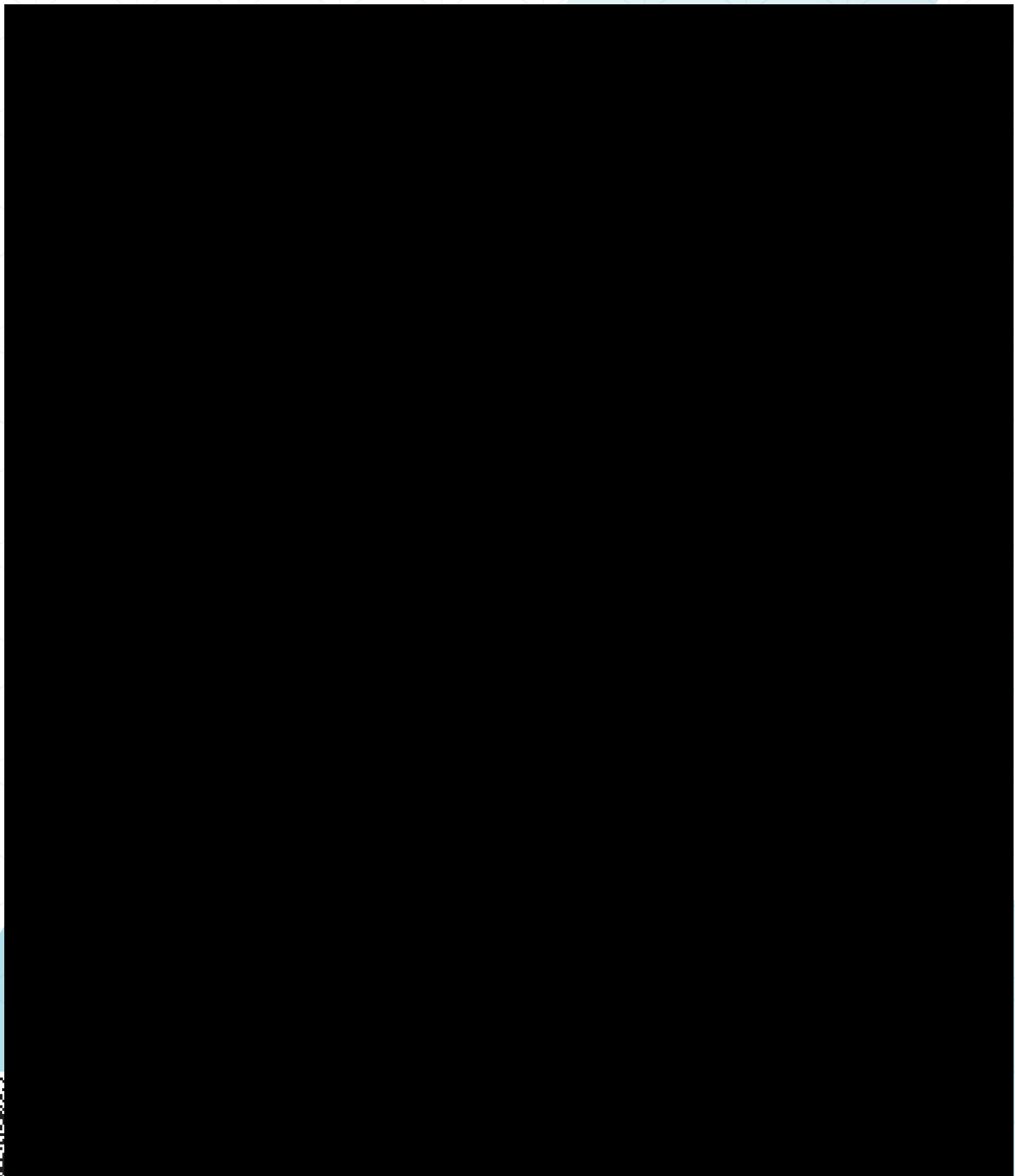
# A&ZMED

Personal Protective Equipment

-  HIGH EFFICIENCY FILTRATION
-  BREATHABLE AND COMFORTABLE
-  SAFETY PROTECTION



## TECHNICAL DATASHEET A&ZMED Mask FFP2







## EU TYPE EXAMINATION CERTIFICATE

**Certificate No: 2163-PPE-1306**

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Suat KAÇMAZ  
UNIVERSAL CERTIFICATION  
Director



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General Manager  
19/08/2020

**CE**  
**2163**

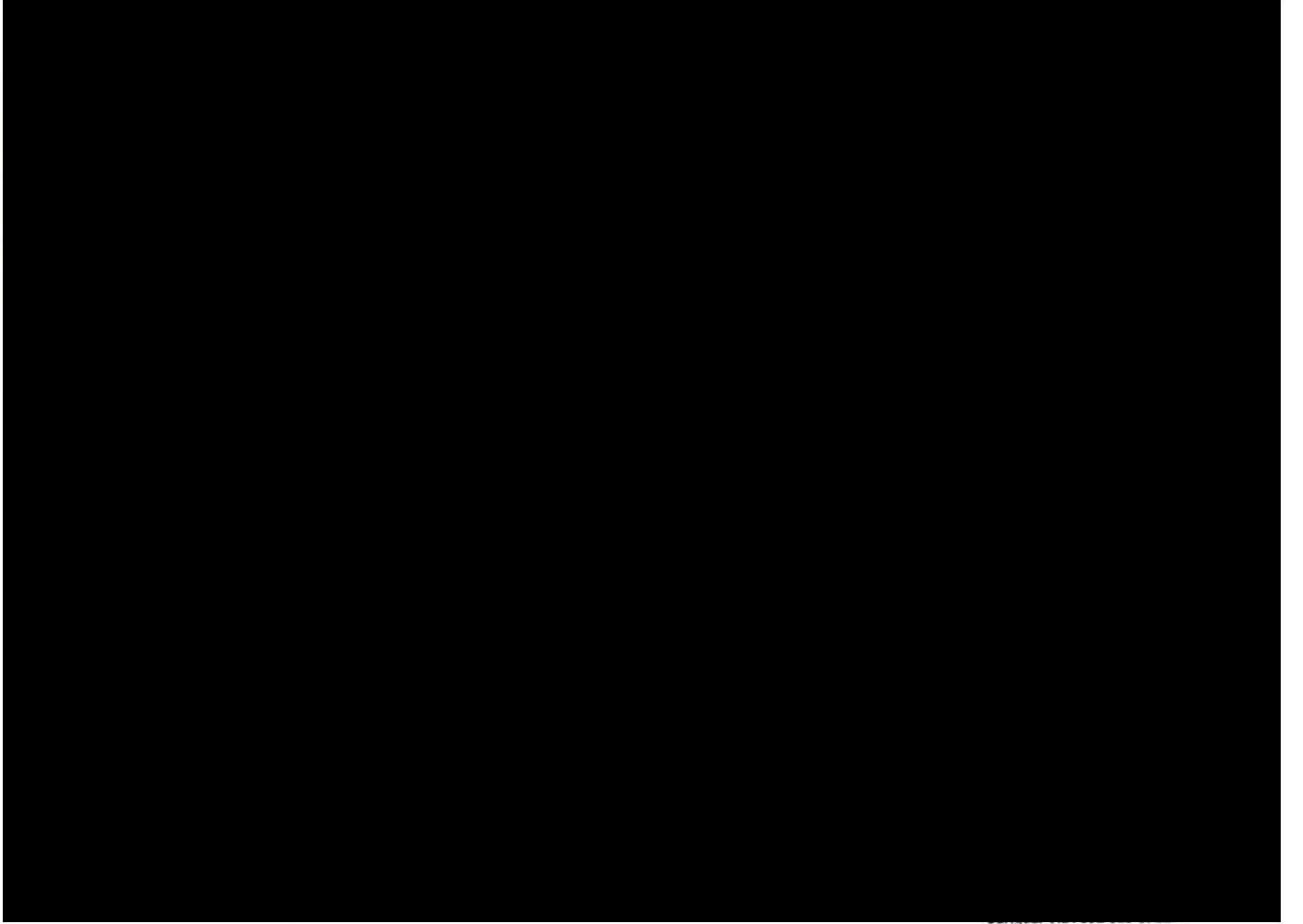




**UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES TRADE CO.**  
Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye, Istanbul / TURKEY

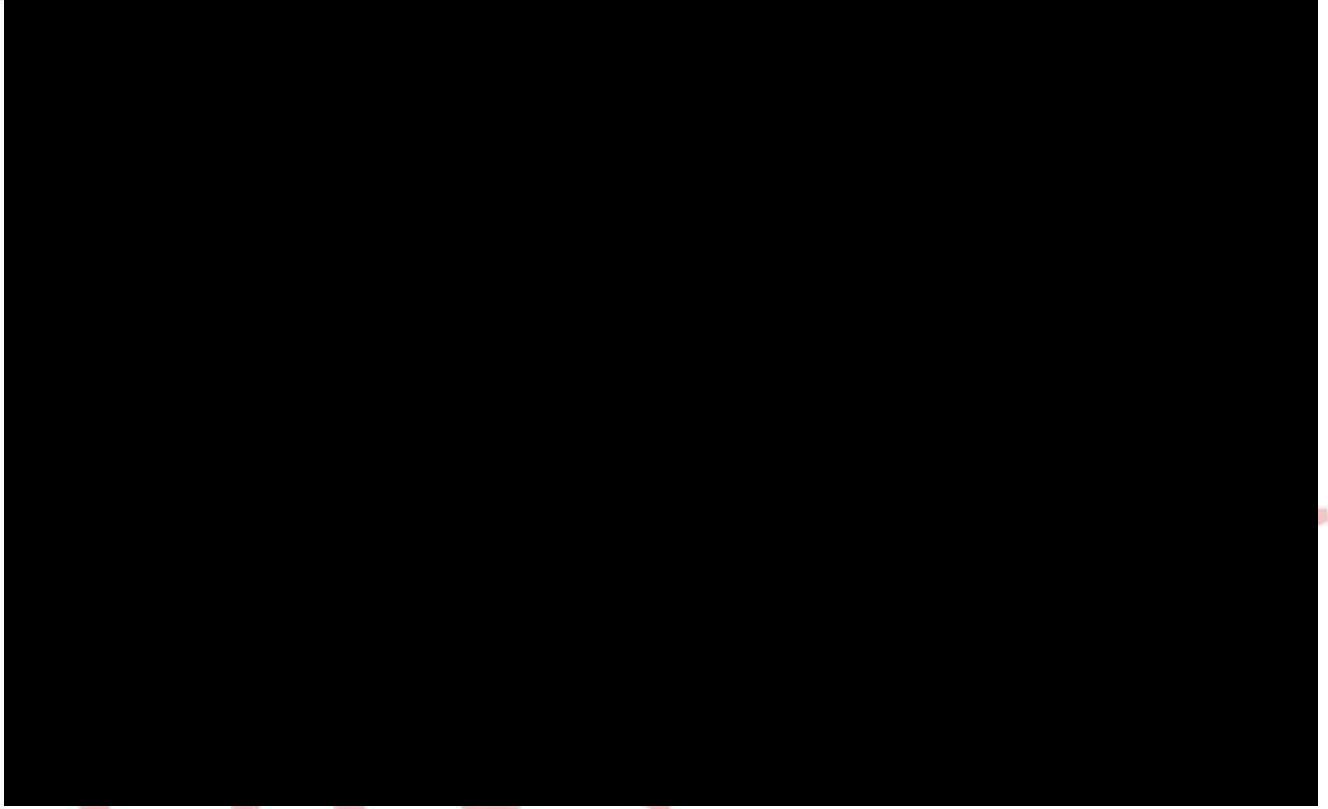
## TEST REPORT

**Report Date:** 17.08.2020  
**Report Number:** 08-2020-T-0309

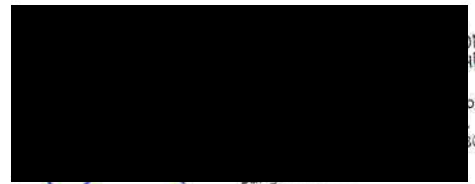


**Suat KAÇMAZ**  
Director

**1. REPORT SUMMARY**



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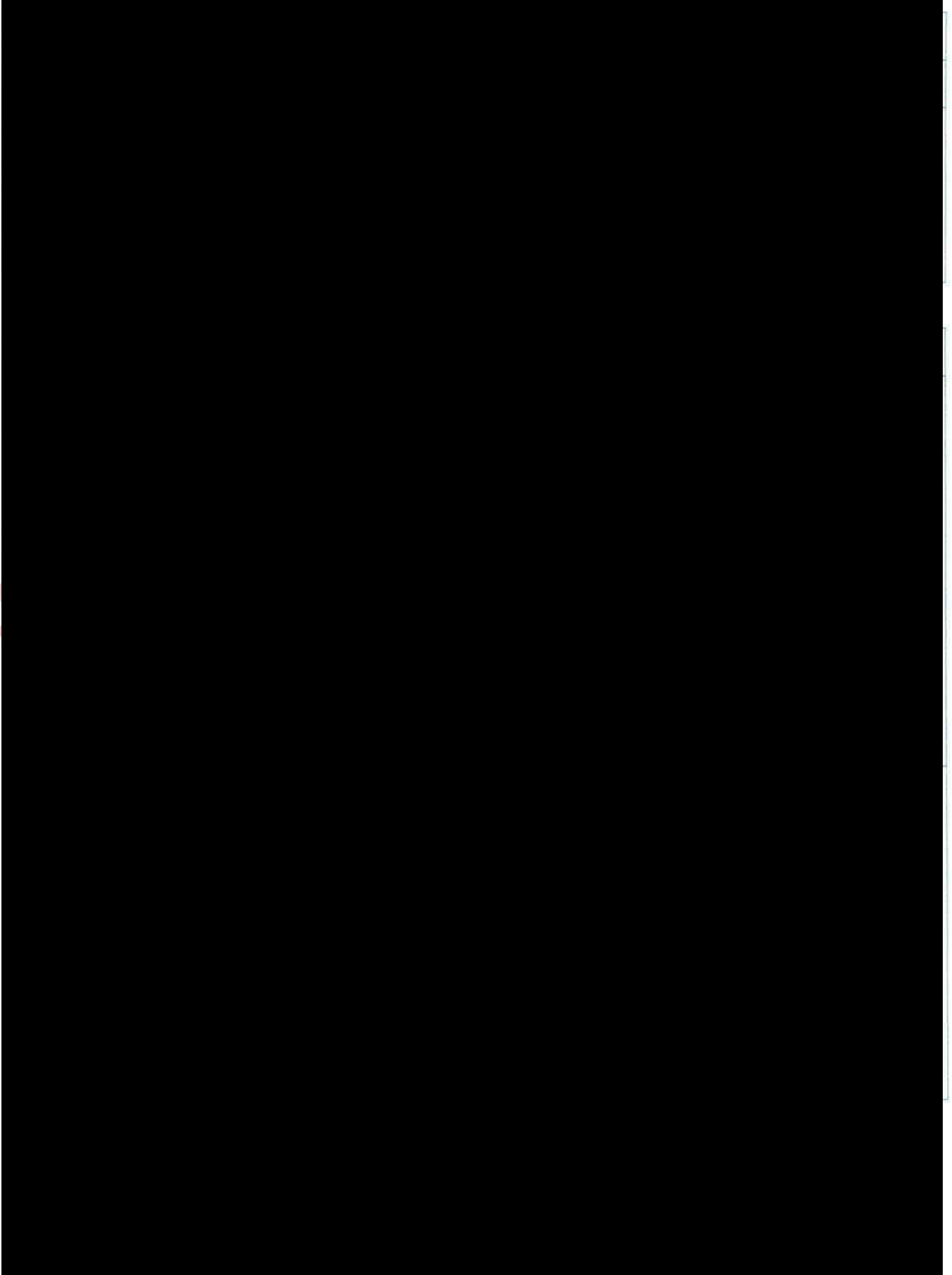


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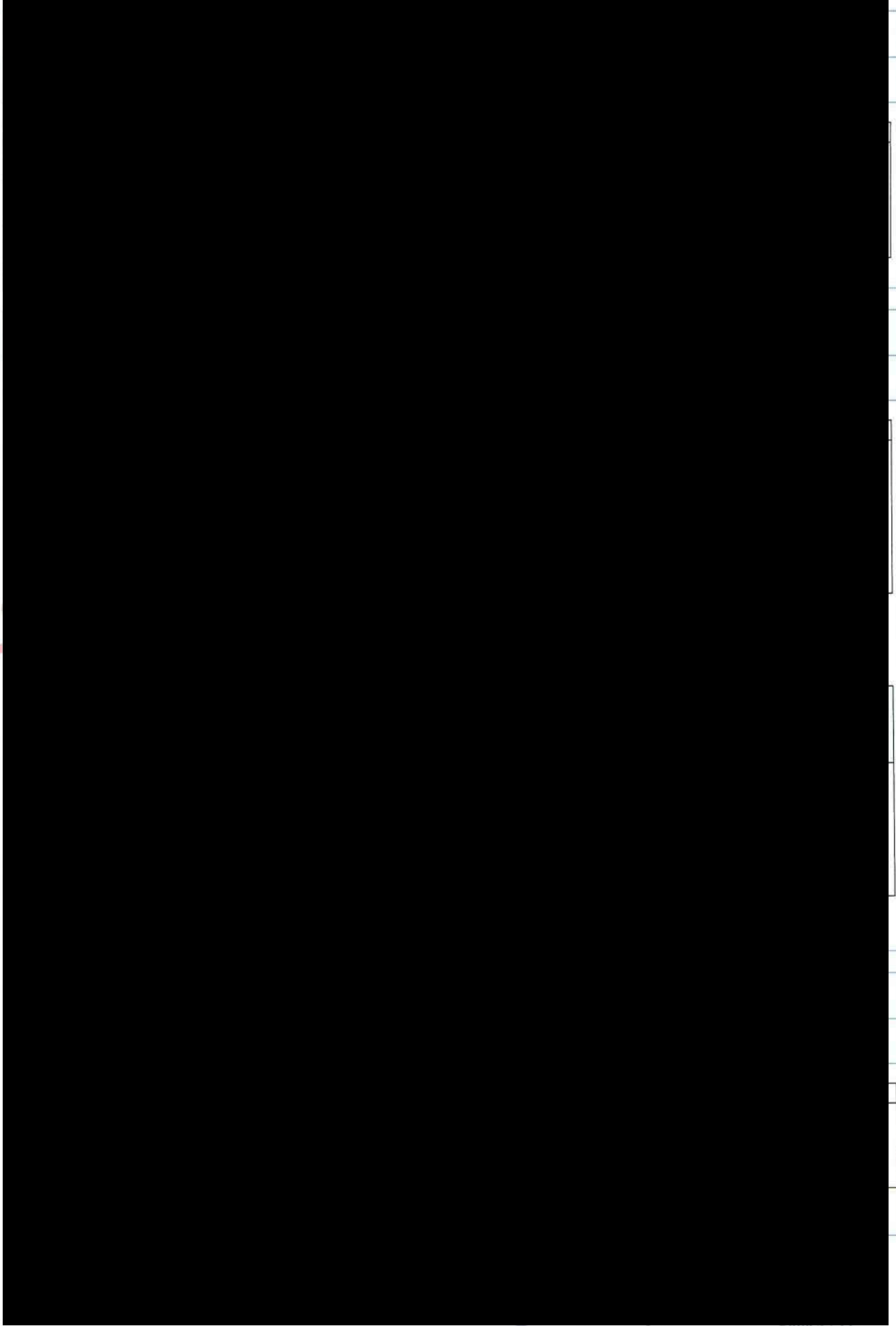


2. *TEST RESULTS and EVALUATION*





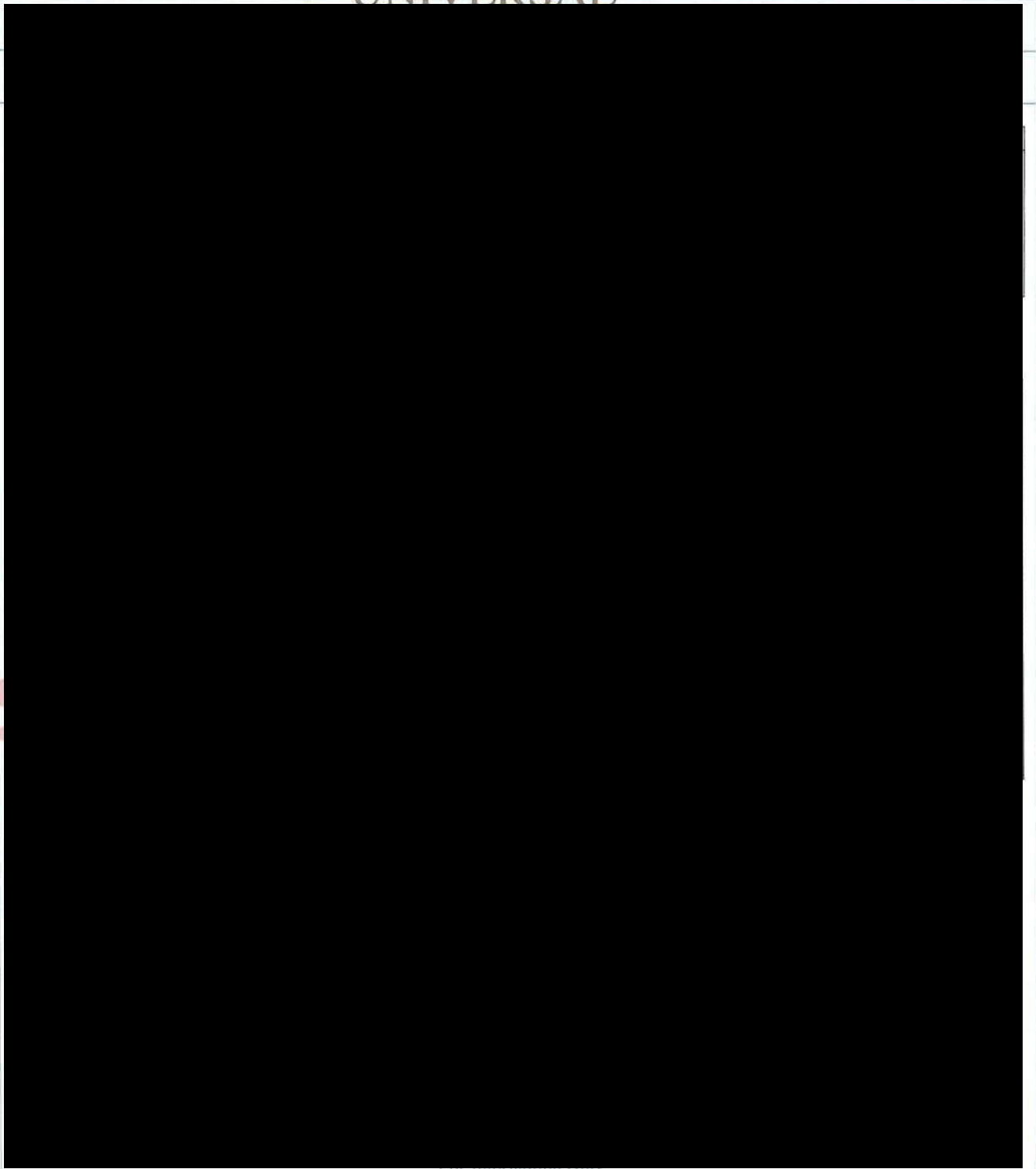
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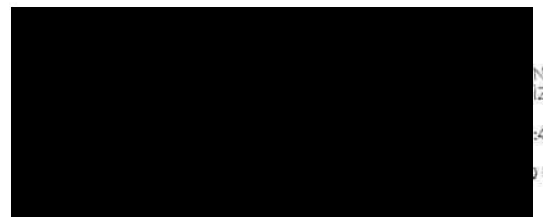




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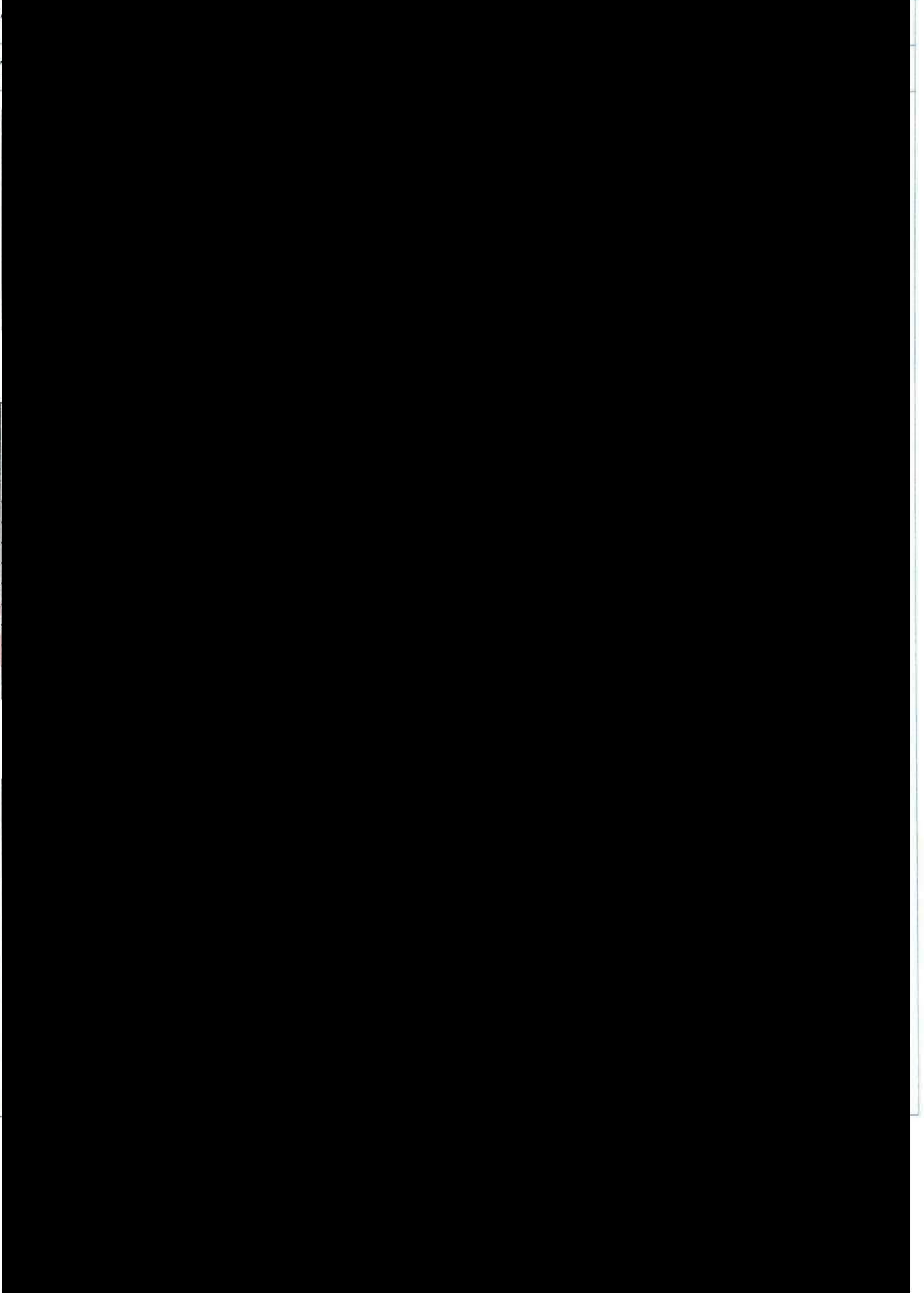
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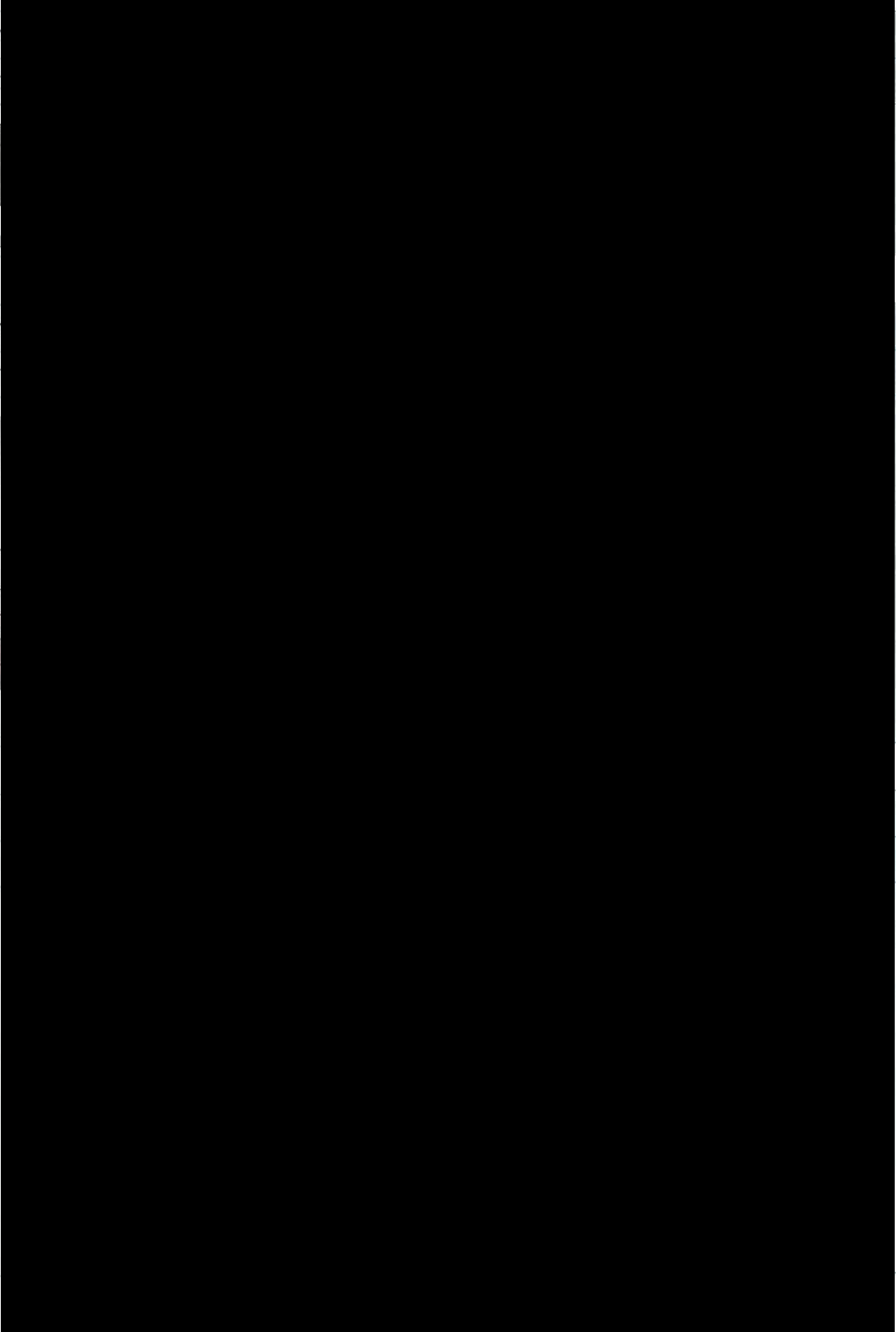


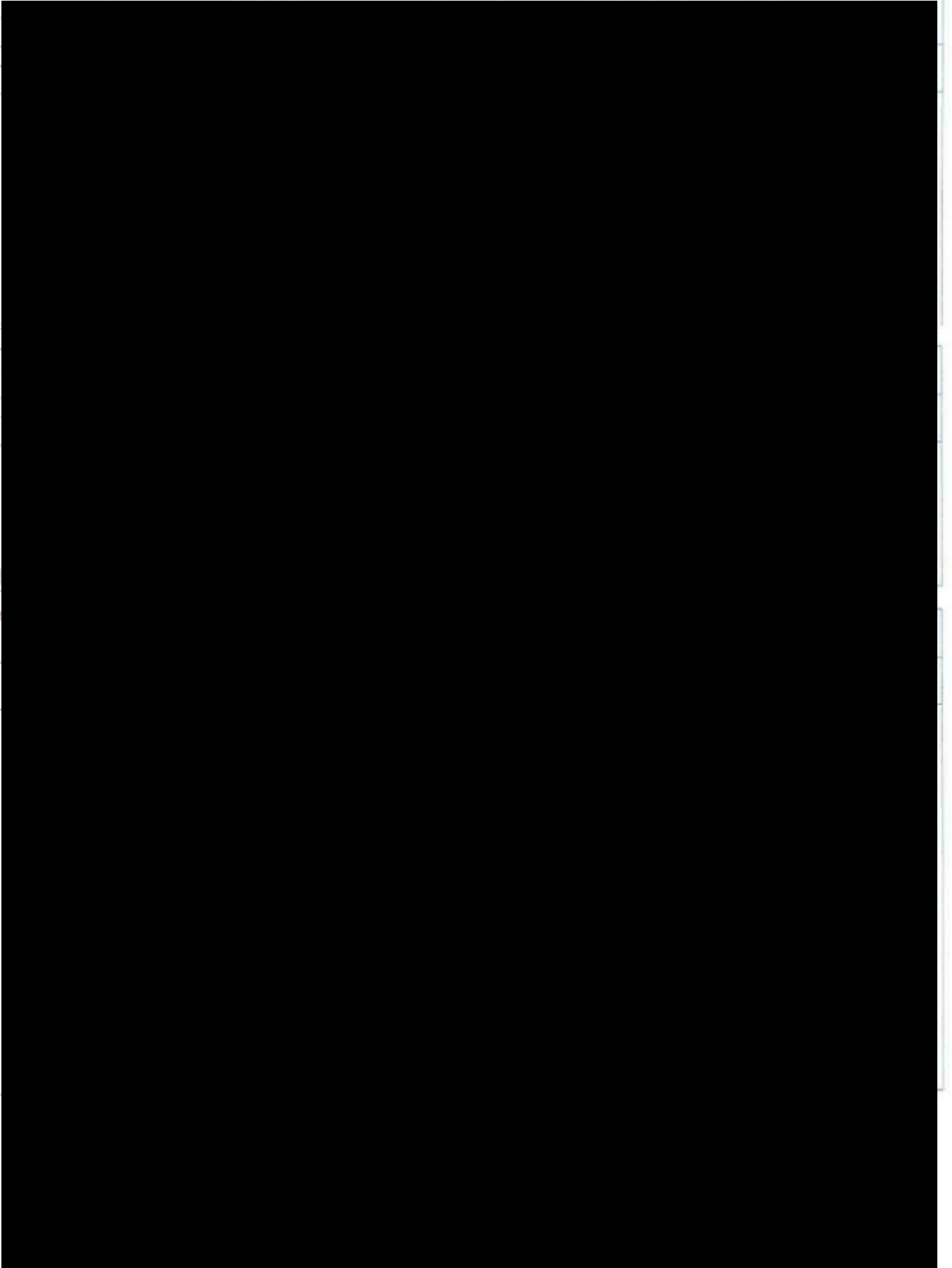
Telefon: 0216 455 80 80 Faks: 0216 455 80 08  
Sarıgazi V.D. 892 025 8722





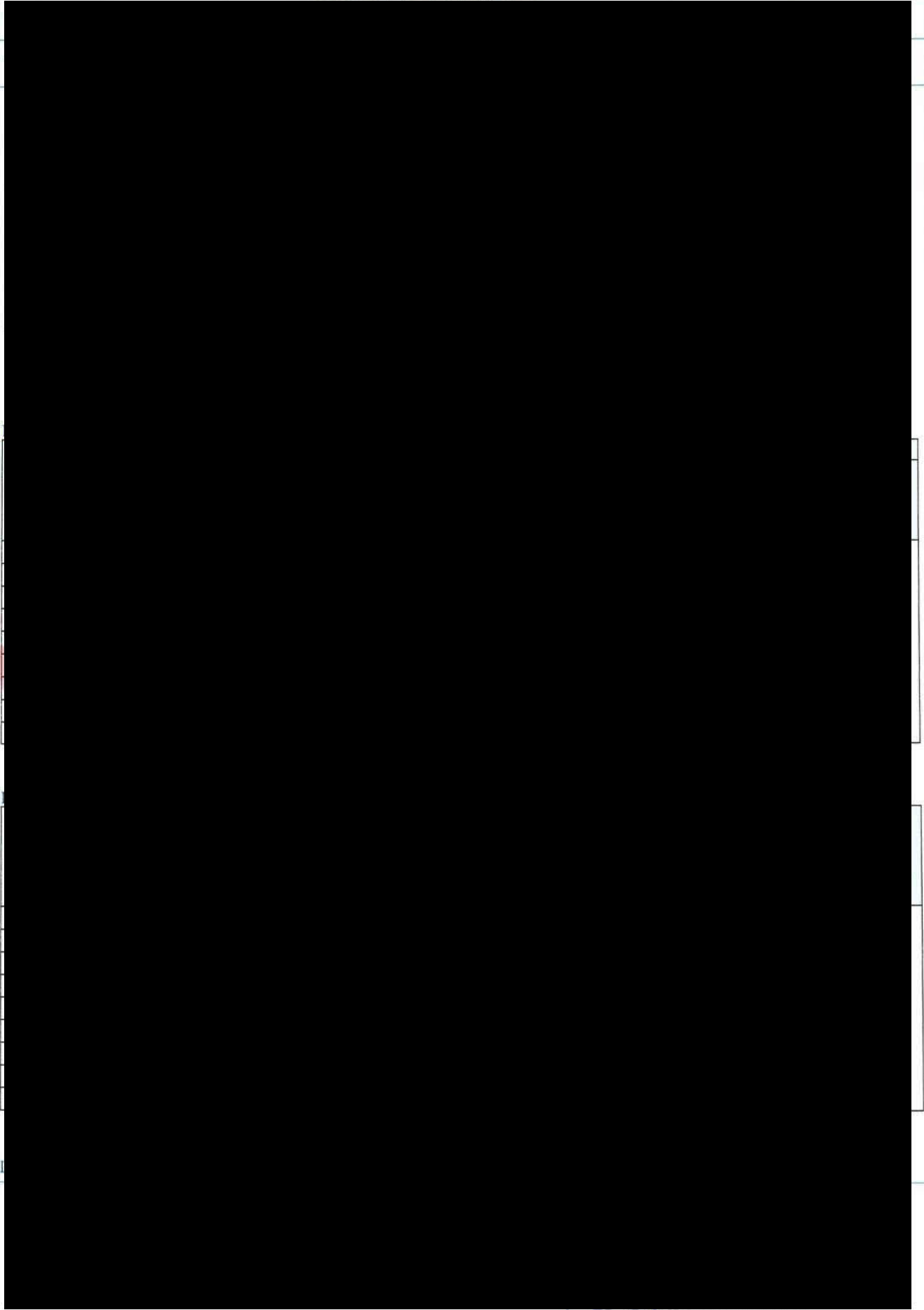
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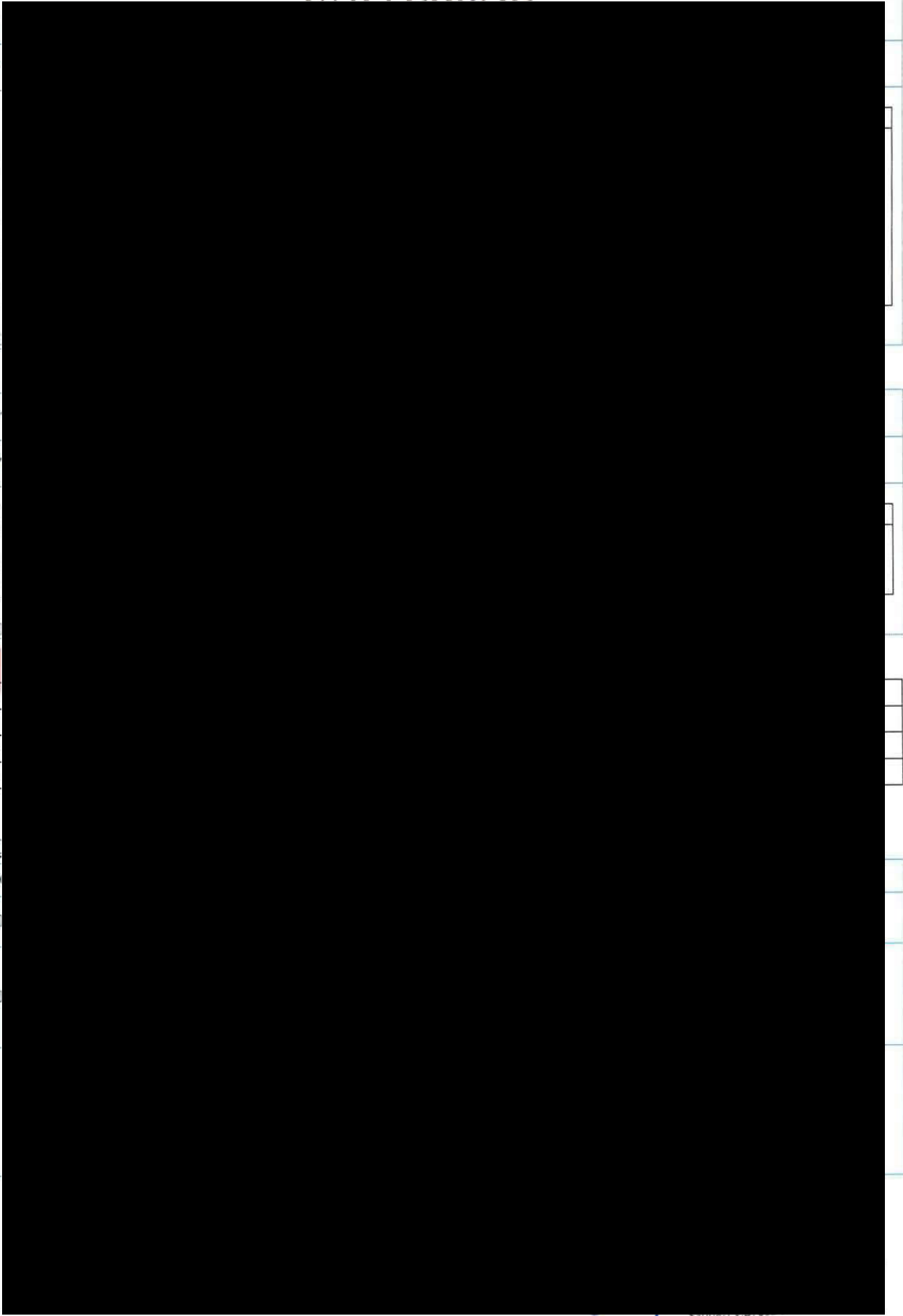


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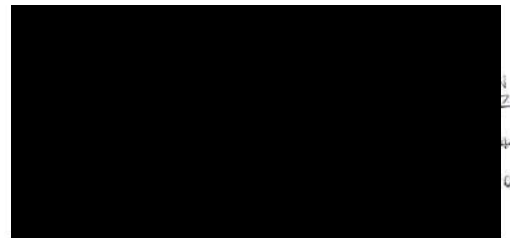


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- End of Report -



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