

Declaration of Conformity

Manufacturer: Shantou T&K Medical equipment factory Co.,Ltd

Address: No.8 Workshop, Wanji South Second Street, North Taishan Road, Longhu District, Shantou City, Guangdong Province, P.R.China

EU Authorised Representative:

Company: Osmunda Medical Technology Service GmbH

Address: Von Oppen-Weg 15, 14476 Potsdam, Germany

DIMDI code: DE/0000047267

Product name: Disposable medical face mask

Model: TNK-KZ

UMDN code: 12-447

Classification: Class I

Rule: According to Rule 1, Annex VIII, Chapter III of (EU) MDR 2017/745

Conformity assessment route: ANNEX II + ANNEX III + Article 19 of (EU) MDR 2017/745

We hereby declare that the above mentioned product meets the provision of the Medical Device Regulation (EU) MDR 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.



Standard Applied:

EN ISO 13485:2016	EN ISO 14971:2012	EN 14683:2019+AC: 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

Place, Date of Issue:

Shantou, 22th April 2020

Represented by Legal Representative:

Name: Hanjie Zheng

Function: Legal representative

Signature:



*The signature is signed on behalf of
Shantou T&K Medical equipment factory Co.,Ltd*