



Declaration of Conformity



General applicable directives:

Medical Device Directive: MDD 93/42/EEC

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Authorized Representative:

Person: DEBON FRANCE

Address: Les Académies Aixoises,
75 rue Paul Sabatier ,13090 Aix-en-Provence, France

Manufacturer: ShangHai Everpure Medical Plastic Co., Ltd.

Address: No 2418, Tingfeng Rd., Jinshan, Xinnong, Shanghai, China

Product: Cardboard Mouthpieces

Classification: Class I

We hereby declare that **Cardboard Mouthpieces(Item No.847510 & 847682)** conform to the essential safety requirement of 93/42/EEC, and comply with the following standard. All supporting files are retained under the premises of manufacturer and notified body .

Standards:

EN980: 2008

EN1041: 2008

ISO14971: 2007

ISO10993-1: 2009

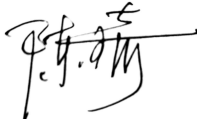
ISO10993-5: 2009

ISO10993-10: 2009

ISO13485/AC2007/AC2009: 2003

Name : Chen Qi

Position : General Manager

Signature : 

Stamp:

Date: 2020/8/04