



HORIGEN

GUANGDONG HORIGEN MOTHER& BABY PRODUCTS CO., LTD.

ADD: NO.18, Pingnan Industrial Zone, Mianbei Street, Chaoyang District Shantou Guangdong China

TEL: 86-754-83613668 FAX: 86-754-83843338 WEBSITE:www.horigen.cn

Declaration of Conformity

Manufacturer : GUANGDONG HORIGEN MOTHER& BABY PRODUCTS CO., LTD.

Address: NO.18, Pingnan Industrial Zone, Mianbei Street, Chaoyang District Shantou Guangdong China

EU Authorised Representative :

Shanghai International Holding Corp.GmbH (Europe)

Address : Eiffestrasse 80,20537 Hamburg Germany

E-mail : antonsissi@hotmail.com

Device : Single-use Medical Face Masks

Model : KZ-170A

LOT NO.: HNR20200618 HNR20200619 Adult 50pcs/box

Classification (MDR, Annex VIII) : Class I

Conformity assessment route : ANNEX II+ANNEX III

We herewith declare that the above mentioned product meet the provisions of the following regulation (EU) MDR 2017/745. All supporting documentations are retained under the premises of the manufacturer .



General applicable regulation :

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices .

Standard Applied :

EN ISO 13485:2016	EN ISO 14971:2012	EN 14683:2019	BS EN ISO 15223-1:2016
EN ISO 10993-1:2009/AC:2010	EN ISO 10993-5:2009	ISO 10993-10:2010	EN 1041:2008

Signature : *Linda*

Date : 2020-9-28

