

CERTIFICATIONS

The Vector Gait & Safety System is manufactured and guaranteed to perform according to the regulations set forth by the following compliance bodies/organizations:

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



Listing Number: D203102



Class I CE



Intertek

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.



Vector Elite is certified by Underwriters Laboratories (UL) to 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.

