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EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1248/N1

Zhende Medical Co., Ltd.
Gaobu Town, 312035, Shaoxing City, Zhejiang Province, China

It is certified that the manufacturer's technical file (Dated 10.05.2023) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment

Brand Name	:	Zhejiang Zhende
Type / Model	:	ZD-001 (see annex)
Sizes	:	Single size, fit all
Class	:	FFP2 NR
Additional Properties	:	-
PPE Definition	:	Single use particle filtering half mask for protection against solid and liquid aerosols, is a folding type, 4 layered, without valve, with ear straps, internal adjustable nose bar, sponge bar under nose bar and adjusting buckles for ear straps.
PPE Category	:	III

Details are provided in annex 2163-PPE-1248/N1-1 of this certificate.

The following harmonised standards have been applied:

EN 149:2001+A1:2009, Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

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

- 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

This certificate is initially issued on **09/08/2020** and renewed on **24/04/2025**, will be valid for 5 years from the renewal date, if there is no change in the design of the product and relevant harmonised standards and legislation.

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

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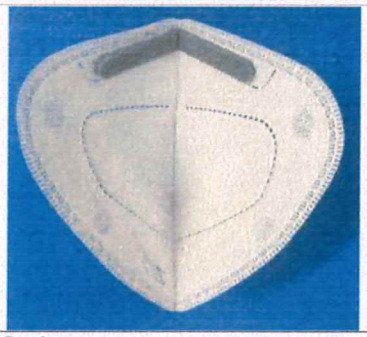
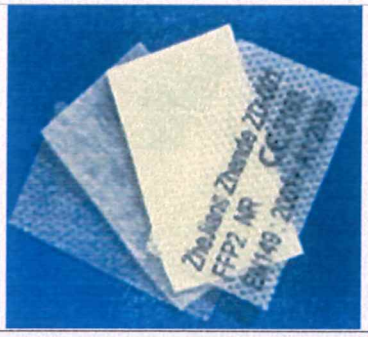
Bu belge standart ve yasal şartlarda herhangi bir yasal değişiklik olmaması durumunda ve her yıl yapılacak gözetim ve denetimlerine bağlı olarak gözetim ve denetimlerini takiben belge numarası değişmeksizin yayın tarihi güncellenerek yeniden düzenlenecektir. *This sertificate will be in the absence of any changes in standart and legal terms, and with the survellance audits to be concuted annually following the survellance audits, updating the publication date without changing the certificate number.*

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Annex 2163-PPE-1248/N1-1

PRODUCT PHOTOS


Component	Material	Grade
1st layer (Outer)	Spunbond Fabric	60 gsm
2nd layer	Meltblown Fabric	50 gsm
3rd layer	Air Cotton	45 gsm
4th layer (Inner)	Spunbond Fabric	35 gsm
Nose Clamp	PP + Galvanized Iron	Length: 90 mm, Width: 5mm
Sponge Bar	Sponge	Length: 9 cm , Width: 1cm
Ear Strap	Spandex	18 cm
Ear Strap Buckle	Silicone gel	6.8mm*9.3mm

EN 149:2001 + A1:2009 TEST VALUES

Test	Evaluation	Classification
Penetration of Filter Material	< %6 under 95 l/min flow rate for NaCl and Paraffin Oil aerosols	FFP2
Total Inward Leakage	All 50 exercise measurement results are smaller or equal to 11%, and all 10 individual's arithmetic mean is smaller or equal to 8%	FFP2
Breathing Resistance (Inhalation)	< 0,7 mbar under 30 l/min flow rate and < 2,4 mbar under 95 l/min flow rate	FFP2
Breathing Resistance (Exhalation)	< 3 mbar under 160 l/min flow rate	FFP2
Carbon dioxide content of the inhalation air	< %1	Succeeds
Flammability	No flame	Succeeds
Practical Performance	Conforms	Succeeds
Clogging	Not measured	-
Reusability	The manufacturer claims the mask as non-re-usable	NR

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