

Layers

3 layers

## CERTIFICATE

**Certificate Number** 

Model(s)

**Product Classification** 

AI-MDD-0012/03/2020

Manufacturer : Zhejiang Haipai Pharmaceutical Co., Ltd.

Address Floor 1 And Floor 2, Building 2, Xixiang Jinyuan, Nanbaixiang Street,

Standard sizes

17.5×9.5cm

Ouhai District, Wenzhou City, Zhejiang Province, China

Length (±5%)

17.5

Width (±5%)

Product(s) : Disposable medical mask

Related Directive : 93/42/EEC Medical Device Directive

: Class I

Technical File Document
Number: TCF-ZJHP-001

First Issue Date and Place : 2020.03.24 & 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 tehenical 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 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 fullfill the essential requirements of the related Directive(s), before affixing CE mark on the product(s).

Özgür Viodan General Manager

NOTICE BELGELENDIRME MUAYENE VE DENETIM HIZMETLERI A.Ş. AI-MDD-0012/03/2020

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