

EU Certificate

Quality Management System

REGULATION (EU) 2017/745 on Medical Devices

Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 2120274-1

Manufacturer: Shenzhen Viatom Technology Co., Ltd.
901, Building West, Lepu Tower,
No.66 Xingke Road, Xili Community,
Xili Street, Nanshan District,
Shenzhen, 518055 Guangdong
P.R. China

EUDAMED Single
Registration No.: CN-MF-000012182

Products: Products of class IIa:
Z120504 - HOLTER SYSTEM INSTRUMENTS FOR
CARDIOVASCULAR PARAMETERS
Z120503 - ELECTROCARDIOGRAPHS
Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Z120301 - ANAESTHESIA AND PULMONARY VENTILATION
SUPPORT INSTRUMENTS

Authorized representative(s): MedNet EC-REP GmbH
Borkstrasse 10 48163 Muenster Germany

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.

Report No.: 10924490-100

Effective date: 2025-07-07

Expiry date: 2029-01-17

Issue date: 2025-07-07

Jason Pan

Jason Pan

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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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-01-08
1	Address change and Product extension	2025-07-07

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