

Certificate [REDACTED]

The management system of

ZHEJIANG HONGYU MEDICAL COMMODITY CO., LTD.

No.668 Chanhua Road, Fotang Town Industrial Functional Area,
322002 Yiwu City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425 Module C2

For the following activities

Manufacture of HONGYU ([REDACTED]) single use
particle filtering half mask.

(Note: All products marked CE [REDACTED] must have a valid EU type-
examination certificate issued under Module B or a valid EC type-
examination certificate issued under Article 10 of Directive
89/686/EEC.)

This certificate is valid from 24 October 2020
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 24 October 2020

Authorised by

[REDACTED]
Finnish Accreditation Service
[REDACTED]

SGS FIMKO OY, Notified Body [REDACTED]
Takomotie 8, FI-00380 Helsinki, Finland
[REDACTED] www.sgs.com

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Certificate [Redacted]

ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD

No. 668 ChanHua Road Fotang Town Industrial Functional Area
322002 Yiwu City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

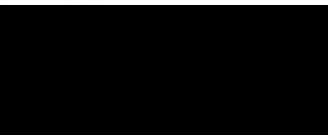
It is certified that the manufacturer's technical file and the PPE product detailed on
page 2 have been assessed and found to be in accordance with

Regulation (EU) 2016/425 Module B, EU type-examination

This certificate is valid from 29 September 2020 until 29 September 2025

1. Certified since 29 September 2020

Authorised by



Finnish Accreditation Service



SGS FIMKO OY, Notified Body

Tokomietie 8, FI-00280, Helsinki, Finland
www.sgs.com

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extent of the law.

ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD

Regulation (EU) 2016/425 Module B, EU type-examination

Issue 1

PPE Product

[redacted] single use particle filtering half mask.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149:2001 + A1:2009 (Respiratory protective devices – Filtering half masks to protect against particles) for a performance classification FFP2 NR.

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production

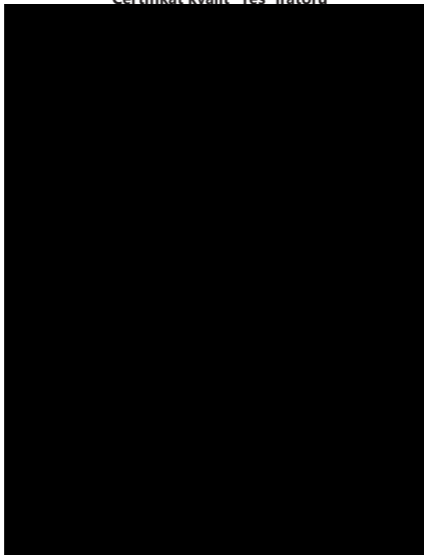
[redacted]
Finnish Accreditation Service
[redacted]

Certification is based on technical file reference [redacted],
dated 2020/08/07

SGS Reference Number UK [redacted]

This certificate remains the property of SGS Fimko Oy to whom it must be returned on request

Certifikát kvality inštrátora



EU DECLARATION OF CONFORMITY

Manufacturer

Name: ZHEJIANG HONGYU MEDICAL COMMODITY CO.,LTD
Address: No. 668 ChanHua Road Fotang Town Industrial Functional Area
322002 Yiwu City, Zhejiang Province PEOPLE'S REPUBLIC OF CHINA

Declares that the new PPE described hereafter



is in conformity with the provisions of regulation (EU) 2016/425 of the European parliament and of the council of 9 March 2016 on Personal protective equipment, and Conformity with the requirements of above regulation is testified by complete adherence to the following technical specifications:

EN 149: 2001+A1:2009

Is identical to the PPE which is the subject of EU type-examination for Regulation (EU) 2016/425 issued by SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland, Notified Body number: [REDACTED]

Is identical to the PPE which is subject to the procedure set out in module C2 of Regulation(EU)2016/425 Personal Protective Equipment under the supervision of the notified body SGS Fimko Oy, Takomotie 8,FI-00380 Helsinki, Finland, Notified Body number:0598

The product(s) of the declaration described above is in conformity with the requirement of following test reports:

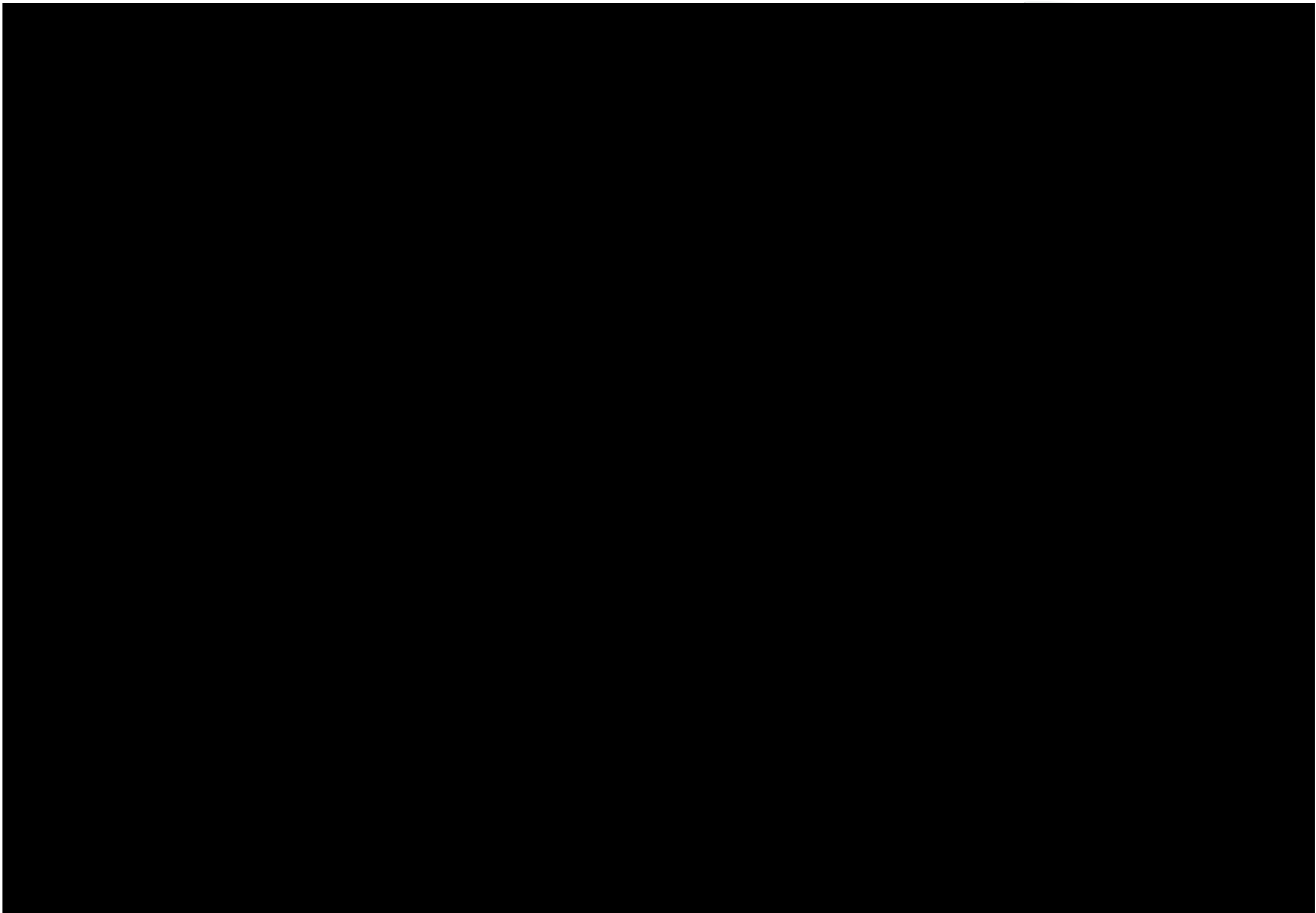
Report No. : [REDACTED]

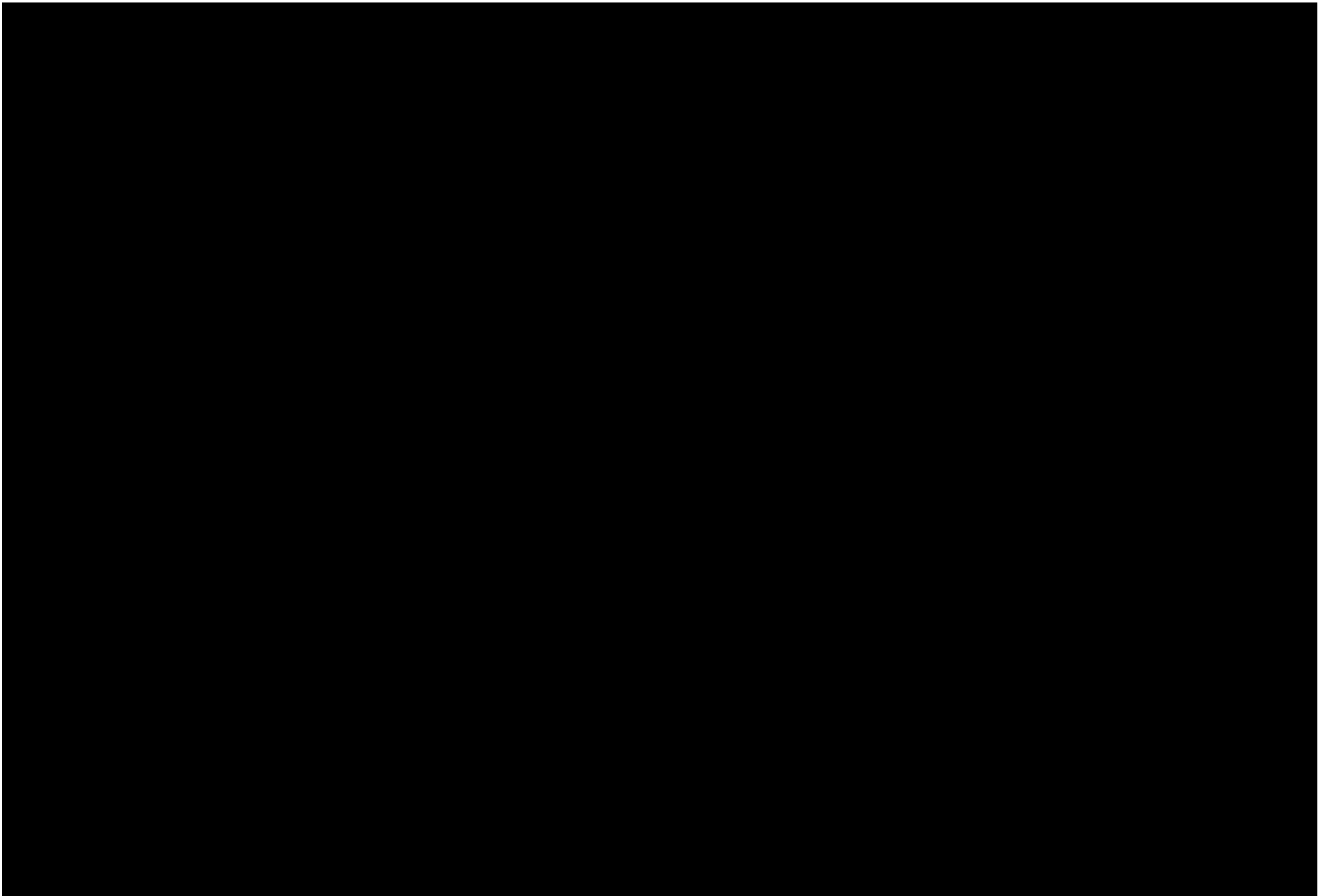
Place : Yiwu
DATE :August 07 2020

[REDACTED]

Name
On behalf of Company

A red circular stamp with Chinese characters and the number 3307260001 is partially visible behind the signature area.







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

Obchodné meno uchádzača:	MTC SLOVAKIA, a.s.
Sídlo uchádzača:	Kuzmányho 940/11, 031 01 Liptovský Mikuláš
IČO:	36013749
Meno a priezvisko štatutárneho zástupcu	Tatiana Svítková, člen predstavenstva
IČ DPH:	2020125734
Názov banky:	Tatra banka, a.s.
Číslo účtu (IBAN):	
Telefónne číslo:	
E-mailová adresa:	tatiana.svitkova@magic.sk

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	11 212,50

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 Liptovskom Mikuláši, dňa 02.03.2021

Ta





**STÁTNÍ ÚSTAV
PRO KONTROLU LÉČIV**

Šrobárova 48
100 41 Praha 10



E-mail: posta@sukl.cz
Web: www.sukl.cz

ADRESÁT

umbrellaline 2010 s.r.o.
Eduard Rojíček

ZASTOUPEN

Porta Medica s.r.o.

ADRESA

Havlíčková 1680/13
Nové Město
Praha
110 00

Číslo jednací

sukl18853/2021

Spisová značka

sukls125/2021

Vyřizuje / e-mail

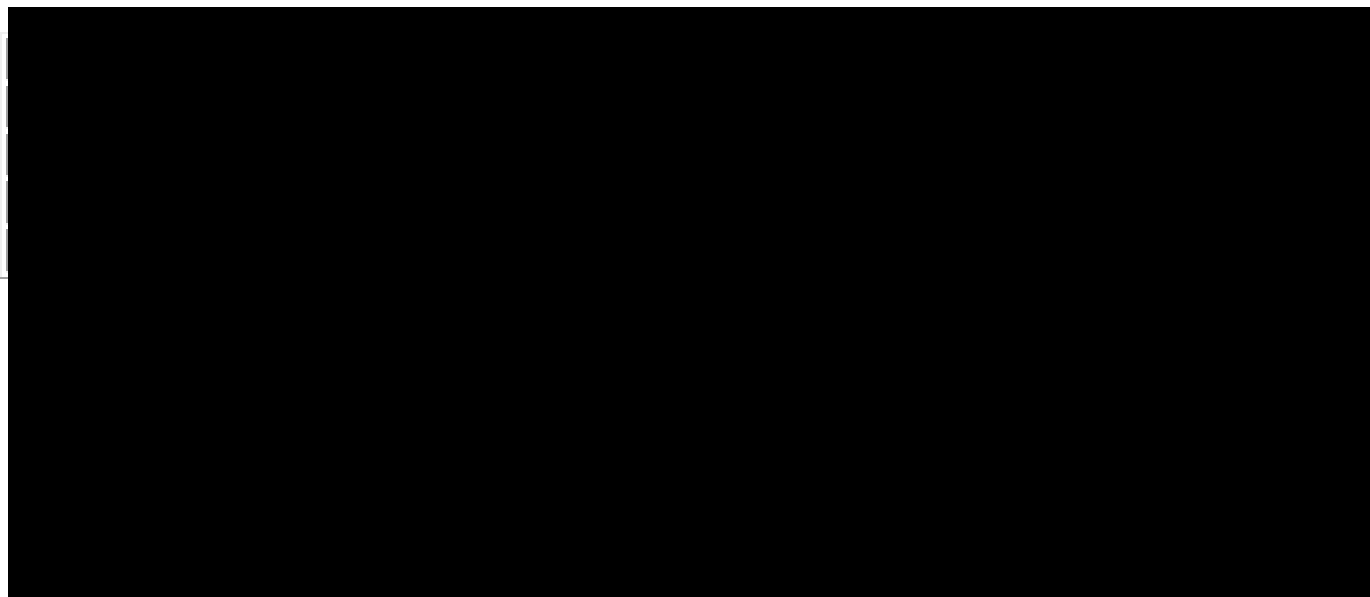
Ing. Monika Šlesingerová
monika.slesingerova@sukl.cz

Datum

21. 01. 2021

POTVRZENÍ SPLNĚNÍ OHLAŠOVACÍ POVINNOSTI

Státní ústav pro kontrolu léčiv, se sídlem v Praze 10, Šrobárova 48, jako správní orgán příslušný na základě § 9 písm. b) zákona č. 268/2014 Sb., o zdravotnických prostředcích a o změně zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, potvrzuje tímto splnění ohlašovací povinnosti níže uvedené osoby.



Platnost registrace osoby pro výše uvedené činnosti činí pět let ode dne vydání tohoto potvrzení.

Toto potvrzení nezahrnuje detailní přehled všech údajů, které byly předmětem dříve potvrzených ohlášení.

Ing. Petr Vykypěl
vedoucí Oddělení registrací a notifikací
Odbor zdravotnických prostředků
Státní ústav pro kontrolu léčiv