

## DECLARATION OF CONFORMITY

Manufacturer: WENZHOU HONSUN MEDICAL INSTRUMENT Co., LTD

Address: Building 3 East, Hongdian Industrial Estate, 325000Wenzhou, Zhejiang, P.R.China.

European Representative: Shanghai International Holding Corp. GmbH (Europe)

Representative: Eiffestrasse 80, 20537 Hamburg, Germany.

Product Name: **Otoscope**

Classification(MDD, Annex IX): I , rule 5

Conformity Assessment Route: Annex VII

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.

### 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 of 5 September 2007.

(Electromagnetic Compatibility Directive) 89/336/EEC , 92/31/EEC, 93/68/EEC

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

**Certificate:** No. Q1N 10 12 74340 003

**Expiration date of the Certificate:** 2020-02-13

**Date CE mark was affixed:** start of CE marking lot : 20100003

**Identifier of Notified Body:** CE0123

**Place, Date of Issue:** Wenzhou, 2020-02-13

Signature:



Name: **zhengyu Cheung**

Position: General Manager