# EC Declaration of Conformity

According to the **Medical Devices Directive 93/42/EEC** Annex IX, Rule 1

*on **Class I** Medical Device*

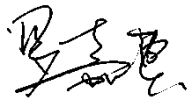
Doc. No. ZE-T01-DYZZS-200609, V1.0

On the basis of the referenced test report(s), sample(s) tested of the below product have been found to comply with the standards harmonized with the directives listed on this verification at the time the tests were carried out. Other standards and Directives may be relevant to the product. This verification is part of the full test report(s) and should be read in conjunction with it <them>.

| | |
|---|---|
| **Applicant Name:** | GUANGDONG ZHIER MEDICAL INSTRUMENTS CO., LTD. |
| **Address:** | No. 1-5 Chongyong Road, Zhongchong Village Committee, Leliu town, Shunde District, Foshan City, Guangdong, China |
| **Product Description:** | Medical face mask Non-sterile |
| **Models/Type References:** | ZE-01 |
| **Brand Name(s):** | / |
| **Standard(s)/Directive(s):** | EN ISO 14971: 2012<br>EN ISO 13485: 2016<br>EN 1041: 2008<br>EN ISO 15223-1: 2016<br>EN ISO 10993-1: 2018<br>EN 62366: 2008<br>BS EN 14683: 2019 +AC: 2019 |
| **Conformity assessment procedure:** | EC Declaration of Conformity (Annex VII) + Technical Files |
| **EC representative:** | Share Info Consultant Service LLC Repräsentanzbüro |
| **Address:** | Heerdter Lohweg 83, 40549 Düsseldorf |

This DoC is valid from 09 June, 2020.

Authorized by:



**Signature**
**General Manager**
**Place: Foshan, China**
**Date: June. 09, 2020**

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