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

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| MANUFACTURER: | GRANDWAY TECHNOLOGY (SHENZHEN) LIMITED<br>NO.5, the SECOND INDUSTRIAL ZONE, ZHUKENG COMMUNITY, LONGTIAN STREET, PINGSHAN DISTRICT, 518118 SHENZHEN, Guangdong, PEOPLE'S REPUBLIC OF CHINA |
| MEDICAL DEVICE: | DIGITAL AUTOMATIC WRIST BLOOD PRESSURE MONITOR<br>MD3111 |
| CLASSIFICATION – *ANNEX IX:* | **CLASS IIA, RULE 10** |
| *CONFORMITY ASSESSMENT ROUTE:* | ANNEX II.3 |

**<THIS DECLARATION OF CONFORMITY IS ISSUED UNDER OUR SOLE RESPONSIBILITY>**

WE, GRANDWAY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES AMENDED ACCORDING TO 2007/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 SEPTEMBER, 2007
WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY

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

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| **EN ISO 13485:2016** | **IEC 60601-1-6:2010+A1:2013** | **ISO 10993-10:2010** |
| **IEC 60601-1-2:2014** | **IEC 60601-1-11:2015** | **ISO 81060-2:2013** |
| **EN ISO 81060-1:2012** | **IEC 62304:2006+A1:2015** | |
| **EN 1060-3:1997+A2:2009** | **IEC 62366-1:2015** | |
| **EN ISO 14971:2012** | **IEC 80601-2-30:2009+A1:2013** | |
| **IEC 60601-1:2005+A1:2012** | **ISO 10993-5:2009** | |

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| NOTIFIED BODY: | TÜV SÜD PRODUCT SERVICE GMBH<br>RIDLERSTER 65, D-80339 MÜNCHEN, GERMANY |
| *IDENTIFICATION NUMBER:* | 0123 |
| (EC) CERTIFICATE(S): | G1 061379 0028 Rev.01 |
| DATE OF EXPIRY: | 2023-08-31 |
| EC REP<br>EUROPEAN REPRESENTATIVE: | Shanghai International Holding Corp.GmbH (Europe)<br>Eiffestrasse 80, 20537 Hamburg, Germany |

START OF CE-MARKING:

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| PLACE, DATE OF DECLARATION: | NO.5, the SECOND INDUSTRIAL ZONE, ZHUKENG COMMUNITY, LONGTIAN STREET, PINGSHAN DISTRICT, 518118 SHENZHEN, Guangdong, PEOPLE'S REPUBLIC OF CHINA,<br>22-Jan-2021 |
| SIGNATURE: | *NAME: PATRICK CHOW*<br>*POSITION: GENERAL MANAGER* |