



# 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 for Flexible Endoscope**

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

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

**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

12.01.2006.

  
**Xie Minzheng**



**General Manager**

(place and date)

(name and signature, function)