

## **Electronic Product Certificate**

**Abbreviated Radiation Safety Report** 

This certifies that:

I-Therm Medical, Inc. 282 South Street Blue Hill, ME 04614 United States

has submitted its Radiation Safety Report to the U.S. Food and Drug Administration pursuant to part 1002 of Title 21, US Code of Federal Regulations, such submission having been verified as currently effective on the date hereof by Registrar Corp:

Product Trade Name:

I-Therm

Accession Number:

1480113-000

Date Submitted:

October 27, 2014

U.S. Agent /

Registrar Corp

Registrant Contact:

144 Research Drive, Hampton Virginia, 23666 USA

Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such submission has been completed upon request and presentation of this certificate until June 30, 2025 unless terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. Holder assumes all risk, releases Registrar Corp, waives, and will hold harmless and indemnify Registrar Corp from any and all claims in connection with this product, its labeling, radiation safety reporting, commerce or use. Submission of a Radiation Safety Report does not constitute approval of the firm, document or device by the U.S. Food and Drug Administration. Any representation that creates an impression of official approval because of report submission or the assignment of an accession number is misleading. The U.S. Food and Drug Administration does not issue certificates of reporting, nor does the U.S. Food and Drug Administration recognize certificates of reporting. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp\*

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Registrar Corp

Dayed: / October 27, 2014