# TM DECLARATION OF CONFORMITY
# MEDICAL DEVICES DIRECTIVE 93/42/EEC

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| MANUFACTURER: | *Shenzhen Med-link Electronics Tech Co.,Ltd.*<br>*Build 2, HuaFu Ind. park, HuaWang Road,LongHua,*<br>*BaoAn ,ShenZhen, P.R.China* |
| EUROPEAN REPRESENTATIVE: | *C.K.Medical international*<br>*Laan van Cattenbroeck 10, 3703 BM Zeist The Netherlands* |
| PRODUCT: | *Name: Temperature Probes,*<br>*Model: SEE ATTACHED LIST* |
| CLASSIFICATION: | *II a, Rule 10* |
| *CONFORMITY ASSESSMENT ROUTE:* | *EC DIRECTIVE 93/42/EEC ANNEX II.3* |

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE MDD 93/42/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

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

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| NOTIFIED BODY: | TÜV SÜD PRODUCT SERVICE GMBH<br>RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY |
| *IDENTIFICATION NUMBER* | CE 0123 |
| (EC) CERTIFICATE(S): | *EC CERTIFICATE(S) NUMBER(S):* G1 08 07 67303 003 |
| START OF CE-MARKING: | *2006-Oct-06*<br>*2008- Oct-06 NB IS CHANGED* |
| PLACE, DATE OF ISSUE: | *SHENZHEN CITY, 2011-9-7* |
| SIGNATURE: | Manlin Te General Manger<br>*NAME*<br>*POSITION (RESPONSIBLE SENIOR EXECUTIVE)* |

# LIST OF (HARMONISED - EN) STANDARDS
## FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED

| No. | Standard Name | Reference No. |
|---|---|---|
| 1. | Medical device risk management to medical devices application | ISO14971：2007 |
| 2. | Term, symbol and information of medical device— information of medical device manufacturer offering | EN1041：2008 |
| 3. | Performance of electrical thermometers for continuous measurements | EN 12470-4:2000 |
| 4. | Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests | EN 60601-1-2-2001 |
| 5. | Medical electrical equipment –Part 1:General requirements for basic safetyand essential performance | EN 60601-1:1990+A1+A2+A13 |
| 6. | Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process | ISO10993-1：2003 |
| 7. | Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity | ISO 10993-10: 2002/Amd.1:2006 |
| 8. | Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity | ISO 10993-5-2009 |
| 9. | Graphical symbols for use in the labelling of medical devices | EN 980:2008 |
| 10. | Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current≤16 A per phase) | EN 61000-3-2:2006 |
| 11. | Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection | EN 61000-3-3:2008 |
| 12. | Directive 2011/65/EU of the European parliament and of the council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. | 2011/65/EU |

## *MODEL CODE LIST OF TEMPERATURE PROBES*

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|---|---|---|---|---|
| W0001A | W0013F | W0003D | W0006B | W0009B |
| W0001A | W0001I | W0003E | W0007A | W0010A |
| W0001B | W0002A | W0003F | W0007B | W0010B |
| W0001B | W0002B | W0004C | W0007C | W0011B |
| W0001C | W0002C | W0004D | W0007D | W0013A |
| W0001C | W0002D | W0004E | W0022B | W0013B |
| W0001D | W0003A | W0022A | W0008A | W0013C |
| W0001D | W0003B | W0004F | W0008B | W0013D |
| W0001E | W0021C | W0005A | W0008C | W0013E |
| W0001F | W0004A | W0005B | W0008D | |
| W0020E | W0004B | W0006A | W0009A | |