Health Canada / Santé Canada

TO ALL CANADIAN AND FOREIGN MANUFACTURERS

Attention to persons responsible for regulatory affairs and quality systems

FINAL DECISION

CESSATION OF RECOGNITION OF ORION REGISTRAR INC. AS A REGISTRAR BY HEALTH CANADA

APPLICATION

The cessation of recognition of Orion Registrar Inc. by Health Canada as a registrar affects all CANADIAN and FOREIGN manufacturers:

- holding class II, III, and IV medical device licences supported by a quality system certificate issued by Orion Registrar Inc.
- applying for class II, III and IV medical device licences with a quality system certificate issued by Orion Registrar Inc.
- applying for class II, III and IV medical device licence amendments with a quality system certificate issued by Orion Registrar Inc.
- in the process of having their quality system registered under CMDCAS by Orion Registrar Inc.

CONTEXT

On June 10, 2005, Health Canada ceased to recognize Orion Registrar Inc. (ORI) as a registrar in accordance with section 32.5 of the *Medical Devices Regulations* (Regulations). Health Canada took this action on the grounds that ORI no longer met the requirements of section 32.1 of the Regulations.

Health Canada's recognition of a registrar is predicated on the registrar's continuing accreditation by the Standards Council of Canada (SCC). ORI's accreditation was suspended by the SCC on June 10, 2005. Consequently, as of June 10, 2005, Health Canada stopped accepting ORI quality system certificates in support of any new medical device licence applications and amendments to existing medical device licences. Existing QMS certificates issued by ORI and provided in support of issued licences remained valid until further notice.

A registrar whose accreditation has been suspended by the SCC may appeal the suspension. Based on information submitted in support of the appeal, the SCC will decide whether the accreditation should be withdrawn or reinstated. Health Canada may reinstate the recognition of a registrar under Section 32.1 of the Regulations if and when the suspension of their accreditation by the SCC is lifted.

ORI's accreditation was withdrawn by the SCC on September 14, 2005. Pursuant to this decision, ORI must immediately cease all registration activities conducted under the SCC accreditation and must no

longer hold itself out as being qualified or accredited by the SCC. ORI is also required to recall, and return to the SCC, any registration certificates currently in the marketplace that carry the SCC mark. These activities are required to be completed within thirty (30) days, and include all certificates issued under CMDCAS.

Since ORI was not successful in having the SCC reinstate ORI's accreditation, Health Canada will not reinstate the recognition of ORI as a registrar for the purposes of the Regulations.

INFORMATION

Manufacturers holding ORI quality system certificates will receive a letter from Health Canada advising the manufacturers that they must submit a new quality system certificate from a recognized registrar in support of their medical device licence by a date specified in the letter. Non-compliance by the specified date will result in medical device licences supported by ORI quality system certificates being suspended. In the absence of a valid medical device licence, a manufacturer will be in breach of the Regulations if the manufacturer sells Class II, III or IV medical devices in Canada, advertises these medical devices for the purpose of sale in Canada or imports the devices into Canada.

ADDITIONAL INFORMATION

For additional information on regulatory issues and procedures with respect to medial device quality systems, Health Canada can be contacted by writing, calling, faxing, or e-mailing the following:

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