

Mindray defibrillators amongst the world's first to receive EU Medical Device Regulation certification



Medical device provider Mindray has become one of the first manufacturers in the world to receive certification for its defibrillators, under the European Union's newest Medical Device Regulation (MDR).

One of Europe's largest providers of defibrillators, Mindray supplies the devices to healthcare providers and community settings across many parts of the continent, where they are used in life-threatening scenarios for patients in cardiac arrest.

Now, four of Mindray's BeneHeart series defibrillators have become amongst the first to earn certification under the EU's tightened MDR controls. This includes three new models that are about to be launched, as well as the already widely used flagship BeneHeart D6.

Sudden cardiac death and arrhythmia account for up to 20% of all deaths throughout the world, according to academic research. Defibrillators deliver an electrical shock to restore a patient's normal cardiac rhythm and are a key medical equipment to sustain the patient's life.

Under MDR, defibrillators, as a high-energy life-support device, have been up-classified to the highest Class III for direct impact on patients' internal organs and systems, and thereby a potential risk of further injury or even life threat. This classification requires manufacturers to provide more details of technical documents and clinical evidence, and to go through a conformity assessment conducted by a notified body.

Mindray's BeneHeart series defibrillators earned accreditation for quality and effectiveness. The devices use mature 360J biphasic technology with automatic impedance compensation, which can significantly reduce the amount of current passing through the heart during defibrillation and reduce the risk of potential damage to myocardial tissue and the patient's skin. Automatic impedance compensation

functionality can also measure impedance of the patient and automatically adjust discharge voltage and discharge time. Mindray's newly certified defibrillators shorten the whole defibrillation process to 7.5 seconds.

Fast and high-quality defibrillation has been widely recognised for a greater chance of resuscitation success and effective reduction of the myocardial tissue damage.

Shao Lingyun, General Manager of Mindray Central R&D Management, said: "These certifications are sound validation of our long-term efforts to secure robust product development and quality management system. Mindray's product development is fully compliant with the ISO 13485 medical devices Quality management system. We have invested in the design and development and clinical validation of our products from the very beginning and worked closely with international healthcare professionals and institutions to continually improve our product effectiveness and secure a high and stable level of product quality. It is through these incremental efforts that Mindray is confident in bringing about meaningful changes to the healthcare practices and outcomes."

Introduced in 2017 to replace the existing Medical Device Directive (MDD), the MDR established a more stringent regulatory framework to govern the production and distribution of medical devices, requiring companies to advance and demonstrate greater product development and quality control capacities, with a transition period currently extending to 2027 and 2028, depending on risk classification. Mindray has now received MDR certification of almost all its flagship products, including patient monitors, ventilators, electrocardiographs, and infusion pumps, reinforcing the company's ability to continue to provide innovative and high-value solutions to healthcare professionals.

ENDS

Notes to editors

For research on deaths associated with sudden cardiac death and arrhythmia, please see <https://pubmed.ncbi.nlm.nih.gov/29967683/>

About Mindray

Mindray is a leading developer, manufacturer, and supplier of medical device solutions and technologies used in healthcare facilities around the globe. The company empowers healthcare professionals through innovative, high-value solutions that help create the next generation of life-saving tools of patient monitoring and life support, in-vitro diagnostics, and medical imaging. For more information, please visit <http://www.mindray.com> .