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

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|---|---|
| **MANUFACTURER:** | **Harbin Xiande Technology Development Co.,Ltd**<br>Room 927,No.434,postal street,Nangang District,<br>Harbin City,Heilongjiang Province. |
| **MEDICAL DEVICE:** | Medical infrared Thermometer,GP-300 |
| **CLASSIFICATION - ANNEX IX:** | Class Ⅱa, Rule 10 |
| **CONFORMITY ASSESSMENT ROUTE:** | Annex Ⅱ excluding chapter 4 |

WE, （Harbin Xiande Technology Development Co.,Ltd） HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

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| **NOTIFIED BODY:** | Ente Certificazione Macchine Srl |
| **IDENTIFICATION NUMBER:** | CE 0123 |
| **(EC) CERTIFICATE(S):** | 3J200331.HXTDC08 |
| **EC REP**<br>**EUROPEAN REPRESENTATIVE:** | Via Ca'Bella,243-Loc.Castello di Serravalle-40053<br>Valsamoggia(Bo)-ITALY |

**START OF CE-MARKING:** 2020-03-25 (Date or Lot or serial number)

**PLACE, DATE OF DECLARATION:**

**SIGNATURE:** President

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## Appendix: list of (harmonised - EN) standards

| No. | Serial Number | Title and Description |
|---|---|---|
| 1 | EN 60601-1: 1990+A1:1993+A2:1995 | Medical Devices Part1: General Requirements for Safety and Amendment 1, Amendment 2 |
| 2 | EN 60601-1-2: 2007 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests |
| 3 | EN 60601-1-4:1996+A1: 1999 | Medical Devices Part 1-4: General Requirements for Safety - Programmable Medical Electrical Equipment |
| 4 | EN 60601-1-6:2010 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability |
| 5 | EN 62304:2006 | Medical device software - Software life-cycle processes |
| 6 | EN 62366:2008 | Medical devices - Application of usability engineering to medical devices |
| 7 | EN 60601-2-25: 1995+A1:1999 | Particular requirements for the safety of electrocardiographs |