



# Declaration of Conformity



according to the Medical Devices Directive 93/42/EEC

**Manufacturer:** Shanghai Yanshun Scope Parts & Accessories Co., Ltd

**Address:** No. 3-A Xinli Rd., Chonggu Qinqu Shanghai 201706 China

**We declare under our sole responsibility that**

**the Medical Device** Product Name : Insertion Tube, Universal Tube, Bending Rubber, Bending Mesh, Bending section, Biopsy Channel

Type/model, batch/serial number, possibly sources and number of items (Where applicable) : Inapplicability

**of class** according to annex IX of directive 93/42/EEC : Class I

**meets all the provisions of the directive 93/42/EEC which apply to it.**

Applied harmonised standards, national standards or other normative documents	ISO 13485:2003	EN 980:2003
	ISO 14971:2000	ISO 10993.1: 2003
	EN 1041:1998	ISO 10993.10: 2002

Conformity assessment procedure : MDD 93/42/EEC Annex V

Notified Body (if consulted) : TÜV Rheinland Product Safety GmbH CE0197

Shanghai

01.05.2020

(place and date)

**Xie Minzheng**

(name and signature, function)

**General Manager**

