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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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

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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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A Member of the BSI Group of Companies.