# DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE 2007/47/EEC) CONCERNING MEDICAL DEVICES

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| **MANUFACTURER:** | Shenzhen Creative Industry Co., Ltd.<br>Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA |
| **MEDICAL DEVICE:** | Spot-Check Monitor |
| **Model:** | PC-102, PC-203, PC-303 |
| **CLASSIFICATION - ANNEX IX:** | Class IIa, Rule 10 |
| **CONFORMITY ASSESSMENT ROUTE:** | Annex II excluding(4) |

WE, **Shenzhen Creative Industry 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 (AMENDED BY DIRECTIVE 2007/47/EEC) CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

**STANDARDS APPLIED:**

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| ISO 13485:2016 | EN/ISO 14971: 2012 | EN 60601-1: 2006+A1: 2013 |
| EN 60601-1-2: 2007+AC2010 | IEC60601-1-6:2010+A1：2013 | EN 80601-2-30: 2011 |
| ISO 80601-2-61: 2011 | EN/ISO 80601-2-56: 2009 | IEC 60601-1-11: 2015 |
| ISO 10993-1: 2018 | ISO 10993-5: 2009 | ISO 10993-10: 2010 |
| EN ISO 14155: 2011/AC:2011 | EN 1041: 2008+A1:2013 | ISO 15233-1: 2016 |

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| **NOTIFIED BODY:** | TÜV SÜD PRODUCT SERVICE GMBH<br>RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY |
| **IDENTIFICATION NUMBER** | 0123 |
| **(EC) CERTIFICATE(S):** | G1 049076 0016 Rev .02 |

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| **EUROPEAN REPRESENTATIVE:** | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestraβe 80, 20537 Hamburg, Germany |

**START OF CE-MARKING:** OCT.15, 2010

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| **PLACE, DATE OF DECLARATION:** | Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA, |
| **SIGNATURE:** | 张翔 |
| **NAME:** | FEB 05, 2020 |
| **POSITION:** | Management Representative |