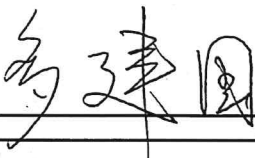


**DECLARATION OF CONFORMITY  
TO COUNCIL DIRECTIVE 93/42/EEC  
CONCERNING MEDICAL DEVICES**

	<b>MANUFACTURER:</b>	Harbin Xiande Technology Development Co.,Ltd Room 927, No.434, postal street, Nangang District, Harbin City, Heilongjiang Province.		
	<b>MEDICAL DEVICE:</b>	Medical infrared Thermometer, GP-300		
	<b>CLASSIFICATION - ANNEX IX:</b>	Class II a, Rule 10		
	<b>CONFORMITY ASSESSMENT ROUTE:</b>	Annex II excluding chapter 4		
<p>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.</p>				
STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.				
	<b>NOTIFIED BODY:</b>	Ente Certificazione Macchine Srl		
	<b>IDENTIFICATION NUMBER:</b>	<b>CE</b> 0123		
	<b>(EC) CERTIFICATE(S):</b>	<u>3J200331.HXTDC08</u>		
	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="padding: 2px;">EC</td><td style="padding: 2px;">REP</td></tr></table>	EC	REP	Via Ca'Bella, 243-Loc.Castello di Serravalle-40053 Valsamoggia(Bo)-ITALY
EC	REP			
	<b>EUROPEAN REPRESENTATIVE:</b>			

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

<b>PLACE, DATE OF DECLARATION:</b>	
<b>SIGNATURE:</b>	 President

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

**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