



# Quality Assurance



## CE Mark

The CE Marking approval process certifies that Defibtech is in full quality compliance with European Union (EU) Directives for Medical Devices for its automated external defibrillators and accessories. The units also conform to the Irish Medicines Board requirements for medical devices and our company details as the sole distributor for Ireland are recorded by them.



## FDA Clearance

The United States Food and Drug Administration (FDA) granted Defibtech 510(k) clearance to market its automated external defibrillators. The AEDs are marketed under the Lifeline & Reviver names.



## ISO-9002 - Manufacturing

Defibtech has its headquartered in Guilford, Connecticut and manufactures all of its defibrillators in the United States in a state-of-the-art ISO-9002 certified facility.



## ISO-13485 – Quality Assured Medical Device

We don't just sell defibrillators we provide complete support, Defibtech maintain a quality management system for all our units. This means we track design, production, sales and services for each defibrillator. We contact you with software upgrades, when defibrillation pads and batteries need to be replaced. When you use the unit we download the data and provide a free service check. This is the highest level of service audit system available for medical devices.

**Free Service Checks** – every two years we will contact you to call to the location where the AED is installed and do a free full service check this includes any software or protocols updates on the unit to assure you that your AED is ready to perform a rescue.

**Warranty** – the defibtech AED has a full five-year warranty from date of purchase. In the unlikely event that the unit requires maintenance we will collect the unit and install a new replacement within one working day while the unit is serviced.

**Medical Overview** – after you use the AED unit, if you require we will provide you with a free medical audit of all the information recorded by the unit. Also we will check out the unit for free and make sure it's ready to perform another rescue.

**Complete Event Review** – The AED records all ECG medical data internally, which can be accessed with the aid of our free software that can be downloaded from our website. An optional data card can be added to record all audio making it possible for a complete review of any event.