

# Certificate of Registration



Certificate Number  
SCC-0076

Initial Certification Date  
May 12, 2010

Certificate Issue Date  
May 12, 2010

Certificate Expiry Date  
May 12, 2013



The following organization's quality management system has been assessed and registered by Intertek Testing Services NA Ltd. as conforming to the requirements of:

## ISO 13485:2003

### Organization:

## Spectra Medical Devices, Inc.

Main Site: 260-F&H Fordham Road, Wilmington, Massachusetts, 01887, USA

Additional Site:

Purchasing - 1305 Anam Building, 702-10 Yeoksam-Dong, Gangnam-Gu, Seoul, 135-080, Korea

### The Quality Management System is applicable to:

The Design and manufacture of disposable medical needles and other disposable medical devices, as well as the management of contract manufacturing and private labeling services.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement.

A handwritten signature in black ink, appearing to be "J. [unclear]".