

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 (±5%)	Width (±5%)	Layers
	17.5×9.5cm	17.5	9.5	3 layers
	14.5×9.5cm	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 & İstanbul

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.**

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