



**Breco s.r.o.**

Kalvária 3

949 01 Nitra

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+421 [redacted]

## EÚ VYHLÁSENIE O ZHODE

Vydané

podľa Zákona č. 264/99 Z. z. o technických požiadavkách na výrobky a podľa NARIADENIA EURÓPSKEHO PARLAMENTU A RADY (EÚ) 2016/425 z 9. marca 2016 o osobných ochranných prostriedkoch a o zrušení smernice Rady 89/686/EHS

Vyhlásenie o zhode vydáva na výhradnú zodpovednosť:

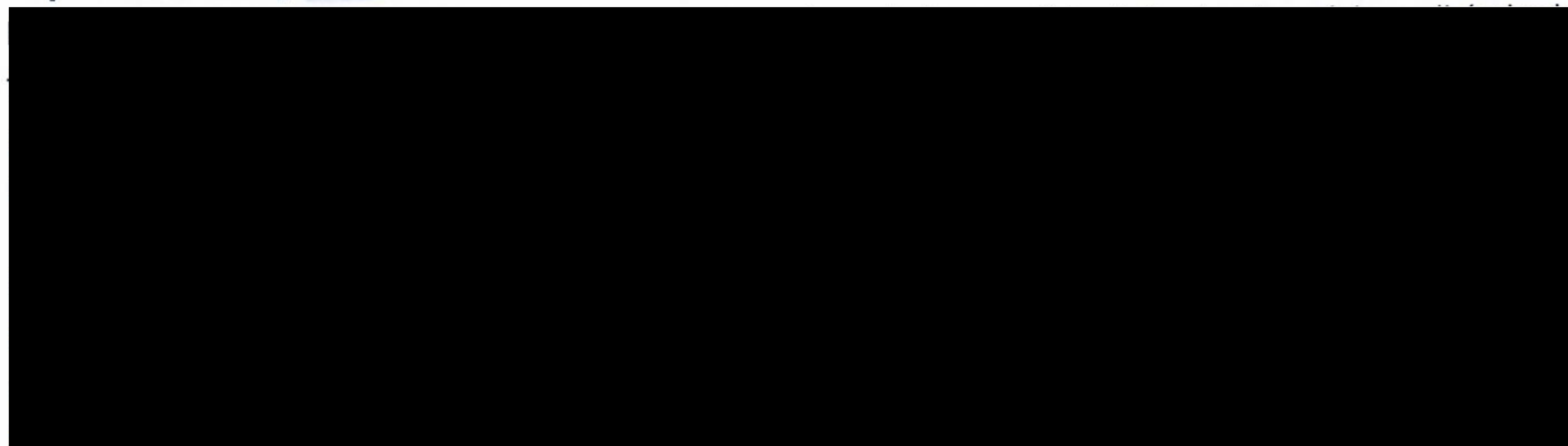
**Obchodné meno:** BRECO s.r.o.  
**Sídlo:** Kalvária 3, 949 01 Nitra  
**IČO:** 52846547  
**DIČ:** 2121153980

Ako dovozca výrobku

**Názov:** Respirátor FFP2  
**Typ:** FFP2-NR  
**Značka:** [redacted]  
**Model:** [redacted]  
**Krajina pôvodu:** Zhejiang Shaohua Medical Equipment Co., Ltd.  
Floor 1, Building 6, Block A, No. E22, Xinke Road, Choujiang Street,  
Yiwu City, Zhejiang Province, China



**Popis a funkcia výrobku:**



**Technické údaje:**

- [redacted]
- [redacted]
- [redacted]
- [redacted]



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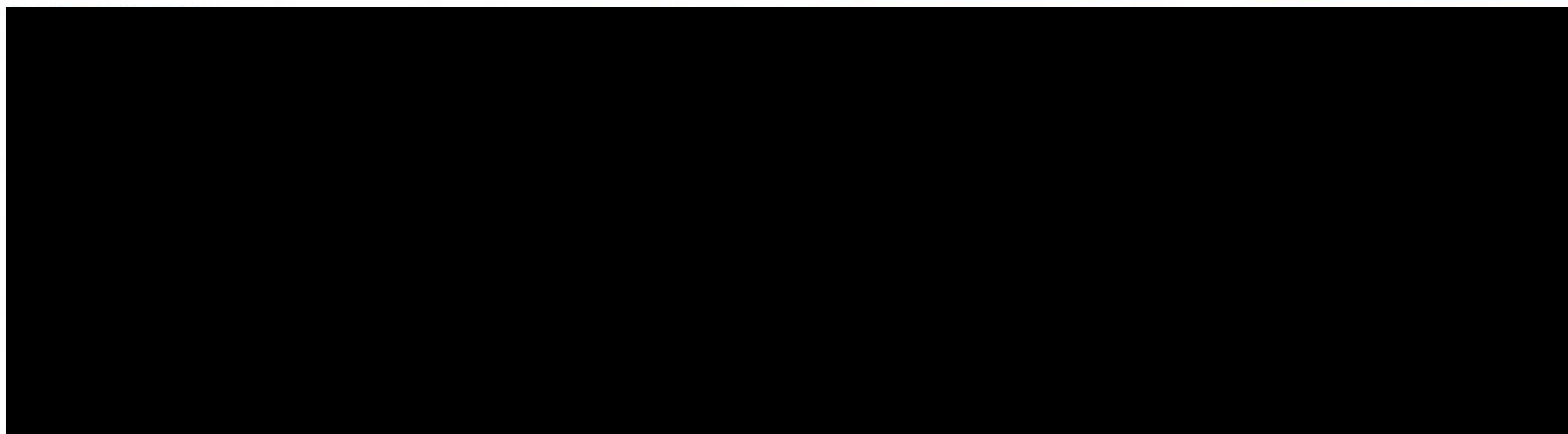
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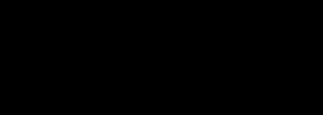
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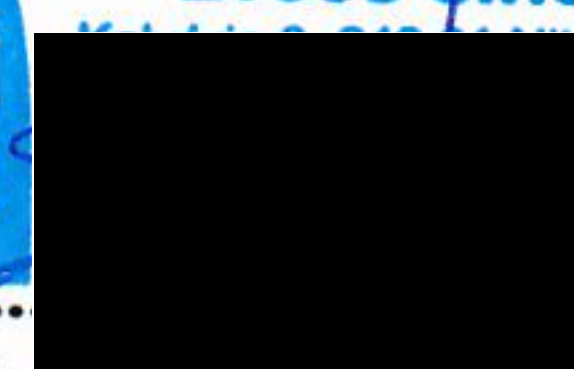
Dovozca vyhlasuje, že

- A. Uvedený výrobok je pri určenom použití bezpečný a prijaté opatrenia, ktorými je zabezpečená zhoda všetkých výrobkov uvádzaných na trh s technickou dokumentáciou, so základnými požiadavkami nariadení vlády, ktoré sa na ne vzťahujú a požiadavkami technických predpisov uvedených v bode B.
- B. Vlastnosti tohto výrobku spĺňajú technické požiadavky, ktoré sa na tento výrobok vzťahujú a ktoré sú uvedené v príslušných nariadeniach vlády, príp. v iných / ďalších / technických predpisoch.
- C. Posúdenie zhody bolo vykonané podľa:  
NARIADENIA EURÓPSKEHO PARLAMENTU A RADY (EÚ) 2016/425 z 9. marca 2016 o osobných ochranných prostriedkoch a o zrušení smernice Rady 89/686/EHS
- D. Pri posudzovaní zhody boli použité harmonizované technické normy:  
EN 149:2001+A1:2009 a má označenie CE 

V Nitre, dňa 1.1.2021



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.....  
Ing. Eva Šmitalová, PhD.  
konateľ

**EU TYPE EXAMINATION CERTIFICATE**

Certificate No. [REDACTED]

Respiratory protective devices, filtering half masks to protect against particles manufactured by  
**Zhejiang Shaohua Medical Equipment Co., Ltd.**  
Floor 1, Building 6, Block A, No. E22, Xinke Road, Choujiang Street, Yiwu City, Zhejiang  
Province, China

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****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 **15/08/2020** and will be valid for 5 years, if there is no  
change in the relevant harmonised standard affecting the essential health and safety  
requirements.



[REDACTED]  
Suat KAÇMAZ  
UNIVERSAL CERTIFICATION  
Director

**CERTIFICATE OF CONFORMANCE****Certificate No:**

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

**Zhejiang Shaohua Medical Equipment Co., Ltd.**Floor 1, Building 6, Block A, No. E22, Xinke Road, Choujiang Street, Yiwu City, Zhejiang  
Province, China

Continues to fulfil the requirements of

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

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

**Product Definition**

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;

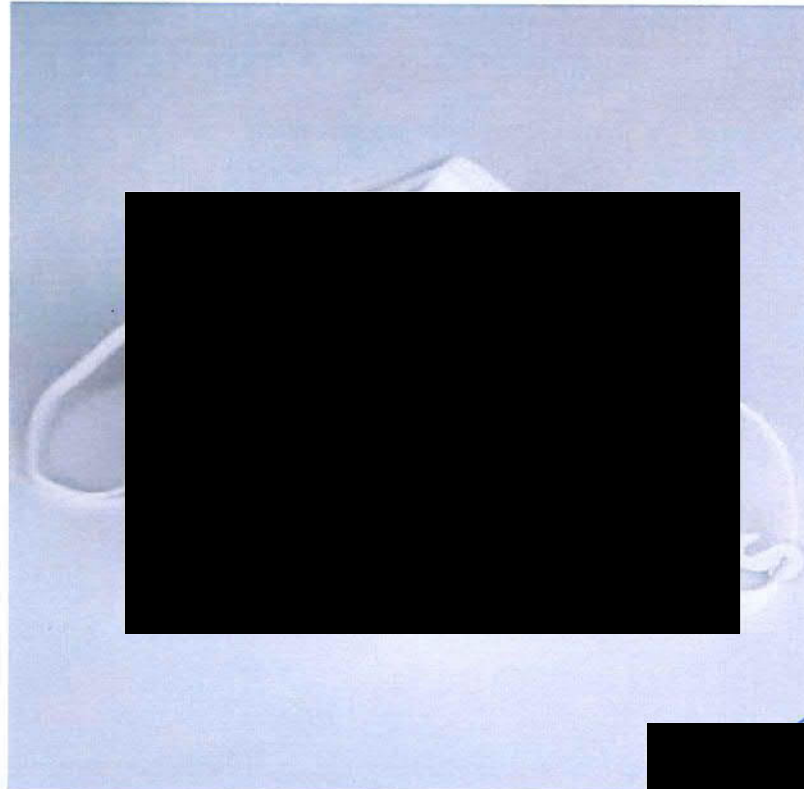
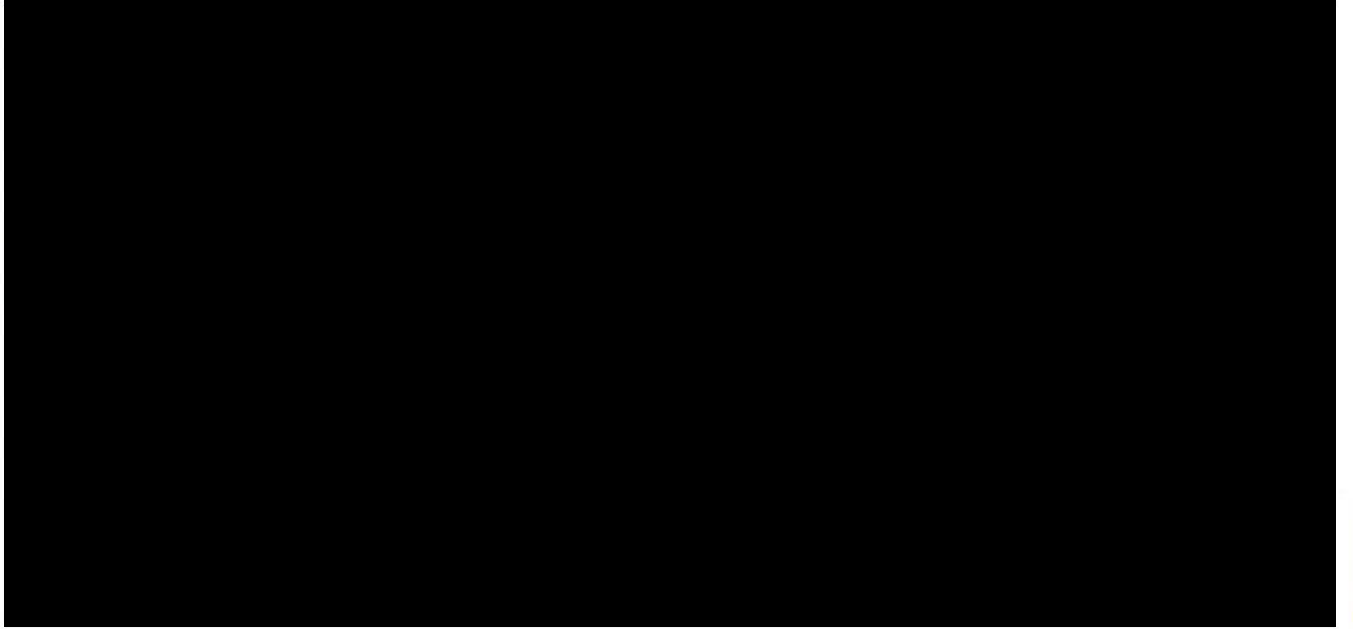
- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

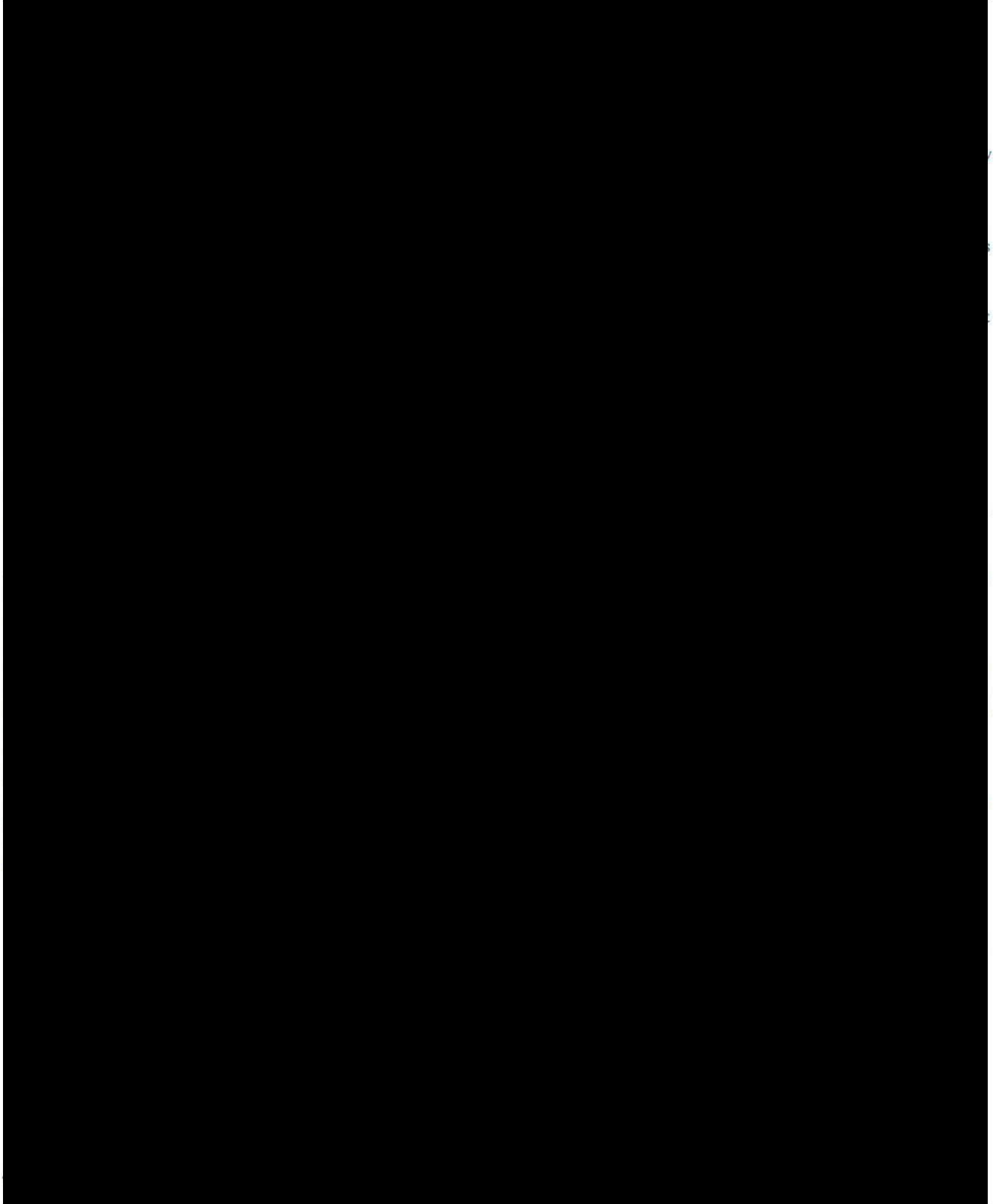
This certificate is issued on **15/08/2020** and will be valid for one year, until **14/08/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

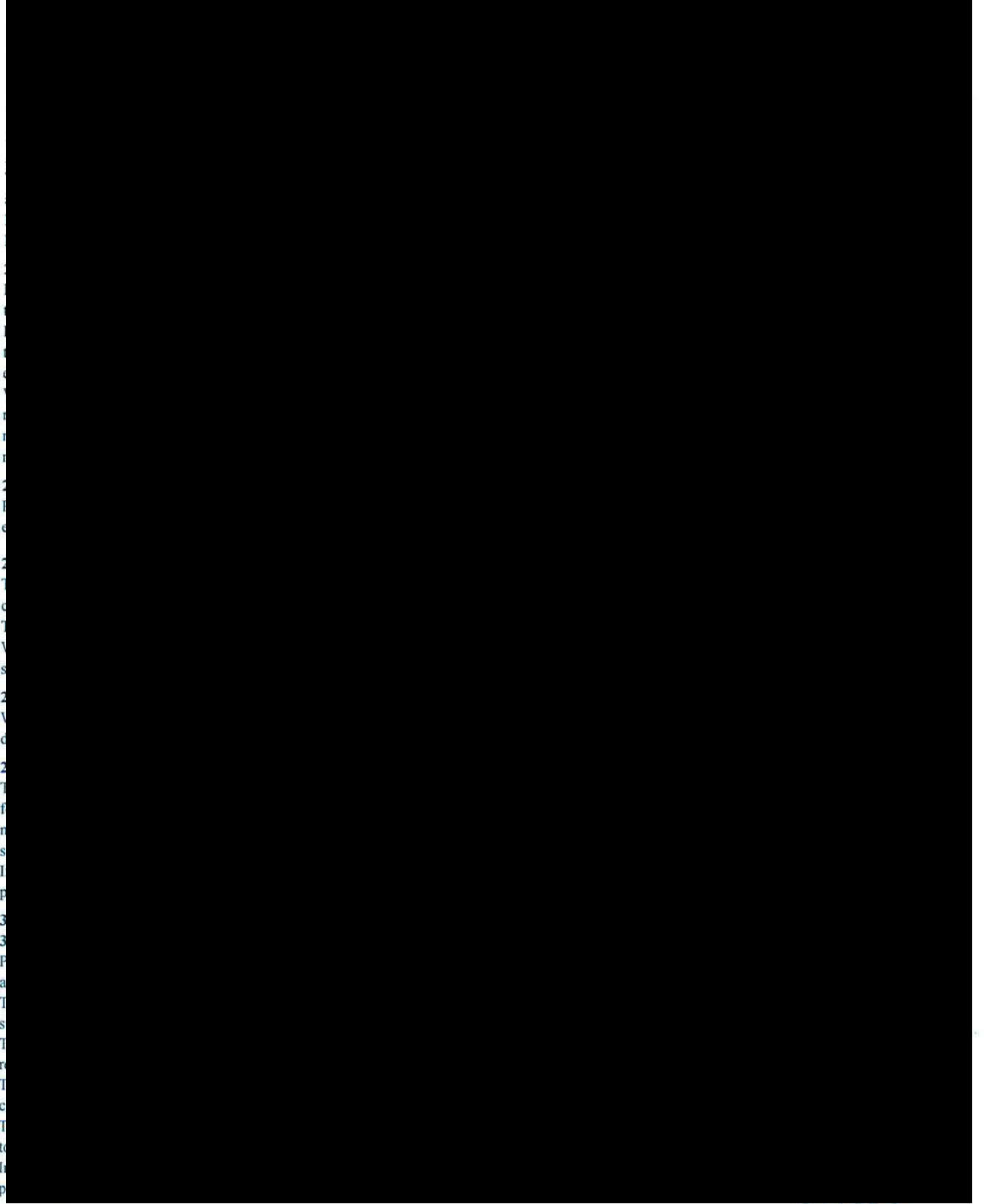
**Suat KAÇMAZ****UNIVERSAL CERTIFICATION**  
Director

**TECHNICAL ASSESSMENT REPORT**

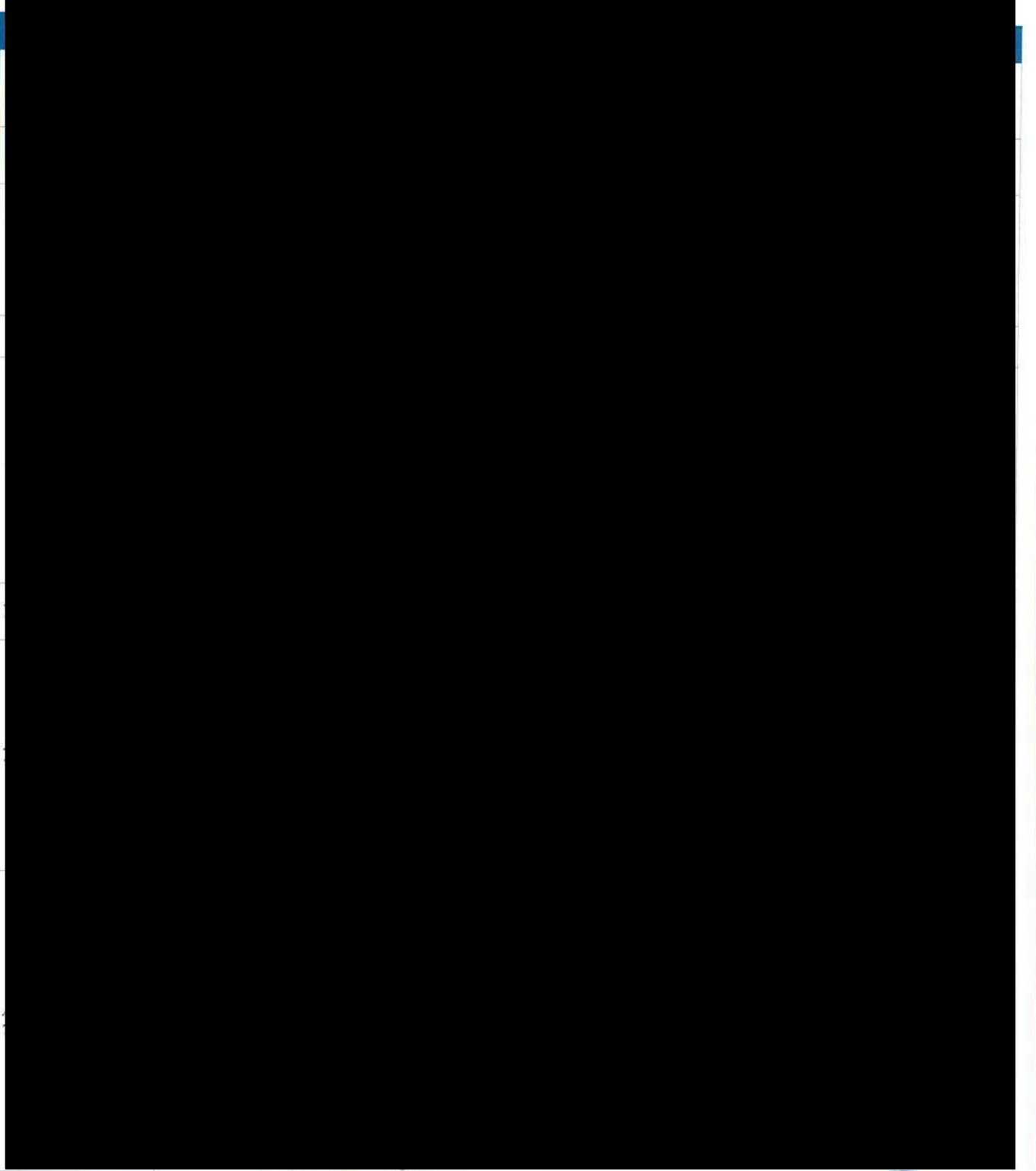
REPORT DATE / NO

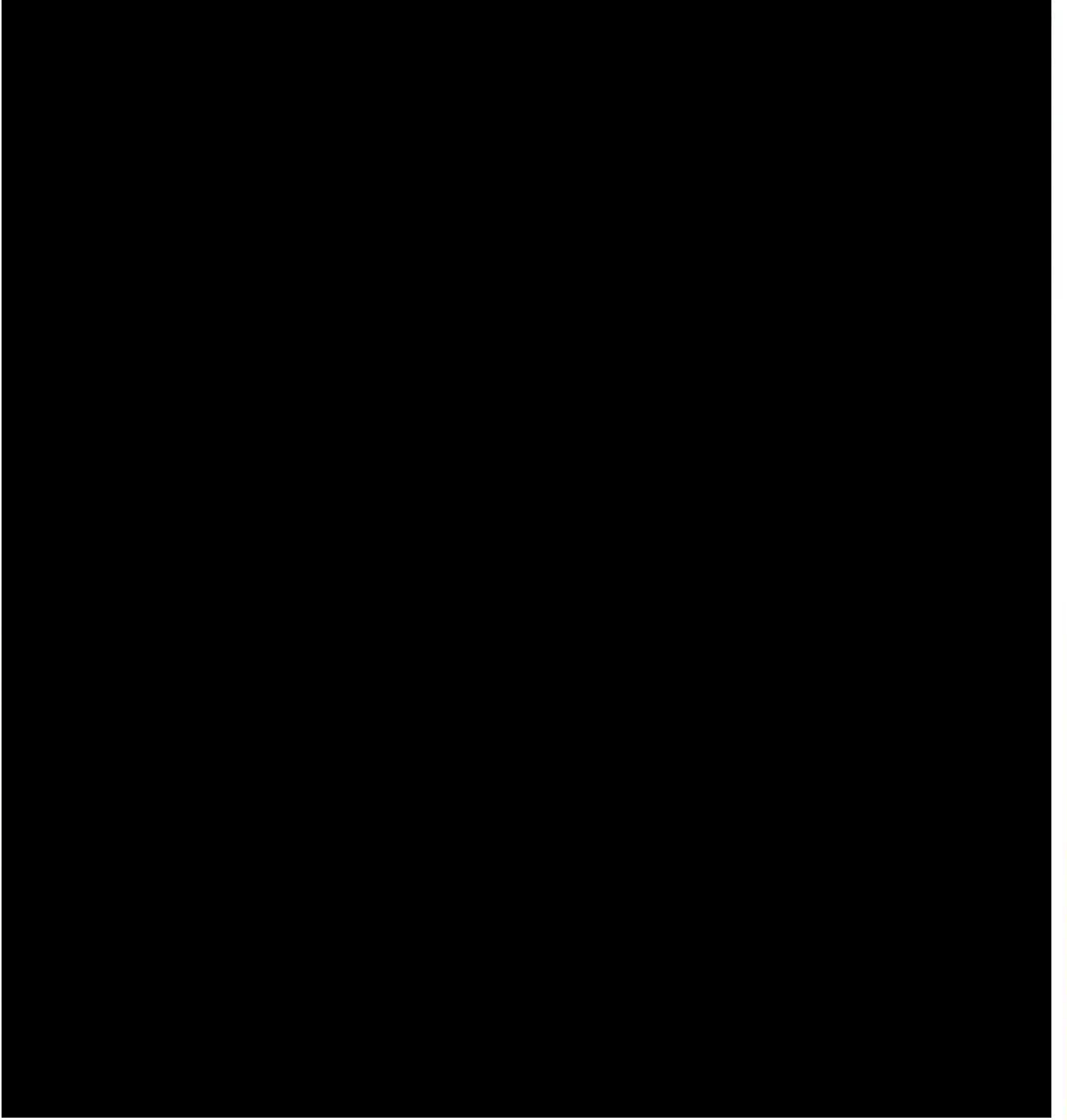


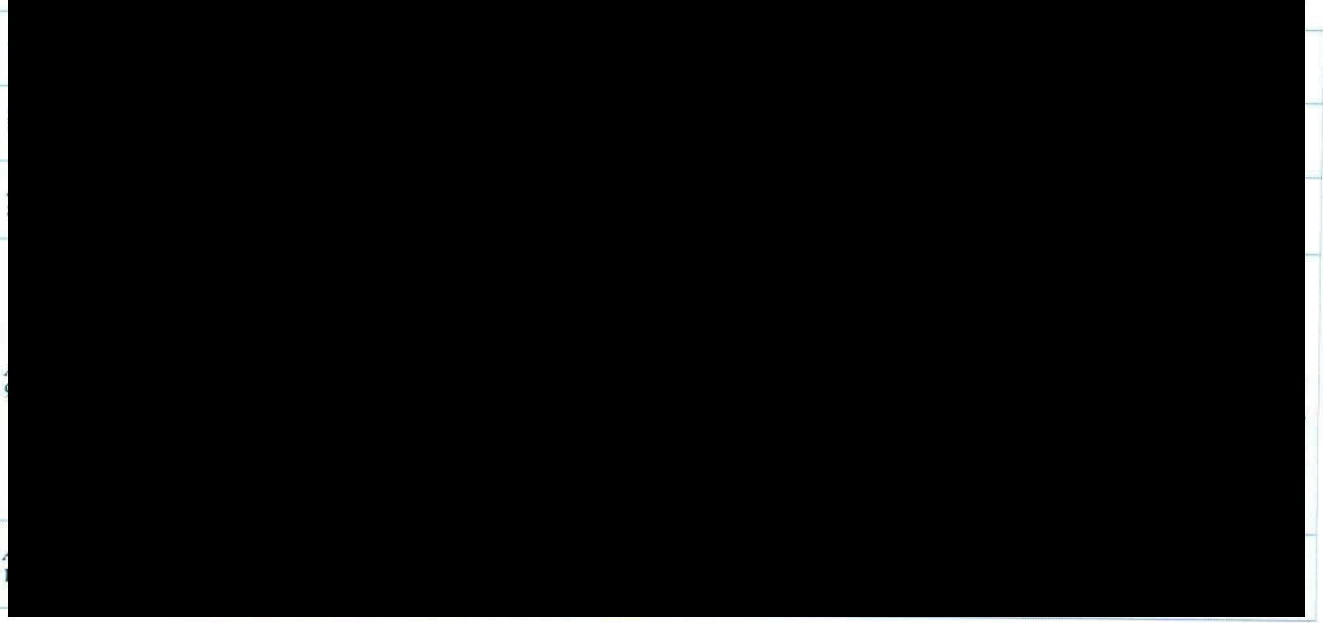




Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the







| PREPARED BY                                                                                                             | APPROVED BY                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <b>Osman CAMCI</b><br>PPE Expert<br> | <b>Suat KAÇMAZ</b><br>Director<br> |





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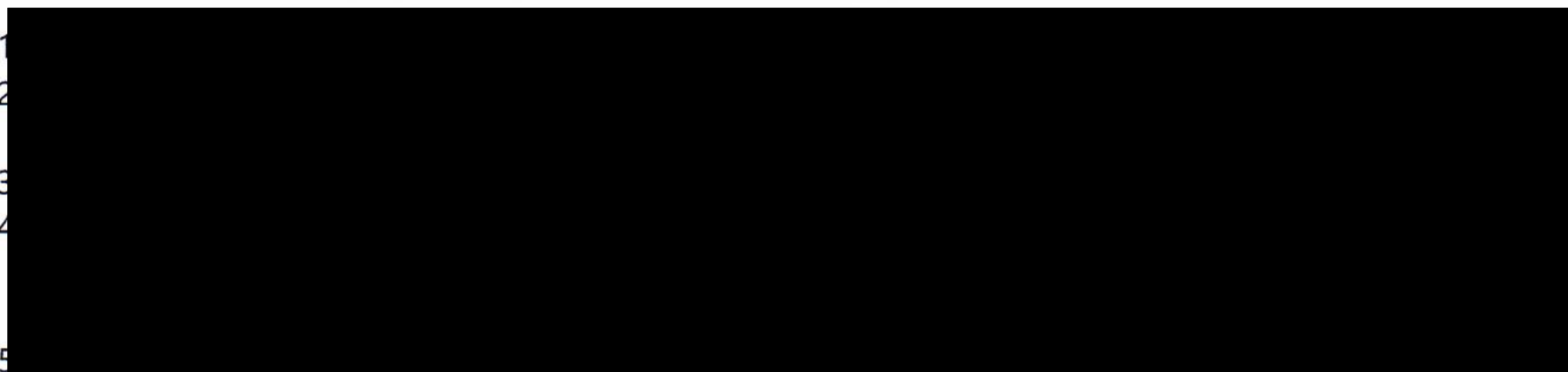
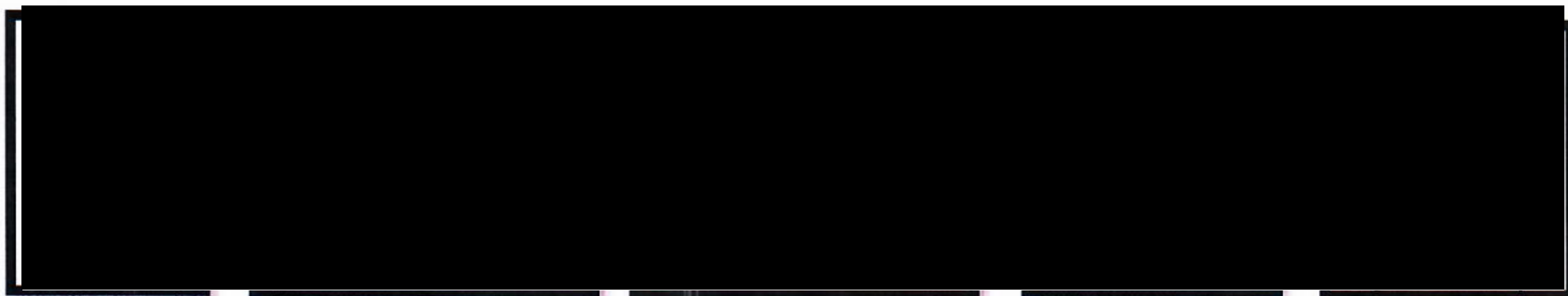
Kalvária 3

949 01 Nitra

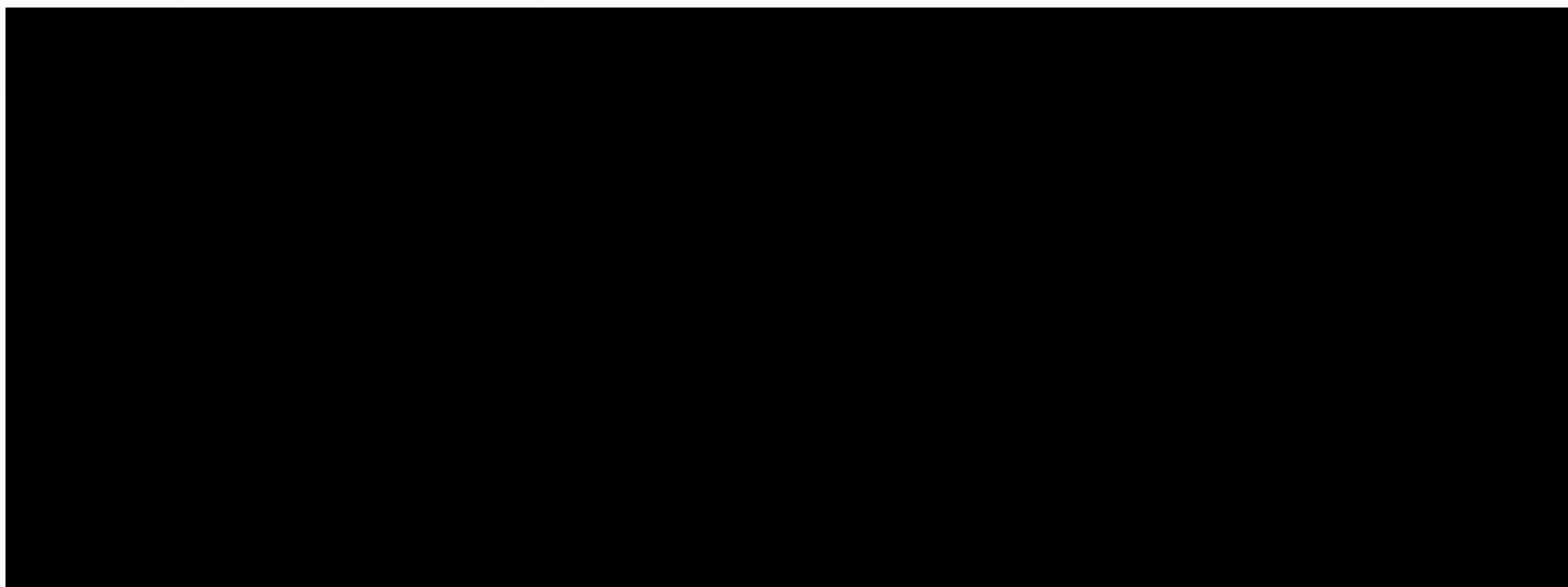
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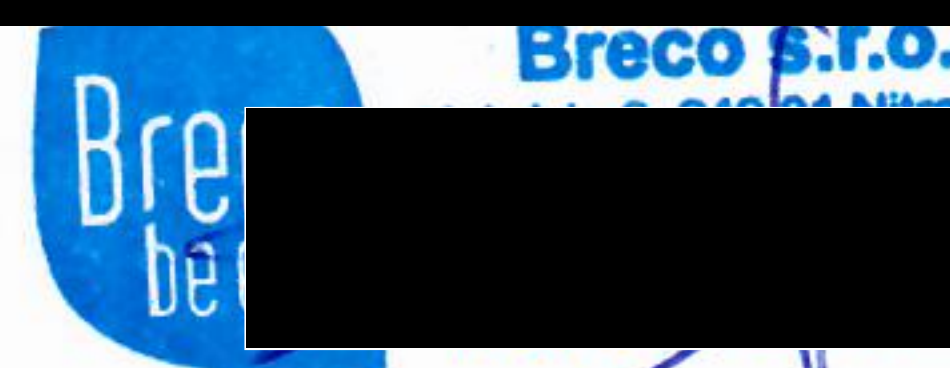
## NÁVOD NA POUŽITIE



## ÚDRŽBA A SKLADOVANIE



V Nitre, dňa 1.1.2021



.....  
Ing. Eva Šmitalová, PhD.  
konateľ



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

|                                         |                                                                                    |
|-----------------------------------------|------------------------------------------------------------------------------------|
| Obchodné meno uchádzača:                | <b>Breco s.r.o.</b>                                                                |
| Sídlo uchádzača:                        | <b>Kalvária 3, 94901 Nitra</b>                                                     |
| IČO:                                    | <b>52846547</b>                                                                    |
| Meno a priezvisko štatutárneho zástupcu | <b>Ing. Eva Šmitalová, PhD.<br/>Mgr. Stanislav Horák</b>                           |
| IČ DPH:                                 | <b>SK2121153980</b>                                                                |
| Názov banky:                            | <b>Tatra banka</b>                                                                 |
| Číslo účtu (IBAN):                      |  |
| Telefónne číslo:                        |                                                                                    |
| E-mailová adresa:                       | <b>info@breco.sk</b>                                                               |

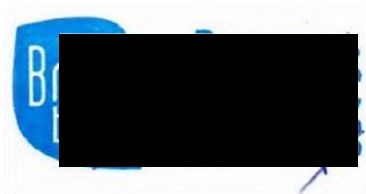
Predmet zákazky: „Respirátor FFP2 bez výdychového ventilu“

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

| N á z o v                                                                                                                  | Celková cena v EUR s DPH |
|----------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Respirátor FFP2 bez výdychového ventilu v celkovom množstve 25 000 ks v súlade s opisom predmetu zákazky tejto výzvy č. 25 | 7 875,-                  |

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.**

V Nitre, dňa 04.03.2021



.....  
Ing. Eva Šmitalová, PhD.  
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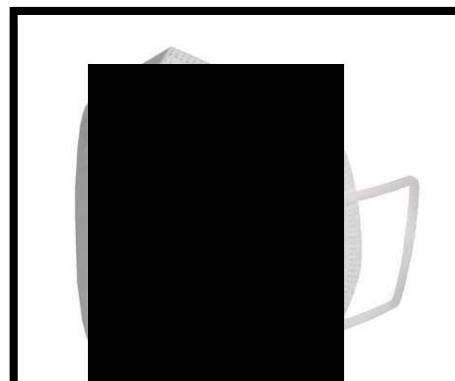
949 01 Nitra

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**TECHNICKÝ LIST**  
Ochranná pomôcka

# RESPIRÁTOR FFP2 NR





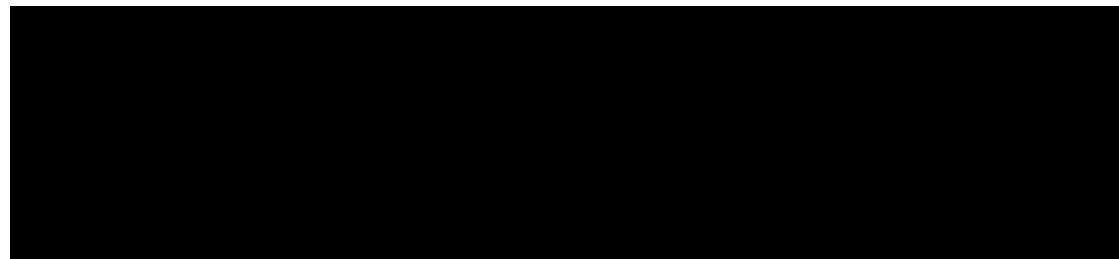
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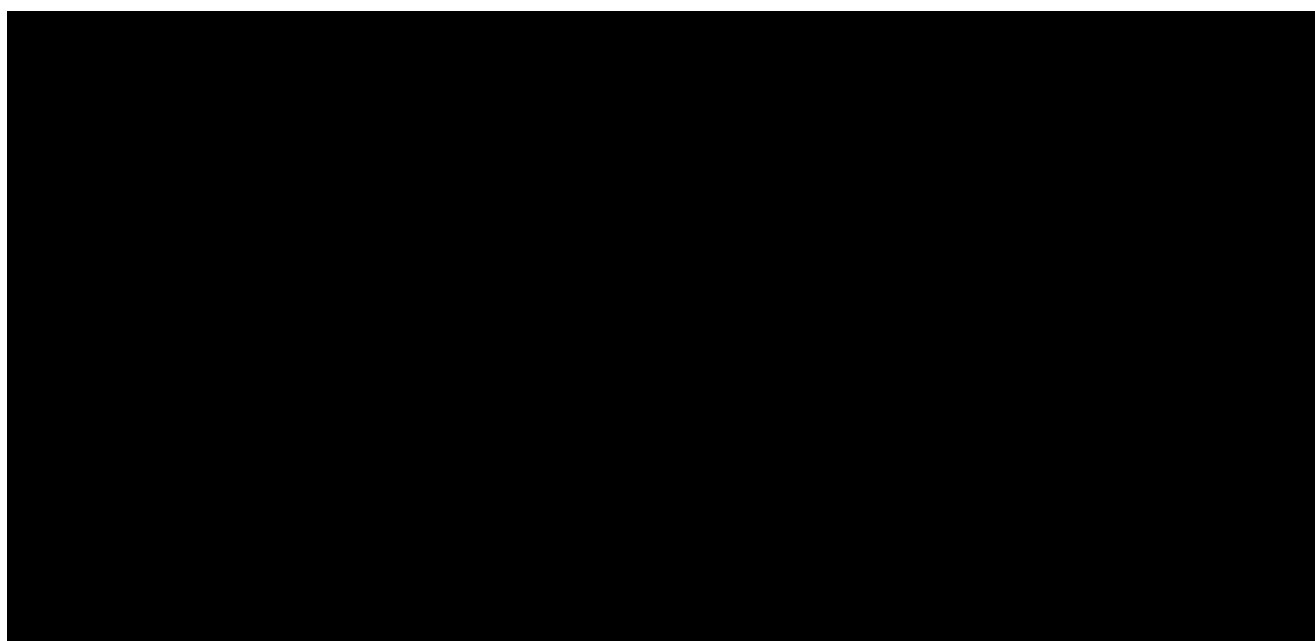
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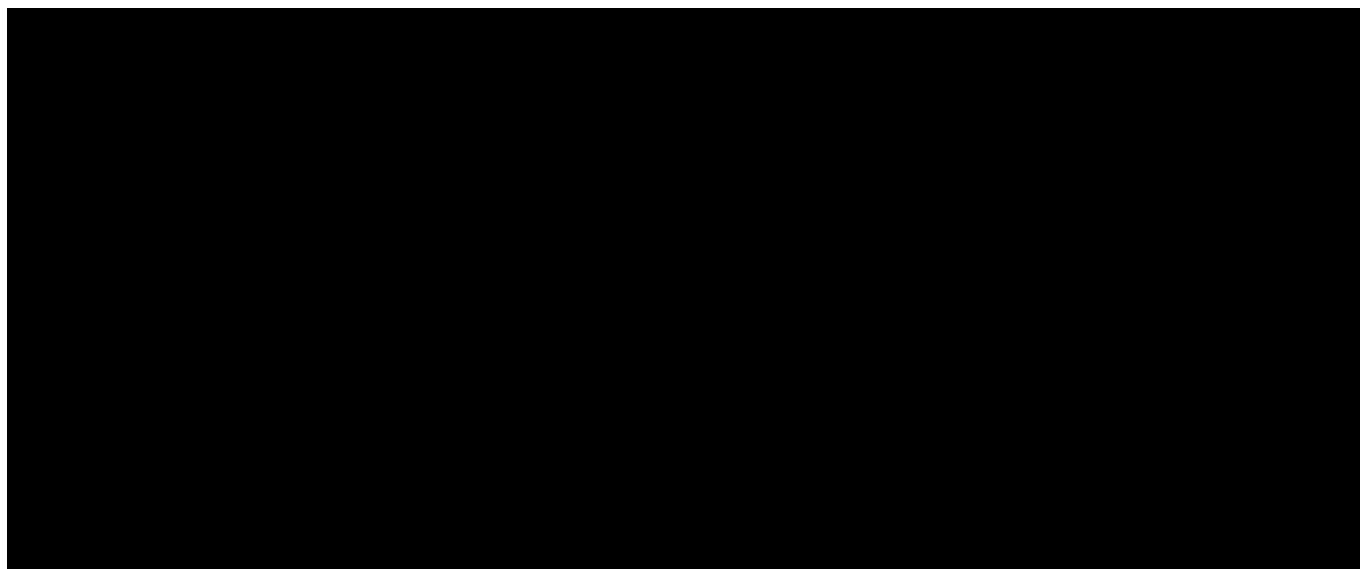
☎ +421



### 3. Návod na použitie



### 4. Údržba a skladovanie





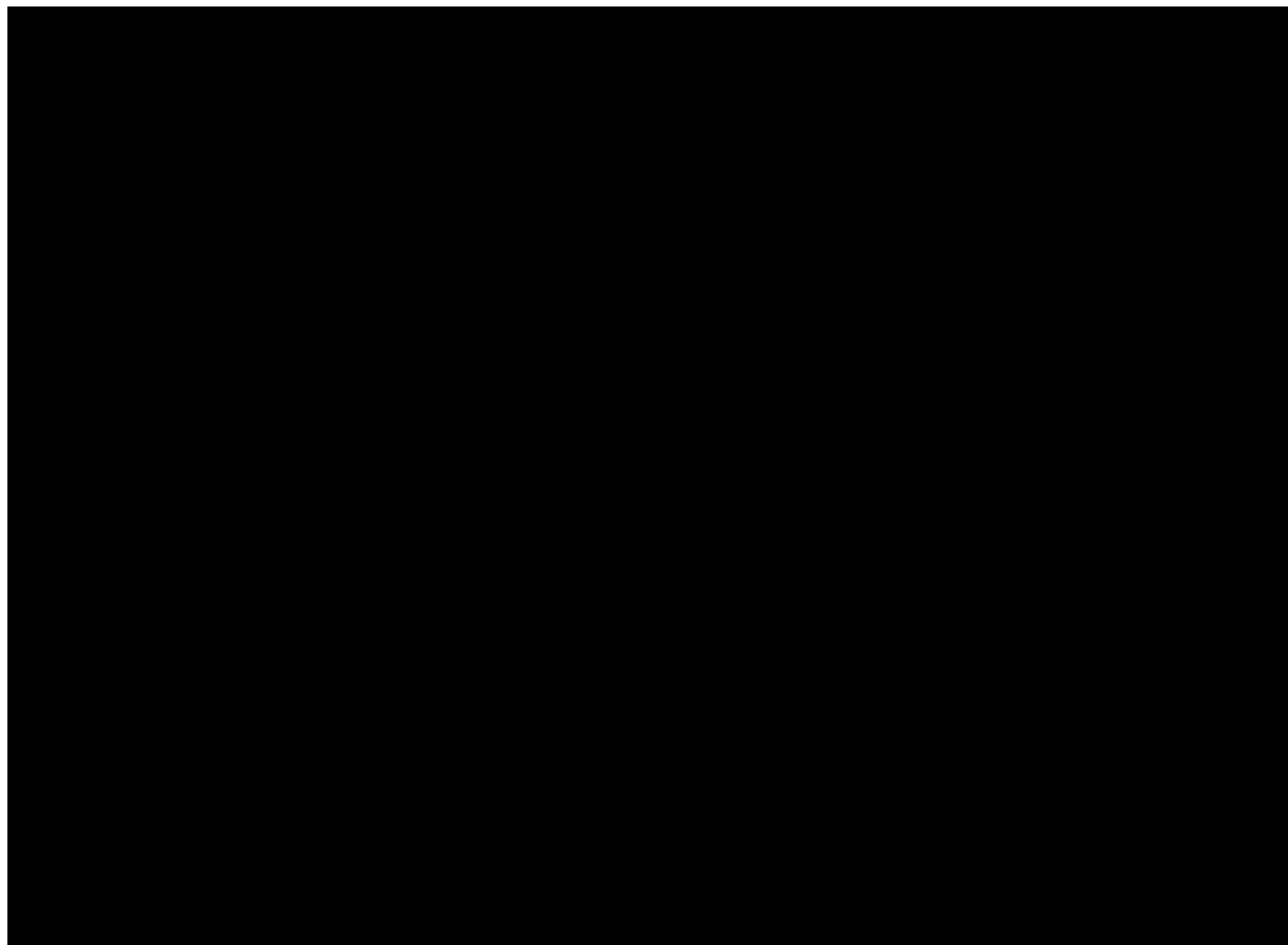
**Breco s.r.o.**

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☎ +42 [redacted]

**V Nitre, dňa 1.1.2021**

.....  
**Ing. Eva Šmítalová, PhD.**  
**konateľ**



**Breco s.r.o.**

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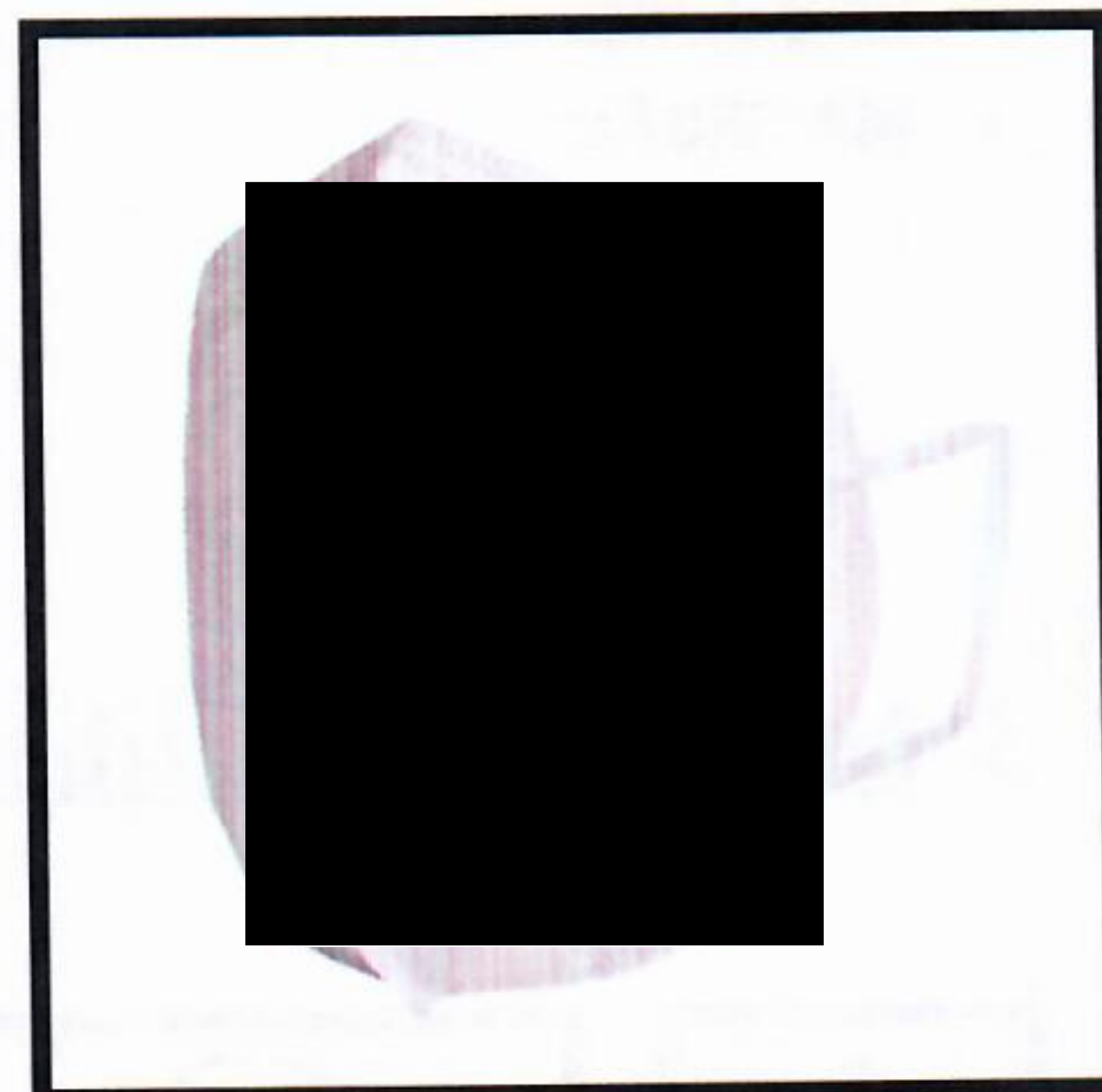
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## TECHNICKÝ LIST

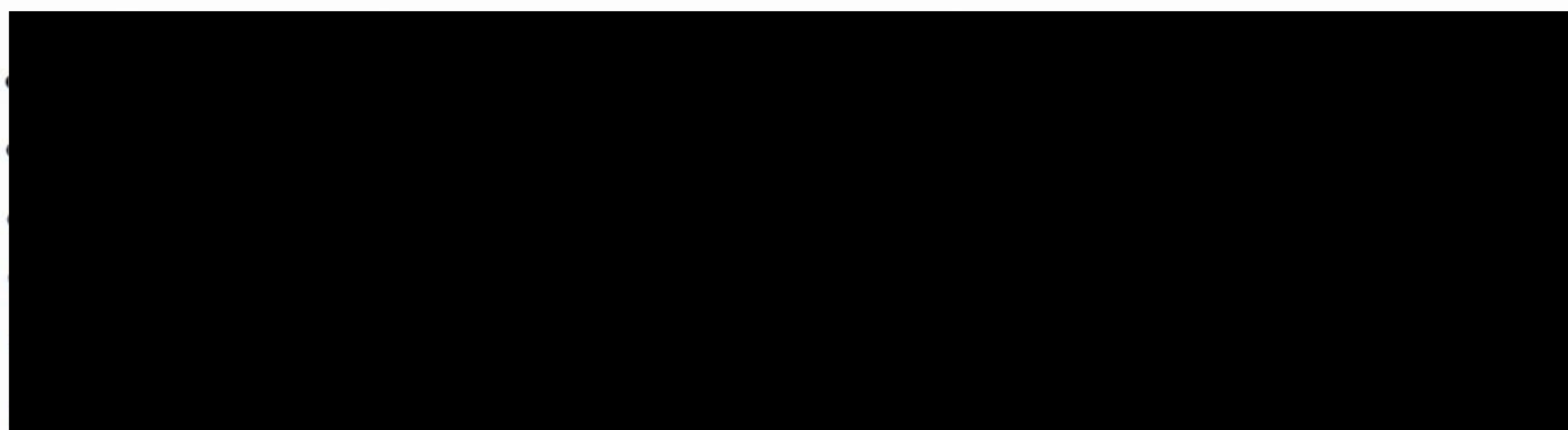
Ochranná pomôcka

# RESPIRÁTOR FFP2 NR

## 1. Popis, použitie



## 2. Technické údaje





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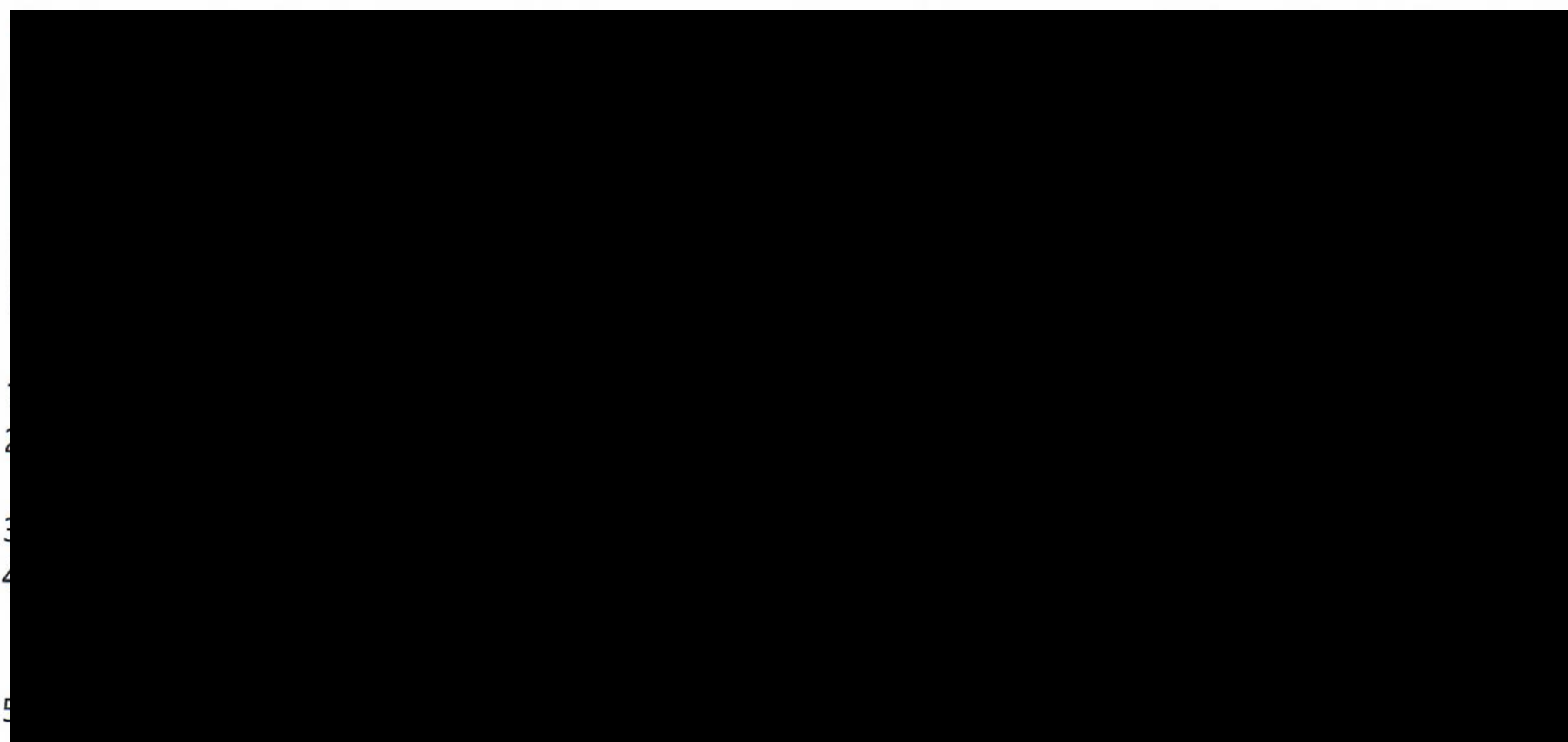
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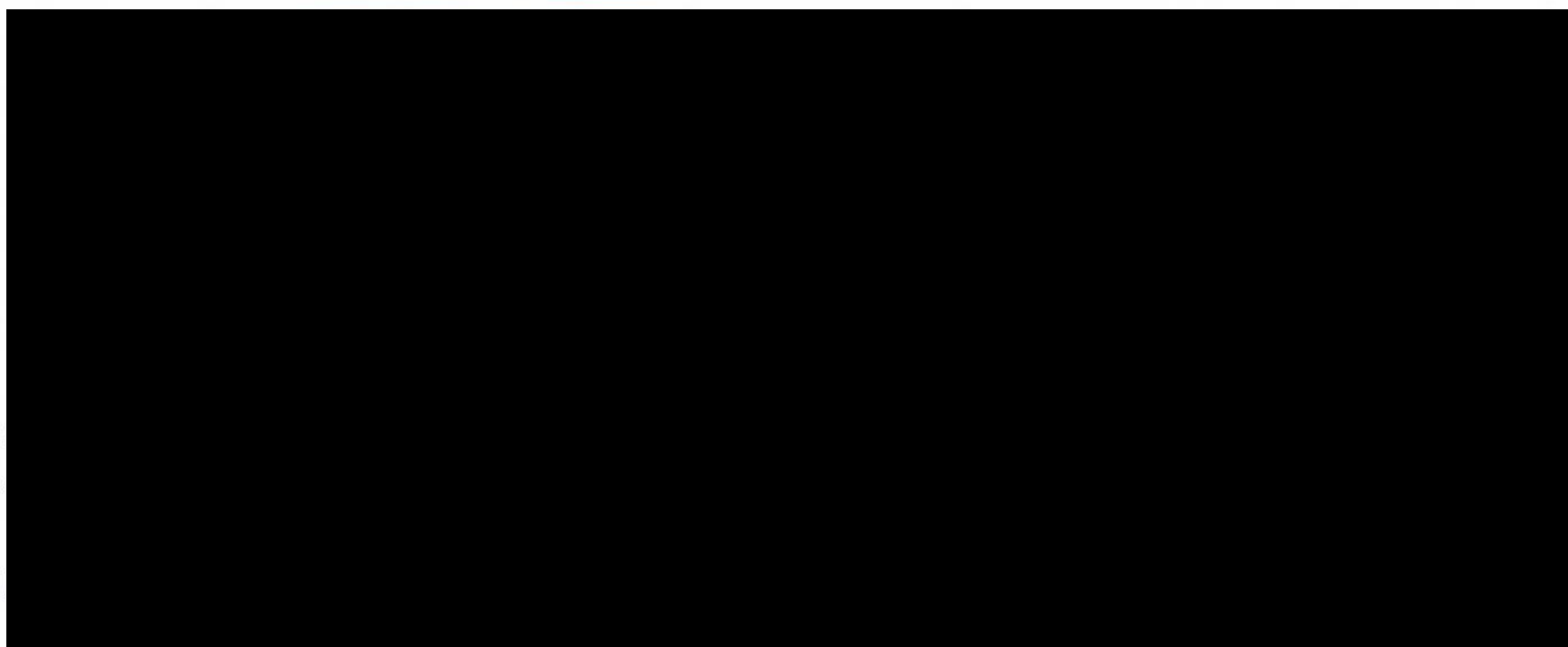
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### 3. Návod na použitie



### 4. Údržba a skladovanie





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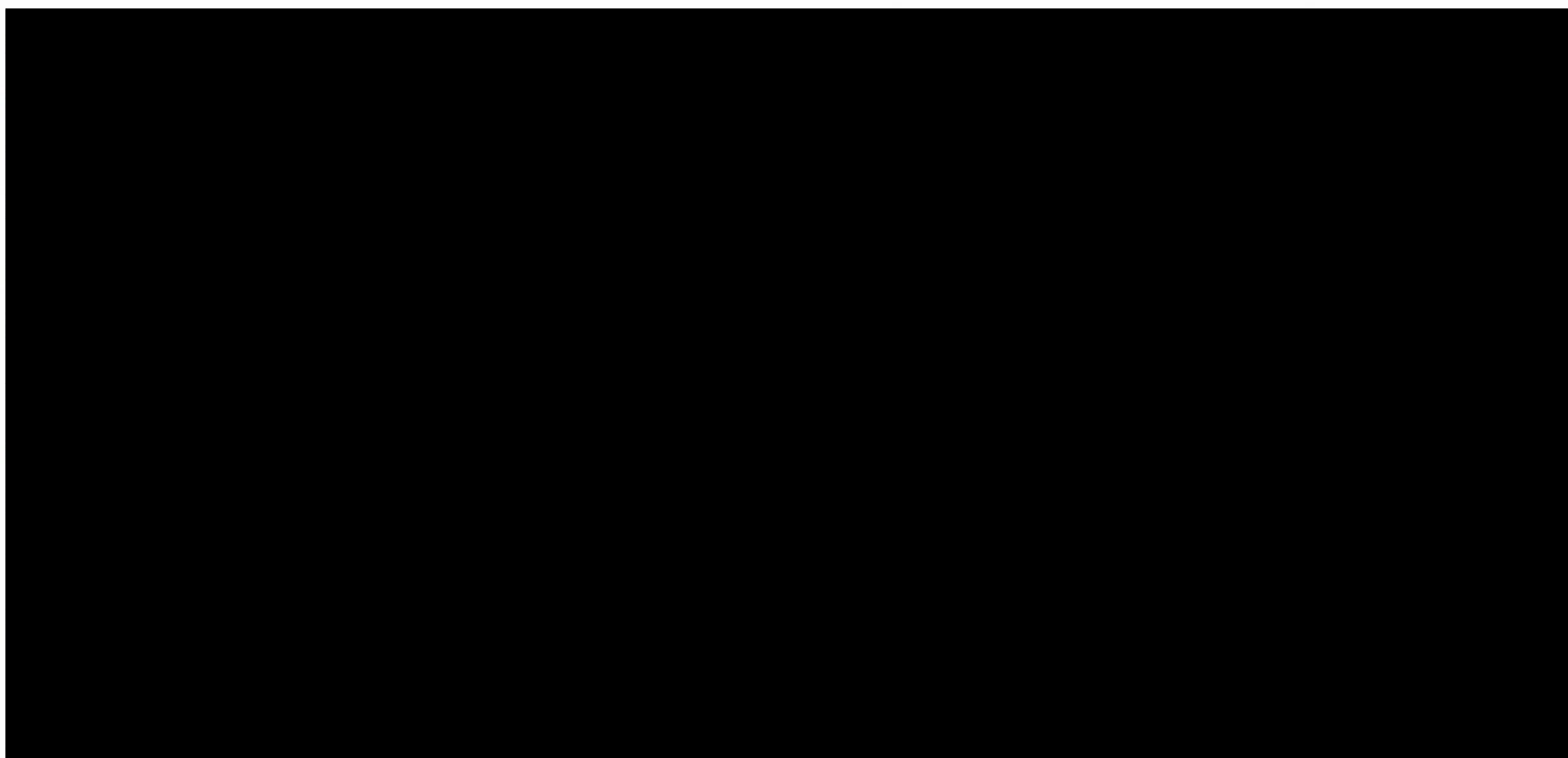
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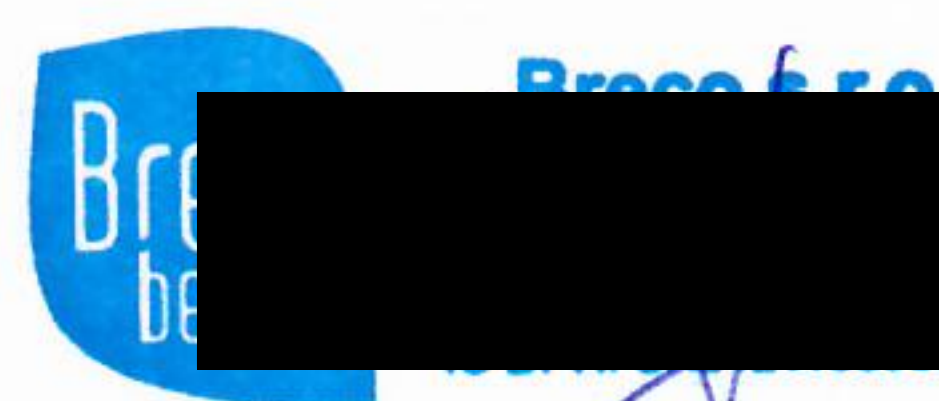
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## 6. Ostatné informácie



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V Nitre, dňa 1.1.2021



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