



# Declaration of Conformity

NO.:ZDYL/QSMDR-43

**1. Manufacturer:**

Name: Zhende Medical Co., Ltd  
Address: Gaobu Town, 312035, Shaoxing, Zhejiang, PEOPLE'S  
REPUBLIC OF CHINA  
SRN: to be applied

**2. European Representative:**

Name: Shanghai international Holding Corp.GmbH(Europe)  
Address: Eiffestraße 80, 20537 Hamburg, Germany.

**3. Product Name:** Medical Mask (Type I / Typell / TypellR)

REF	Specification	UDI-DI
KZDC120003	17cm*18cm-3P 30 pieces/box	6959385777202
Z451C120002	17cm*18cm-3P 30 pieces/box	6959385776953
Z451C120001	17cm*18cm-3P 50 pieces/box	6959385776922
KZDC120006	17cm*18cm-3P 50 pieces/box	6959385778360
KZDC120007	17cm*18cm-3P 50 pieces/box	6959385778506
KZDC120013	17cm*14cm-3P 50 pieces/box	6959385781537
KZDC120014	17cm*18cm-3P 50 pieces/box	6959385781490
KZDC120012	17cm*18cm-3P 50 pieces/box	6959385781278

**4. GMDN Code:** 35177

**5. Intended use:** Medical Mask is intended to cover the user's nose and mouth and provides a physical barrier to fluids and particulate materials.

**6. Classification:** class I

Based on MDR EU2017/745 Annex VIII Rule 1,  
All non-invasive devices are classified as Class I, unless one of the rules set out hereinafter applies

**7. Statement:**

We declare the compliance of the above medical device with the applicable requirements of Medical Device Regulation: REGULATION (EU) 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 Zhende Medical Co., Ltd.

**8. CS:** NA

**9. Standard Applied:**

EN ISO 15223-1: 2016    EN 1041:2008+A1:2013    EN ISO 13485:2016  
EN ISO 14971:2012    EN 14683:2019



Signature: *Chen Ming*

Date of Issue: 2020.06.03

Name: Chen Ming

Position: Regulatory Director

