

	鹿得医疗器械(南通)有限公司 HONSUN (NANTONG) CO., LTD.	NTLD - EC - 01
页码: 1 / 1	DECLARATION OF CONFORMITY	版本号: 2.0

Manufacturer HONSUN (NANTONG) Co.,Ltd
Address No.8 Tongxing Road Nantong Economic & Technological Development area, 226009, Jiangsu Province, P. R. China
EU representative Shanghai International Holding Corp. GmbH (Europe)
Address Eiffestrasse 80, 20537 Hamburg, Germany
Product name Otoscope
HONSUN Code HS-OT10D
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.

Standard Applied: ISO13485:2003 EN60601 -1:2012 EN60601-1-2:2007 EN980:2008 EN1041:2008 ISO14971:2007 ISO10942:2006

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

Place, Effective Date: Nantong, 2019-06-06

Signature _____
Name William Xiang
Position General Manager