Vector Elite Regulatory and Certifications

Bioness Corporate Representative

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The Vector Gait & Safety System was developed, manufactured and guaranteed to perform by the one or more of the regulations set forth by the following compliance bodies/organizations:

1. U.S. Food and Drug Administration (FDA)
2. International Organization of Standards (ISO)
3. Underwriters Laboratories (UL)

Bioness has a core team of highly trained individuals that specialize in meeting the requirements set forth by each compliance body under which the Vector is regulated. Product performance can only be ensured when a certified technician performs service and/or repairs and replaces System components. Worked performed by outside entities, including the customer themselves, cannot and will not be guaranteed by Bioness Inc.

FDA

Listing Number: D203102

Effective June 2013, the FDA made changes to medical device safety and regulatory standards. This includes but is not limited to meeting or exceeding the requirements set forth in standard IEC 60601-1, Edition 3, possessing special safety controls, mandatory performance standards, ensuring good manufacturing practices and complying with post market surveillance. Vector Elite is designed, tested and manufactured to meet and/or exceed these requirements.

ISO

Bioness Inc. is ISO certified thus our products, including Vector, are manufactured under the ISO 13485:2003 standard. The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems. The processes required by ISO 13485:2003, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system.

In order to comply with ISO 13485 a certified Bioness technician must perform the service and maintenance on the System. Bioness has a core team of highly trained individuals that specialize in complying with ISO 13485:2003 when performing service and/or repairing and replacing components.

UL

File Number: E359825. Vector Elite is certified by Underwriters Laboratories (UL) to meet IEC 60601-1, Edition 3 Harmonized Medical Device Standard. UL is an independent, globally recognized agency that certifies, validates, tests, inspects and audits corporations and products. UL certification specifically applies to the safety and essential performance of MEDICAL ELECTRICAL EQUIPMENT AND MEDICAL ELECTRICAL SYSTEMS. Healthcare providers are assured that the equipment being installed and serviced is safe, mechanically & electrically, and performs as stated.