

EC Declaration of Conformity

Manufacturer: WENZHOU HONSUN MEDICAL INSTRUMENT CO., LTD.

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

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

Eiffestrasse 80, 20537 Hamburg, Germany.

Product Name: Otoscope

Model: HS-OT10J-BLACK = SPENGLER Otoscope Smartlight 570310

HS-OT10J-WHITE = SPENGLER Otoscope Smartlight 570311

Classification (MDD, Annex IX): I

Conformity Assessment Route: Annex V.3

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.

Medical device directive

COUNCIL DIRECTIVE 93/42/EEC.

Notified body

TÜV SÜD Product Service GmbH, Ridlerstr, 65,
80339

München, Germany

Identification

CE

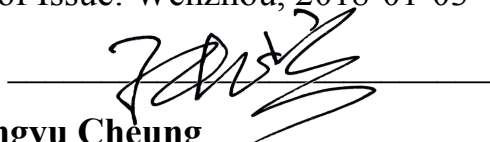
Certification

Q1N161074340007

Expiration date of the Certificate 2020-02-13

Place, Date of Issue: Wenzhou, 2018-01-03

Signature: _____

A handwritten signature in black ink, appearing to read "Zhengyu Cheung", is written over a horizontal line.

Name: **zhengyu Cheung**

Position: General Manager