

Specificații tehnice (F4.1)

[Acest tabel va fi completat de către ofertant în coloanele 3, 4, 5, 7, iar de către autoritatea contractantă – în coloanele 1, 2, 6, 8]

Numărul procedurii de achiziție **IDENTIFICATOR - ocds-b3wdp1-MD-1603697424958**

Denumirea procedurii de achiziție: Achiziții cu costuri mici -Achiziționarea **echipamente medicale (mănuși și măști de unică folosință)**

Autoritatea contractanta **Direcția generală asistență socială și sănătate a Consiliului municipal Chișinău**

Cod CP V		Denumirea bunurilor/serviciilor	Modelul articolului	Țara de origine	Produ-cătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standard e de referință
33100000-1	58	Mască de protecție	Disposabl e Medical Mask	China	Changhou Xinchun Medical	Măști de unică folosință: chirurgicale în 3 straturi 3 pliuri cu fixaj elastic și arc metalo-plastic	Măști de unică folosință: chirurgicale în 3 straturi 3 pliuri cu fixaj elastic și arc metalo-plastic	CE

Semnat: Numele, Prenumele: **Balanescu Olga** În calitate de: **Administrator**

Ofertantul: **SRL Railsmed** Adresa: MD 2052, str. Maria Dragan 19A, Chisinau, Republica Moldova



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Products



Disposable medical mask

Details

【Product Name】	Disposable medical mask
【Product specifications】	17.5cm*9.5cm
【Quantity】	50 per box
【Product performance】	It is composed by melt blown cloth, non-woven cloth, nose clip and mask belt, non-sterile.
【Scope of application】	It is suitable for wearing in general medical environment, blocking the exhalation of oral cavity and nasal cavity or ejecting pollutants.



TEL: 4008650899 Fax: 0519-86050799-808 Mobile: 15061933321 13706110622 13861257289

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Address: Jiangsu province Changzhou City Zheng Lu Zhen Wu Gang Industrial Park Disclaimer | Admin



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 & 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

Esentepe Mahallesi Milangaz Caddesi
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