

EC Declaration of Conformity

Manufacturer: ZHEJIANG HONSUN MEDICAL INSTRUMENT CO., LTD.

Address: Sanjiang Street, Buliding 8 of Art & Crafts Park, Beiao Industrial Estate, 325100 Wenzhou, Zhejiang, P.R.China.

European Representative: Shanghai International Trading Corp. GmbH (Hamburg) Eiffestrasse 80, 20537 Hamburg, Germany.

Product Name: Otoscope

Model Code: **HS-OT10/** HS-OT10C/ HS-OT10D/HS-OT10S/HS-OT10J/HS-OT10B/
HS-OT10N/HS-OT10F/ HS-OT10G/ HS-OT10K/ HS-OT10E/ HS-OT10Y/ HS-OT10H
/HS-OT10L

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.

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.

Standard Applied:

EN980:2008 EN1041:2008 EN ISO 13485:2003/AC: 2007 EN ISO14971:2007

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

München, Germany

Place, Date of Issue: Wenzhou, 2025-08-21

Signature:



Name: **zhengyu Cheung** Position: General Manager