# Declaration of Conformity

## TO REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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| **Legal Manufacturer:** | Name: ViVest Medical Technology Co., Ltd.<br>Address:<br>Unit 205, 206, 207, B1 Building, SIP BioBay Phase 1, No.218 Xinghu Street, Suzhou Industrial Park, Suzhou Area, China (Jiangsu) Free Trade Pilot Zone, 215123 Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA<br>SRN: CN-MF-000015304 |
| **European Representative:** | Name: Shanghai International Holding Corp. GmbH (Europe)<br>Address: Eiffestraße 80, 20537 Hamburg, GERMANY<br>SRN: DE-AR-000000001 |
| **Product Name:** | Automated External Defibrillator |
| **Trade Name:** | N/A |
| **Model & REF Number (part number)** | **Model No.** / **REF No.**<br>PowerBeat X1 / PBX01004<br>PowerBeat X3 / PBX02004 |
| **EMDN Code:** | Z120305: DEFIBRILLATORS |
| **Basic UDI-DI:** | 697310724PB01ET |
| **Intended purpose:** | Automated External Defibrillator (AED) is indicated for use on patients with suspected Sudden Cardiac Arrest (SCA) who are unconscious, unresponsive and not breathing or breathing abnormally. |
| **Risk Class:** | Class III |
| **Classification Rule:** | Rule 22 in Chapter III of Annex VIII of the Regulation (EU) 2017/745 |
| **Conformity Assessment Route:** | Annex IX of Regulation (EU) 2017/745 |

VIVEST

We herewith declare that the above-mentioned product(s) meet the Regulation (EU) 2017/745 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DoC.

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| **Applied Standards:** | See section 1 & 2 of the <M16-DHF-CE-1006 Applied Standards List and GSPR Checklist > | | |
| **Applied EC Directive** | Directive 2011/65/EU: Restriction of the use of certain hazardous substances (RoHS Directive)<br>Directive 2012/19/EU: Waste Electrical and Electronic Equipment Directive<br>Directive 2014/53/EU: Radio Equipment Directive | | |
| **Notified Body:** | Name: TÜV SÜD Product Service GmbH<br>Address: Ridlerstraße 65, 80339 Munich, Germany<br>Actor ID: 0123 | | |
| **(EC) Certificate(s):** | G70 107512 0004 Rev.00 | **Valid until:** | 2024-11-22 |
| | G15 107512 0010 Rev.00 | **Valid until:** | 2025-02-27 |
| **Start of CE-marking:** | 2025-02-27 | | |
| **Place, Date of Issue:** | Suzhou, Jiangsu 2025-02-27 | | |
| **Signature:** | Liu Lucy 2025/02/27<br>Name: Lucy Liu<br>Function: Person Responsible for Regulatory Compliance | | |