

Layers

3 layers

CERTIFICATE

Certificate Number

AI-MDD-0008/03/2020

Zhejiang Zhongdian Artificial Intelligence Technology Co., Ltd. Manufacture

5-2 Level, 9 Building, Yongxing Nanyuan Small And Micro Enterprise Address

Business Park, Binhai Two Road, Yongxing Street, Longwan District,

Width (±5%)

9.5

9.5

9.5

Length (±5%)

17.5

16.5

14.5

12.5

Wenzhou, Zhejiang.

Standard sizes

17.5×9.5cm

16.5×9.5cm

14.5×9.5cm 12.5×9cm

Disposable medical mask Product(s)

Related Directive 93/42/EEC Medical Device Directive

: Class I

Technical File Document

Product Classification

Number

Model(s)

TCF-ZJZD-001

2020.03.20 & Istanbul First Issue Date and Place

Revision Number and Date 00 / --

2024.05.26 Validity Date

This certificate has been issued according to the voluntary application of the manufacturer. NOTICE confirms that a technical file exists for the above mentioned product(s) and Declaration of Conformity prepared by the manufacturer is available. This certificate is valid only for the product(s) described in above mentioned tehcnical file. It is manufacturer's sole responsibility to fullfill all necessary conformity assessment activities according to 93/42/EEC Medical Devices Directive and related standards for the mentioned product(s) before placing them on the market. It is the manufacture's responsibility to compile a full Technical File according to Annex VII of 93/42/EEC in order to comply with the requirements of 93/42/EEC and to appoint a European Representative before placing the products on the European Market. Additionally, the manufacturer is responsible to take necessary actions, such as internal production controls to fullfill the essential requirements of the related Directive(s), before affixing CE mark on the product(s).

Özgür Vicdam General Manager

NOTICE BELGELENDIRME **MUAYENE VE DENETIM HIZMETLERI A.S.**

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