

Declaration of Conformity
TO REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND
OF THE COUNCIL

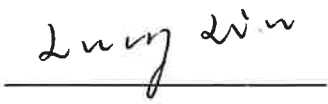
Legal Manufacturer:	Name: ViVest Medical Technology Co., Ltd. Address: Unit 401,501, Building No.2, Zone B, SIP Biobay Phase 5, No.21, Dongyanli Road, Suzhou Industrial Park, 215123 Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA SRN: CN-MF-000015304	
European Representative:	Name: Shanghai International Holding Corp. GmbH (Europe) Address: Eiffestraße 80, 20537 Hamburg, Germany SRN: DE-AR-000000001	
Product Name:	Automated External Defibrillator	
Trade Name:	Automated External Defibrillator	
Model & REF No. (part number)	Model No.	REF No.
	P1	VBP01002
	P3	VBP03052
EMDN Code:	Z12030501: Semi-automatic defibrillators	
Basic UDI-DI:	697310724VP01JB	
Intended purpose:	Automated External Defibrillator (AED) is intended 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	
Statement: 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. Hereby declare, under our sole responsibility, that products made by ViVest comply with the related requirements of the European Community Directive 2012/19/EU on waste electrical and electronic		

equipment (WEEE).

Declare our compliance with the requirements of Directive 2011/65/EU and its subsequent amendment (EU)2015/863, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (hereinafter called, “RoHS-Directive”).

Declare that our products falling within the scope of the Radio Equipment Directive meet the requirements of the Radio Equipment Directive.

Declare our compliance with Article 6, 19-20 of Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC.

Applied Standards:	See section 1 of the Applied Standards List and GSPR Checklist		
Applied EC Directive	Directive 2011/65/EU: Restriction of the use of certain hazardous substances (RoHS Directive) Directive 2012/19/EU: Waste Electrical and Electronic Equipment Directive Directive 2014/53/EU: Radio Equipment Directive		
Notified Body:	Name: TÜV SÜD Product Service GmbH Address: Ridlerstrasse 65, 80339 Munchen, Germany Actor ID: 0123		
(EC) Certificate(s):	G70 107512 0011 Rev. 00	Valid until:	2030-12-17
	G15 107512 0010 Rev. 01	Valid until:	2030-02-13
Start of CE-marking:	2025-12-18		
Place, Date of Issue:	Suzhou, Jiangsu		
Signature:	 Name: Lucy Liu Function: Person Responsible for Regulatory Compliance		