

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 795752 R000

**Manufacturer:** Shenzhen Comen Medical Instruments Co., Ltd

**Address:**

Floor10, Floor11 and Section C of Floor12 of Building 1A &  
Floor 1 to Floor 5 of  
Building 2, FIYTA Timepiece  
Building, Nanhuan Avenue  
Matian Subdistrict  
Guangming District, Shenzhen  
Guangdong  
518106  
China

**Single Registration Number:** CN-MF-000002236

**EU Authorised Representative:** Lotus NL B.V.

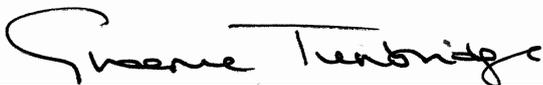
**Address:**

Koningin Julianaplein 10  
1e Verd, 2595AA  
The Hague  
Netherlands

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-12-02**

Current Issue Date: **2025-12-02**

Starting Validity Date: **2025-12-02**

Expiry Date: **2030-12-01**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

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### Device Schedule:

#### Intended Purpose as per the Instructions for Use:

The Automatic External Defibrillator is intended to be used on adults and pediatric patients in a sudden cardiac arrest. The patients must be:

- Unresponsive
- Without respiration or not breathing properly

Voice and/or visual guidance are provided for the operator throughout cardiopulmonary resuscitation (CPR). The Automatic External Defibrillator shall be used in public places and facilities by personnel trained in its operation and in basic life support, advanced cardiac life support or other emergency medical response.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
Automatic External Defibrillator	G3/G3A/G5/G5A/ G3 Fully Automatic/ G3A Fully Automatic/ G5 Fully Automatic/ G5A Fully Automatic/ G6/G6A/G7/G7A/ G6 Fully Automatic/ G6A Fully Automatic/ G7 Fully Automatic/ G7A Fully Automatic	MDA 0305	Class III	69454290AD004GC

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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
Current	30273168	Issued



First Issue Date: **2025-12-02**

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