

Shanghai Everpure Medical Plastics Co.,LTD. 201503

No.2418 Tingfeng Rd. Xinnong Town Jinshan County,Shanghai China



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: CMC Medical Devices & Drugs S.L

Address: C/Horacio Lengo N° 18 CP 29006, Málaga-Spain

Manufacturer: ShangHai Everpure Medical Plastic Co., Ltd.

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

Product: Cardboard Mouthpieces, Nose clips, Replacement pads, oval mouthpiece

Classification: Class I

We hereby declare that Cardboard Mouthpieces, Nose clips, Replacement pads, oval mouthpiece 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

Approvals

Department	Name/Title	Signature	Date
Sales	CEO		29-May.,2023

