

2014-2015

Certificate of Registration

This certificates that:

LifeVac Corp. 83 Rome Street Farmingdale, NY 11735

Is registered with the U.S. Food and Drug Administration pursuant to section 305 of the United States Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, such registration having been verified as currently effective on the date hereof by Registrar Corp.

U.S. FDA Registration No.: 3011053282





CFR - Code of Federal Regulations Title 21

TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER H--MEDICAL DEVICES

PART 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES
Subpart G--General Hospital and Personal Use Miscellaneous Devices
Sec. 880.6740 Vacuum-powered body fluid suction apparatus.

- (a) Identification. A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum collection bottles, suction catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).
- (b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 880.9. [45 FR 69682, Oct. 21, 980, as amended at 63 FR 59229, Nov. 3, 1998]