



Jiangsu Zhiyu Medical Instrument Co., Ltd.

Medical Face Masks

Documentation no. ZY/CF05-11.1

Declaration of Conformity MDR

Date 2020-03-12 Rev. A/0

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Jiangsu Zhiyu Medical Instrument Co., Ltd.**
No. 88 NanYuan Road, Industrial Park, West TaiXing City
254000 JiangSu Province, China

Name and address of the European
Authorized Representative **Llins Service & Consulting GmbH**
Obere Seegasse 34/2, 68124 Heidelberg, Germany

We declare under our sole responsibility that

the medical device: **Medical Face Masks**

Product code **Flat ear loop**

Basic UDI-DI

Intended purpose

This product meets European Standard EN 14683, Type I.
As a medical face mask, it is intended to provide a barrier to minimize the direct transmission of infective agents between staff and patient. It is designed to be fluid resistant to splash and spatter of blood and other infectious materials.
Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

of class: **I**

according to Annex VIII of Regulation (EU) 2017/745

meets the provisions of the Regulation (EU) 2017/745 which apply to it. The declaration of conformity is valid in connection with the batch-related "final inspection report" of the device.

Conformity assessment procedure: **EU Declaration of Conformity referred to in MDR Article 19**

Certificate: **NA**

Notified Body: **NA**

Taixing 2020.3.18
Place, date (地址/日期)

Icay Wang Sales Manager
Name and function (姓名/职务)