

## Declaration of Conformity

Manufacturer: **Zhuhai Vision Medical Technology Co., Ltd**  
**301 Building 4, No. 30 Feipeng Road, GMTCM Park, Hengqin**  
**New Area, Zhuhai City, Guangdong Province 519031 P.R. CHINA**

European **Shanghai International Holding Corp .GmbH (Europe)**

Representative: **Eiffestrasse 80, 20537 Hamburg ,Germany**

Product Name: **Video Endoscope**

Product Type: **Bronchoscope**

Product Model: **BF62, BF58, BF52, BF45, BF42, BF30**

UMDNS Code: **20-475**

Classification (MDD, Annex IX): **Class II a , rule 5 of Annex IX of the MDD 93/42/EEC**

Conformity Assessment Route: **MDD 93/42/EEC Annex II without chapter 4**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

### DIRECTIVES

#### General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

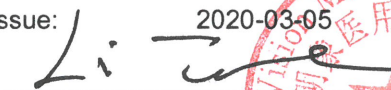
Identification number: CE0123

(EC) Certificate(s): G1 099394 0004 Rev. 00

Expire date of the Certificate: 2023-11-05

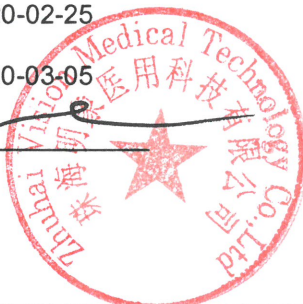
Start of CE Marking: 2020-02-25

Place, Date of Issue: 2020-03-05

Signature: 

Name: Li Tian Bao

Position: General Manager



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European **Shanghai International Holding Corp .GmbH (Europe)**

Representative: **Eiffestrasse 80, 20537 Hamburg ,Germany**

Product Name: **Video Endoscope**

Product Type: **Bronchoscope**

Product Model: **BF20**  
UMDNS Code: **20-475**

Classification (MDD, Annex IX): **Class I , rule 1 of Annex IX of the MDD 93/42/EEC**

Conformity Assessment Route: **MDD 93/42/EEC Annex VII**

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