



EU Declaration Of Conformity

Manufacturer **Zhejiang Haipai Pharmaceutical Co., Ltd**

Address **Floor 1 and floor 2, building 2, Xixiang Jinyuan, nanbaixiang street, Ouhai District, Wenzhou City, Zhejiang Province, China**

EC Representative **Luxus Lebenswelt GmbH**
Kochstr. 1, 47877, Willich, Germany
0049-1715605732

Product: **Disposable Medical Mask**

Model: **17.5cm*9.5cm**

Classification (MDD, Annex IX): **Class I Rule 1**

We herewith declare that the above mentioned products meet the transposition into national law, The provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the DOC.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standards:

EN 14683:2019+AC:2019 Type II;

EN ISO 10993-5:2009;

EN ISO 10993-10:2010;

All applicable harmonized Standards (published in the Official Journal of the European Communities)

Date CE mark was affixed: **April. 16, 2020**

Place, Date: **Wenzhou, 16.04.2020**

Signature: _____

Zhang Xiang

Name/Position: **Xiang Zhang / G.M**

浙江海派医药有限公司
ZHEJIANG HAIPAI PHARMACEUTICAL CO., LTD.