



European Commission

Certificate of Conformity

Manufacturer: Guangdong Horigen Mother & Baby Products Co., Ltd.

Address: No.18, Pingnan Industrial Zone, Mianbei Street, Chaoyang District, 515100 Shantou, Guangdong, PEOPLE'S REPUBLIC OF 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 Mask

Model: KZ-170A

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:

Deputy General Manager



Date of Issue:

21th March 2020