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## **StarFish Medical Analysis: Changes to the Canadian Medical Device Regulations**

**By Rob Keur, August 20, 2015**

Revised versions of the Canadian Medical Device Regulations and the Form for the submission of a class 2 medical device licence application have been posted on the Government of Canada and the Health Canada websites.

The first change requires including the product labeling with a class 2 device license submission. Previously an attestation that the labeling complied with article 21 of the regulations was sufficient. The change is effective immediately since there is no change to the labelling content.

The second change involves making non-corrective contact lenses a class 2 medical device. This was a bit tricky since the regulations require evidence of safety and effectiveness and non-corrective lenses are ineffective from a medical perspective and the cosmetic effectiveness is subjective.

The revised regulation will require all contact lenses sold in Canada to meet the same requirements for safety, quality and labeling.

This change will be effective in a year to give industry a chance to meet the added requirements of implementing a quality system and upgrading labelling.

[Link to the regulations on the Government of Canada site](#)

[Link to the forms page on the Health Canada site](#)