# EU Certificate

**Quality Management System**
**REGULATION (EU) 2017/745 on Medical Devices**
**Annex IX Chapter I, Section 2 and 3 and Chapter III**

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| Registration No.: | HZ 2120274-1 |
| Manufacturer: | Shenzhen Viatom Technology Co., Ltd.<br>4E, Building 3, Tingwei Industrial Park,<br>No.6 Liufang Road, Block 67,<br>Xin'an Street, Baoan District,<br>Shenzhen,518101 Guangdong<br>P.R. China |
| EUDAMED Single Registration No.: | CN-MF-000012182 |
| Products: | Products of class IIa:<br>Z120504-HOLTER SYSTEM INSTRUMENTS FOR CARDIOVASCULAR PARAMETERS<br>Z120503-ELECTROCARDIOGRAPHS<br>Z120302-VITAL SIGNS MONITORING INSTRUMENTS |
| Authorized representative(s): | MedNet EC-REP GmbH<br>Borkstrasse 10 48163 Muenster Germany |

| Certificate history | | |
|---|---|---|
| Revision: | Description: | Issue date: |
| 0 | Initial certification | 2024-01-18 |

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

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| Report No.: | 10920649-120 |
| Effective date: | 2024-01-18 |
| Expiry date: | 2029-01-17 |
| Issue date: | 2024-01-18 |

Frank Feng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.



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