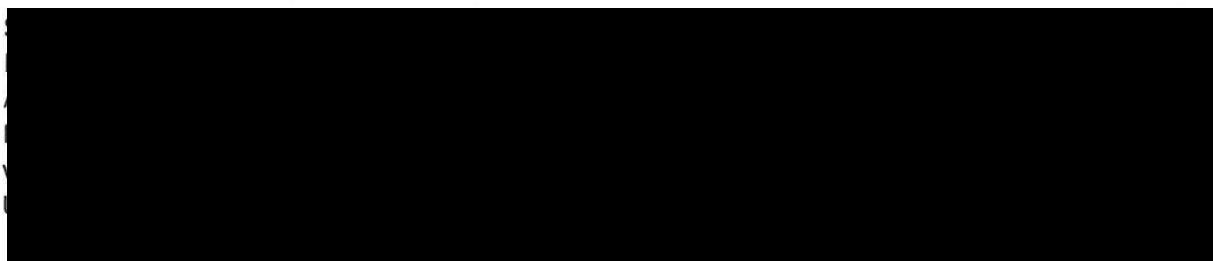
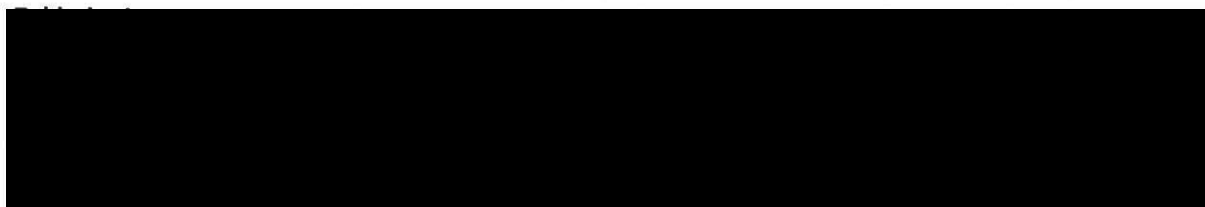


## Návod na používanie – jednorazové ochranné rúško



Perfect Distribution a.s. – organizačná zložka

Kočovce 244, 916 31 Kočovce, Tel: +4 [redacted], E-mail: [info.sk@pfd.agelsk.sk](mailto:info.sk@pfd.agelsk.sk),

Spoločnosť zapísaná v obchodnom registri Okresného súdu Trenčín, oddiel Po, vložka 10279/R,

IBAN: [redacted], IČO: 47719150, DIČ: 4020286765, IČ DPH: SK7120001372 [www.perfectdistribution.sk](http://www.perfectdistribution.sk)



## Príloha č. 2 - Návrh na plnenie kritérií

### Identifikačné údaje:

Názov zákazky: „Výzva č. 10 – Ochranné jednorazové rúška“

Uchádzač: Perfect Distribution a.s. – organizačná zložka

Adresa sídla: Kočovce 244, 916 31 Kočovce

IČO: 47719150

Číslo účtu (IBAN):

Telefónne číslo:

E-mailová adresa: @pfd.agelsk.sk

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

Názov položky:	Cena v eur bez DPH	Cena v eur s DPH
Ochranné jednorazové rúška trojvrstvé v celkovom množstve 20 000ks	396,00	475,20
Všetky ostatné služby (ako napr. dovoz, manipulácia, atď.)	0,00	0,00
Cena spolu:	396,00	475,20

Platca/~~nepláta~~ DPH (nehodiace sa preškrtnite)

**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 Kočovciach dňa 24.11.2021

Pe  
17.org  
Ciel  
Kocovc  
IČO: 47  
Tel: +42  
www.per

Ing. Róbert Vecel, vedúci organizačnej zložky



Item number 1000010123

Excellent

## Face mask with elastic ear loops, type IIR, Abena Excellent, 3 layers, blue, single use

- ✓ Type IIR according to EN 14683:2019
- ✓ With elastic ear loops
- ✓ Soft and comfortable
- ✓ Low respiratory resistance
- ✓ High bacterial filtration
- ✓ Minimizes cross-contamination
- ✓ Hygienic



### Product Description

Medical face mask with soft and strong elastic ear loops and nose clip to ensure proper fit. The mask has a low respiratory resistance and a high bacterial filtration efficiency. The medical face mask are intended to be used in medical settings, to protect the patient from infective agents and the wearer against splashes of potentially contaminated liquids. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.



### Specifications

Base name	Face mask with elastic ear loops, type IIR
Brand	Abena
Sub-brand	Excellent
Color	Blue
Features	Ultrasonic, non-sterile
Single or multiple use	Single use
Material	Metal, PE, PP, spandex
Length/depth	17.5 cm
Width	9.5 cm
Layer quantity	3 layers
Certifications	CE, MD
CE Class (Medical Devices)	Class I
Product or test standards	EN 14683:2019
Directives, regulations and acts	MDR (EU) 2017/745
Storage Instructions	Store dry, room temperature and no direct sunlight.
Product Disposal Instructions	To be disposed of with ordinary household waste. If contaminated, dispose of as clinical waste.
Packaging Disposal Instructions	Can be recycled or incinerated.

### Instructions for use/application

Fit the nose piece and position mask on face, making sure to cover nose and mouth. Place the ear loops around the ears. The mask is put on with the colored layer facing out and should always be completely unfolded.

### Packaging data

Unit	Contains	Length	Width	Height	EAN
cII	1000 pcs	0.52 m	0.39 m	0.18 m	5703538256684
pck	50 pcs	0.185 m	0.1 m	0.08 m	5703538256677



The CE mark guarantees that a product is safe to use and complies with all safety precautions. CE stands for Conformité Européenne (European Conformity) and is mainly found on electronic equipment, safety equipment, construction products and medical equipment.



The product has ultrasonic seals.



The surgical face mask is a type IIR (splash resistant) according to EN 14683.



The product is only for single-use.



The product does not contain latex.



## EC Declaration of Conformity

### 1. Products

No.	Products	UMDNS Code	Classification Rules	Classification	REF
1	Surgical Face Mask Ear Loop, Type IIR	12458	Rule 1	I	1000010123
2	Surgical Face Mask Tie-on, Type IIR	12458	Rule 1	I	1000010124

### 2. Manufacturer

Name: Winner Medical Co., Ltd.

Address: Winner Industrial Park, No.660 Bulong Road, Longhua District, 518109 Shenzhen, CHINA

### 3. EC- Representative

Name: Shanghai International Holding Corp, GmbH (Europe)

Address: Eiffestraße 80, 20537 Hamburg, Germany

### 4. Statement


We hereby declare that above mentioned products with CE marking meet the provisions of Medical Device Directive 93/42/EEC and related harmonized standards. We take full responsibility for all content in this declaration.


### 5. Applicable Standards

EN ISO 13485:2016, EN 1041:2008, ISO 2859-1:1999, EN 14683:2019, ISO 14644-1:2015, EN ISO 14971:2012, ISO 14698-1:2003, ISO 14698-2:2003, ISO 10993-1:2018, ISO 10993-10:2010, EN ISO 10993-5:2009, EN ISO 15223-1:2016, ISO 15223-2:2010, EU/EC MEDDEV 2.7/1

### 6. Conformity Assessment Procedures

EC declaration of conformity (Annex VII) of Council directive 93/42/EEC concerning medical devices for Class I (Non-sterile) medical devices.

Signature (Xu Jing)  Registration and quality system Manager

Date (2020-11-11)  (YYYY-MM-DD) 质量部