ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 107512 0002 Rev. 00

Manufacturer:

ViVest Medical Technology Co., Ltd
Unit 205,206,207,B1 Building, SIP BioBay
No.218, Xinghu Street
Suzhou Industrial Park, Suzhou Area
Suzhou Free Trade Pilot Zone
215123 Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Automated External Defibrillator

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 107512 0002 Rev. 00

Report No.: SH20160801

Valid from: 2021-04-28
Valid until: 2024-05-26

Date, 2021-04-28

Christoph Dicks
Head of Certification/Notified Body

维伟思证书

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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