

At the Heart of IEC 62304 Medical Devices

Challenge:

Terumo sought to ensure improvements in software quality and reduce risk for their life-saving DuraHeart™ Left Ventricular Assist System LVAS device, an implantable device that combines patented magnetic levitation and centrifugal pump technologies to assist the left side of the heart in pumping blood. The DuraHeart LVAS improves circulation throughout the body; decreasing the risk of cell damage and its associated complications.

Solution:

Terumo selected the VectorCAST platform for its ability to support continuous improvement, thus enabling them to demonstrate due diligence and comply with IEC 62304 guidelines.

Details:

Terumo Heart, Inc. is a U.S. subsidiary of Terumo Corporation with headquarters and manufacturing facilities in Ann Arbor, Michigan. The company's focus is the innovation and introduction of products to improve the quality of healthcare for heart failure patients. Terumo Corporation, located in Tokyo, Japan, is a leading developer, manufacturer and global marketer of a wide array of medical products.

