# DECLARATION OF CONFORMITY
# TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
# CONCERNING MEDICAL DEVICES

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| MANUFACTURER: | HONSUN (NANTONG) CO., LTD.<br>NO.8, TONGXING ROAD ECONOMIC & TECHNOLOGICAL DEVELOPMENT AREA, 226009<br>NANTONG CITY,PEOPLE'S REPUBLIC OF CHINA |
| EUROPEAN REPRESENTATIVE: | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestrasse 80, 20537 Hamburg，Germany<br>TEL：0049-40-2513175 FAX：0049-40-255726 |
| PRODUCT: | STETHOSCOPE |
| MODEL: | HS-30A |
| CLASSIFICATION: | CLASS I |
| CONFORMITY ASSESSMENT ROUTE: | Annex V of MDD |

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:

EN ISO 13485:2016 MEDICAL DEVICES- QUALITY MANAGEMENT SYSTEMS-REQUIREMENT FOR REGULATORY PURPOSES

EN ISO14971:2012 MEDICAL DEVICES- APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES

EN 60601-1-2:2007 MEDICAL ELECTRICAL EQUIPMENT-PART 1: GENERAL REQUIREMENTS FOR SAFETY

IEC 60601-1:2005(THIRD EDITION) + CORP.1:2006+ CORP.2:2007+ A1:2012(OR IEC 60601-1:2012 REPRINT)

EN 60601-1-6:2010 MEDICAL ELECTRICAL EQUIPMENT-PART 1-6: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE- COLLATERAL STANDARD:USABILITY

PLACE, DATE OF ISSUE: NANTONG, JIANGSU, P. R. CHINA/JUN. 23, 2020

SIGNATURE: **YOULIANG XIANG(**GENERAL MANAGER)

江苏鹿得医疗电子股份有限公司
HONSUN (NANTONG) CO., LTD.

Digitally signed by Potînga Stela
Date: 2021.09.23 15:06:07 EEST
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