

**CERTIFICATE****Certificate Number****AI-MDD-0004/03/2020****Manufacturer**

: Changzhou Xinchun Medical Device Technology Co., Ltd

**Address**

: 3rd Floor, Building 2 No. 9 Xihe West Road, Wugang village, Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, China

**Product(s)**

: Disposable medical mask

**Model(s)**

Standard sizes	Length ( $\pm 5\%$ )	Width ( $\pm 5\%$ )	Layers
17.5x9.5cm	17.5	9.5	3 layers
14.5x9.5cm	14.5	9.5	

**Product Classification**

: Class I

**Related Directive**

: 93/42/EEC Medical Device Directive

**Technical File Document Number**

: TCF-CZXC-001

**First Issue Date and Place**

: 2020.03.20 &amp; Istanbul

**Revision Number and Date**

: 00 / --

**Validity Date**

: 2024.05.26

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 technical file. It is manufacturer's sole responsibility to fulfill 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 manufacturer'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 fulfill the essential requirements of the related Directive(s), before affixing CE mark on the product(s).

**Özgür Vicdan**  
General Manager



**NOTİCE BELGELENDİRME  
MUAYENE VE DENETİM  
HİZMETLERİ A.Ş.**

AI-MDD-0004/03/2020

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