

## EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-706

Respiratory protective devices, filtering half masks to protect against particles manufactured by  
**Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd.**  
Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding City, Hebei  
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**

**Brand Name:** YINHONG **Model:** YH/KN95-1  
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 **04/06/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KACMAZ  
UNIVERSAL CERTIFICATION  
Director



## CERTIFICATE OF CONFORMANCE

**Certificate No: 2163-PPE-706/01**

Respiratory protective devices, filtering half masks to protect against particles manufactured by  
**Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd.**

Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding City, Hebei  
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

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
YINHONG / YH/KN95-1	FFP2 NR	2163-PPE-706	04.06.2020	2163

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.

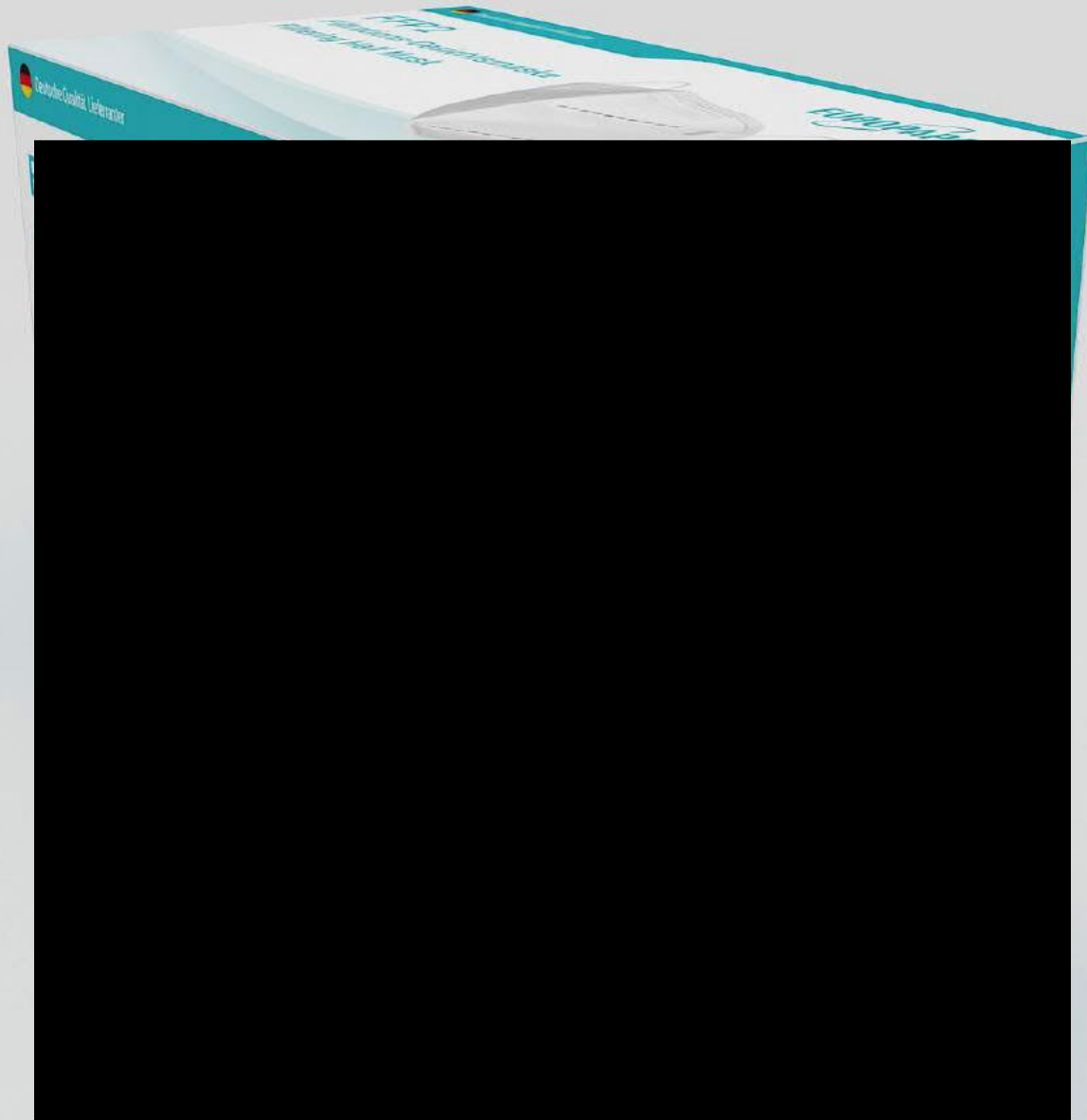
This certificate is issued on **21/06/2020** and will be valid for one year, until **20/06/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirements.

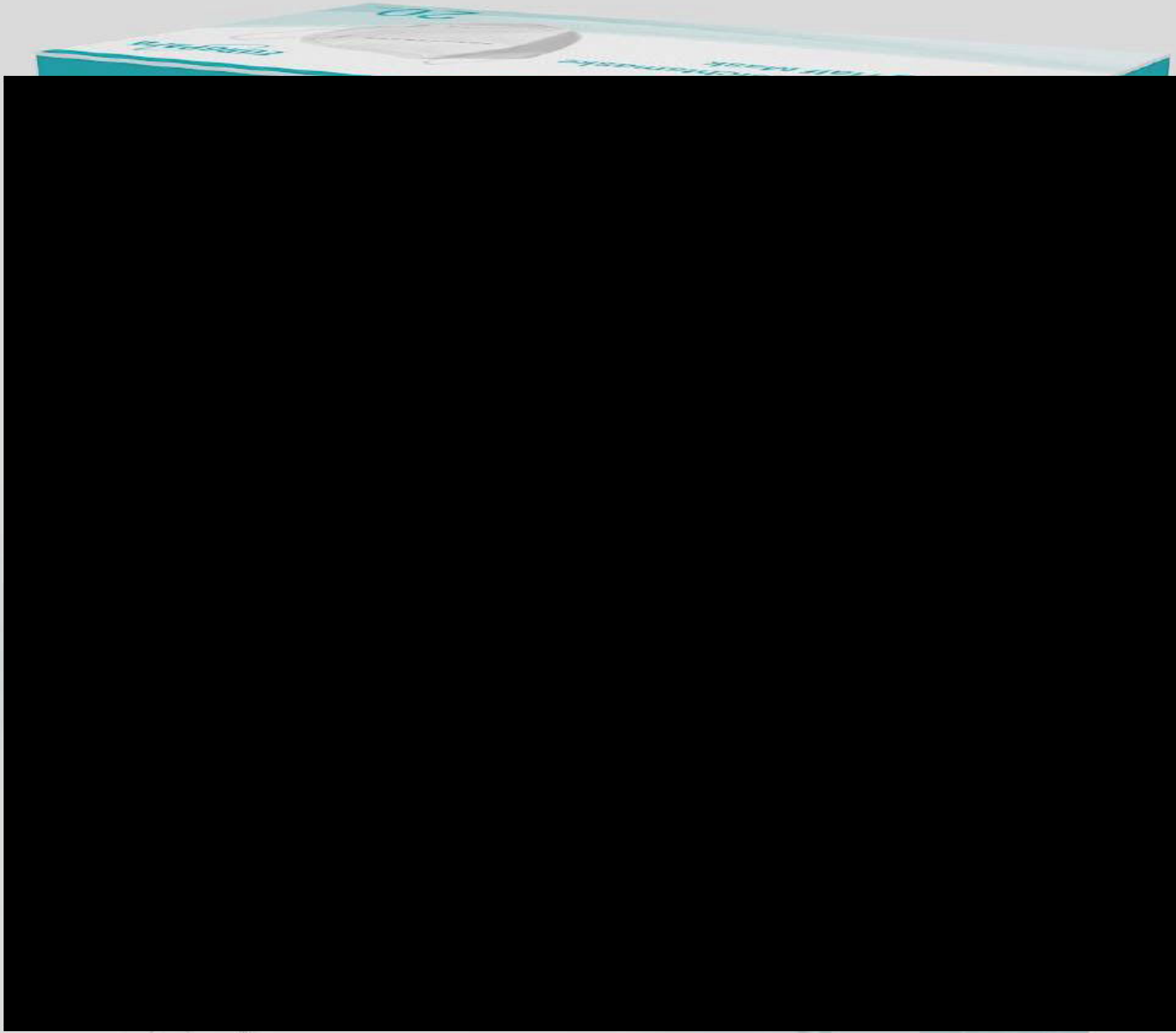




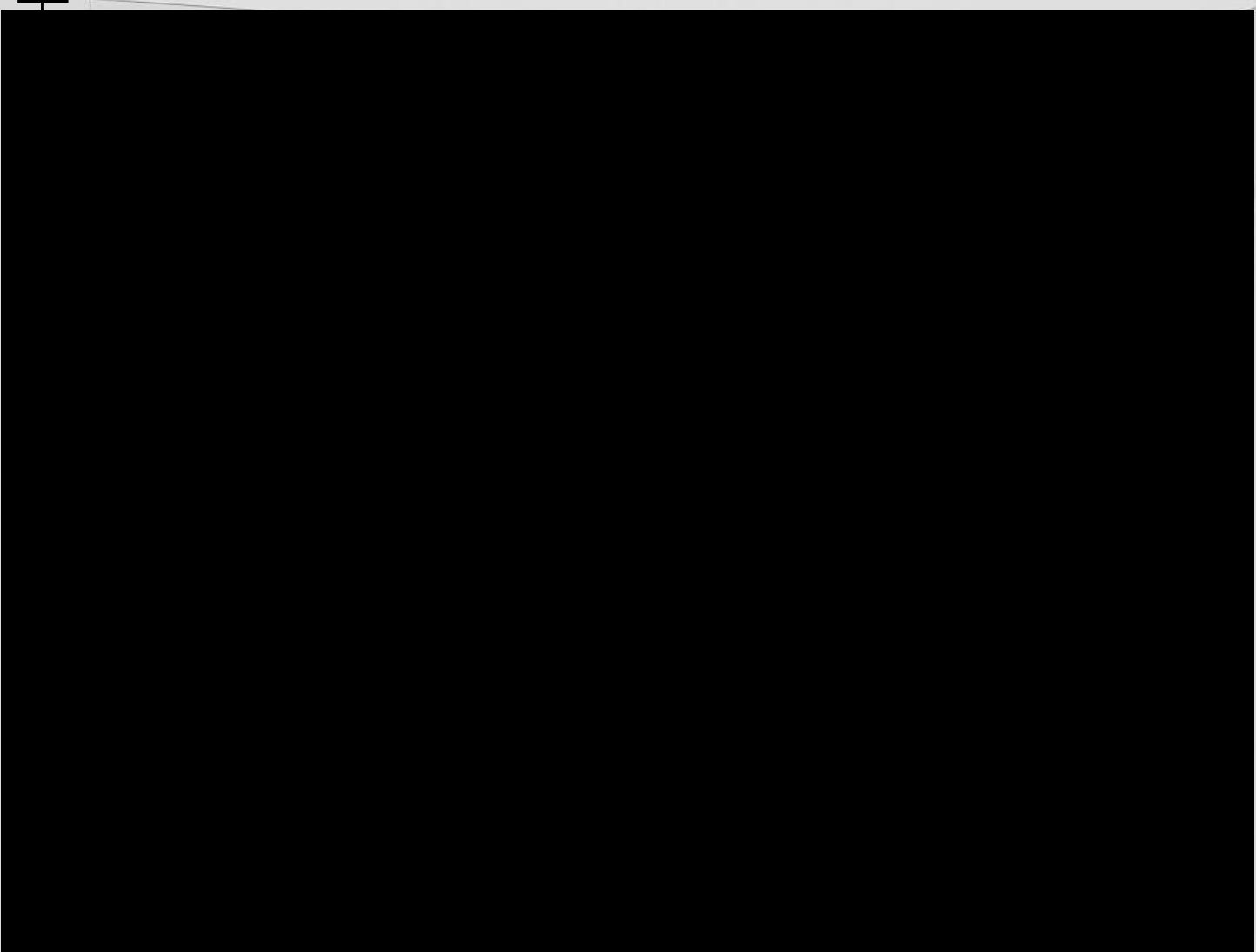
Suat KACMAZ  
UNIVERSAL CERTIFICATION  
Director











Bruttogewicht: 9.6kg  
Gross Weight: 9.6kg

1000 PCS/CTN

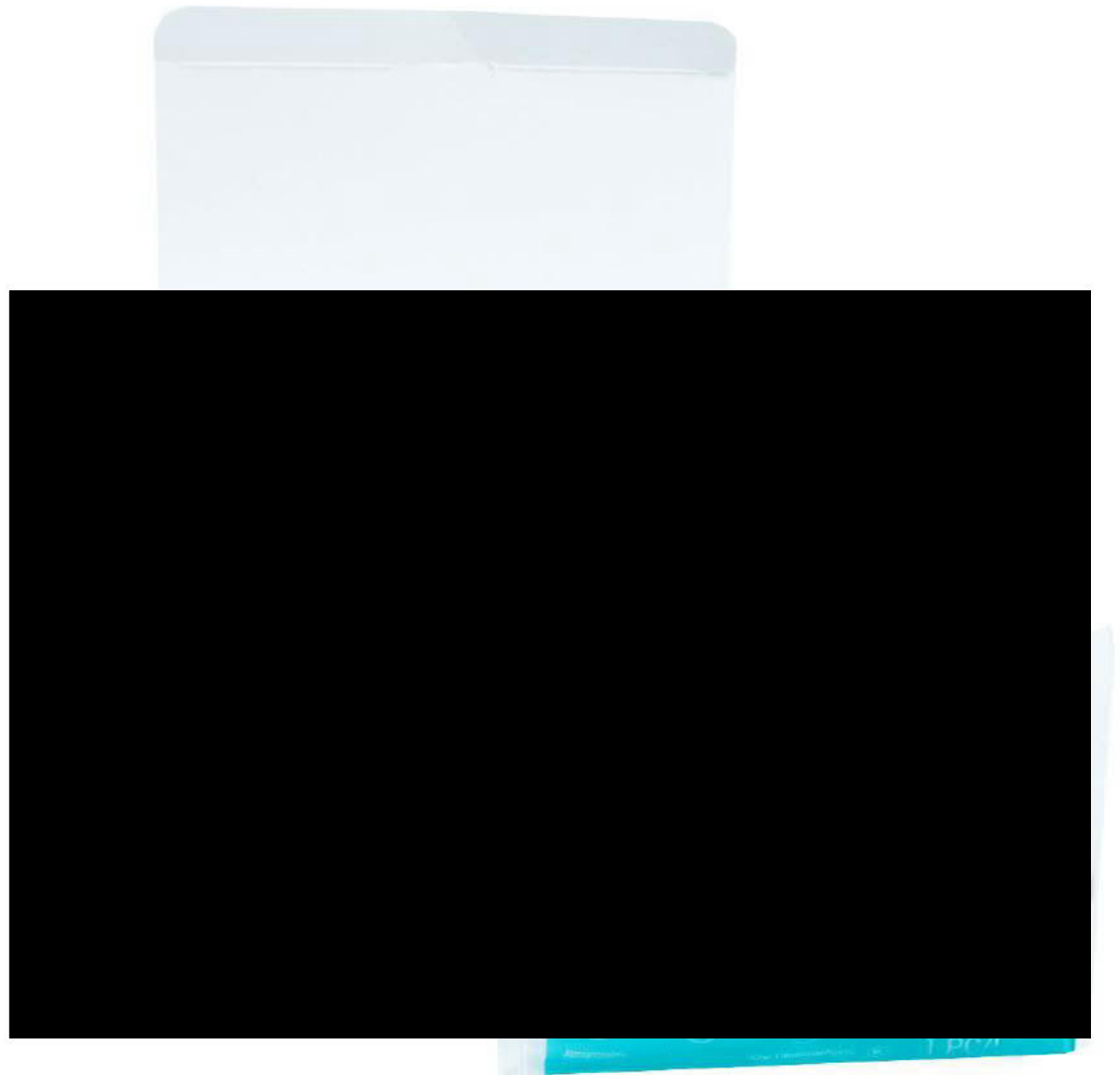
1000 PCS/CTN

1000 PCS/CTN

# Pictures of Real products

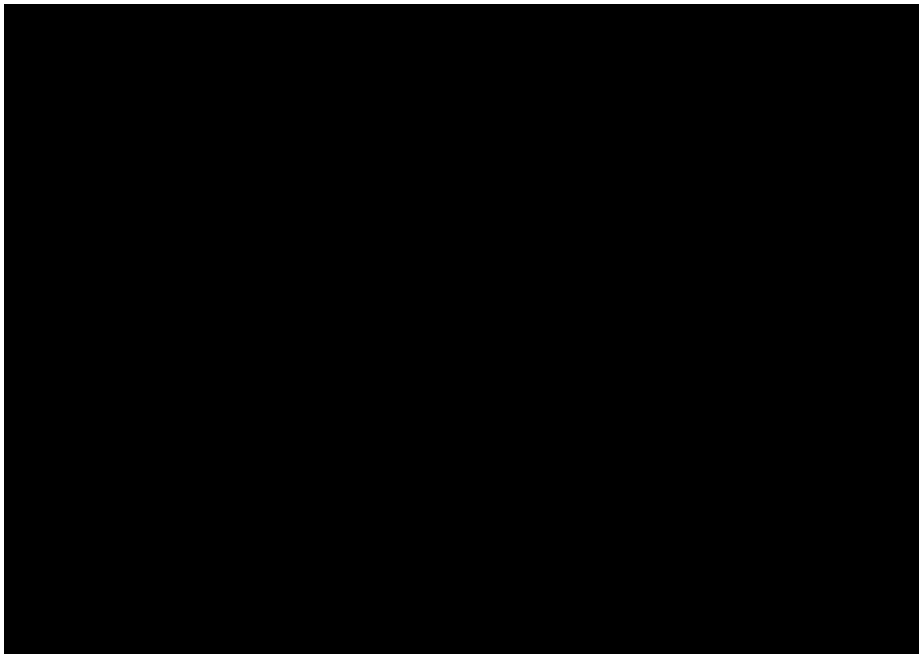


# Single piece package





# Návod na použitie





## Príloha č. 2 - Návrh na plnenie kritérií

### Identifikačné údaje:

**Názov zákazky:** „Výzva č. 1 - Respirátor FFP2 bez výdychového ventilu“

**Uchádzač:** IGLOBAL GROUP SLOVAKIA s.r.o.

**Adresa sídla:** Hviezdoslavovo Nám. 14, 811 01 Bratislava

**IČO:** 52 015 025

**Číslo účtu (IBAN):** [REDACTED]

**Telefónne číslo:** + [REDACTED]

**E-mailová adresa:** iglobal@iglobal.sk

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

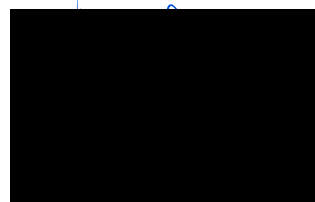
Názov	Celková cena v eur s DPH
Respirátor FFP2 bez výdychového ventilu v celkovom množstve 60 000 ks	16.200,00 EUR

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/zaujemcauchadzac/eticky-kodex-zaujemcu-uchadzaca-54b.html>

V BRATISLAVA dňa .13. 04.2021



pečiatka a podpis osoby oprávnenej  
konat' za uchádzača

Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the  
(EU) 2016/425 Directive

