

## Declaration of Conformity

### Regarding Medical Device Regulation(EU) 2017/745

**Manufacturer:**

Name: Hygeia Medical Co. Ltd.

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**European Representative:**

Name: Shanghai International Holding Corp.GmbH (Europe)

Address: Eiffestrasse 80,20537 Hamburg Germany

Tel: +49-40-2513175

**Product:** Disposable Oral Care Products

With Dentips, Suction swabs, Suction toothbrush

**Code:** ME460302,ME460302T,ME460302T/BULK,ME460302/BULK,ME460301T,ME460301T/BULK  
ME460301,ME460301/BULK,ME460201GT,ME460220GT,ME460220GT/BULK  
ME460201P,ME460220P,ME460200/BULK, ME46200GT-BULK, ME460200P-BULK

**Description :**

Disposable Oral Care Products are regular product for dental department and clinic oral care, included dentips, suction swabs, suction toothbrush. The products are made of medical grade Plastic and Foam which have very good liquid absorbency, soft touch, flexible, non splash and impurity, that is necessary guarantee for clean the teeth and mouth insides.

**Classification: I**

**Rule:** According to Rule 1

**UMDNS::** 15-013

We.Hygeia Medical as the manufacturer of following medical devices, takes sole responsibility and declares conformity with the applicable provisions of Medical Device Regulation(EU)2017/745 concerning medical devices and the following harmonized standards.

EN ISO 14971:2012

EN ISO15223-1:2012 EN 1041:2008+A1:2013 EN ISO 10993-1:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN ISO 13485:2003

**Signature:** Zhao Jingping

**Title:** General Manager



Date: 2021.8.1