# Decorative contact lenses

As of July 16, 2016, decorative contact lenses (also known as cosmetic, coloured or fashion contact lenses) will be regulated as Class II medical devices in Canada. In order to sell these lenses, Canadian manufacturers must get a Class II medical device licence. To help your establishment comply with this requirement, Health Canada is pleased to provide you with the following information.

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# LICENSING

## Decorative contact lenses

Decorative contact lenses are used to change the look or colour of a user's eyes. Unlike corrective contact lenses, they do not correct vision. Decorative contact lenses may also be referred to as cosmetic, coloured or fashion contact lenses.

## Reasons for Health Canada to regulate decorative contact lenses as medical devices

This regulatory change aligns decorative contact lenses with traditional contact lenses, which are already regulated as medical devices. All types of contact lenses have associated risks, including:

- cuts or scratches on the top layer of the eyeball (corneal abrasions)
- allergic reactions (e.g., itchy, watery, red eyes)
- vision impairment
- infections
- blindness

## Time for decorative contact lenses to be regulated as medical devices

On July 16, 2016, decorative contact lenses will become medical devices. At that time, manufacturers will need to comply with the *Medical Devices Regulations* (Regulations). For more information about the Regulations, please visit the following link:
http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/index.html

## Classification of decorative contact lenses

As of July 16, 2016, decorative contact lenses will be considered Class II medical devices. Medical devices are classified into four classes, with Class I representing the lowest risk class and Class IV the highest.

## Requirement for manufacturers

As a manufacturer, you must obtain a medical device licence before advertising or selling any Class II, III or IV medical devices. This means that before you can sell decorative contact lenses in Canada, you will need to get a Class II medical device licence for your lenses.

## Information for applying for a medical device licence

To apply for a Class II medical device licence, manufacturers of decorative contact lenses must get ISO 13485:2003 certification from one of the recognized registrars in the Canadian Medical Device

Conformity Assessment System (CMDCAS). The certificate must contain the Standards Council of Canada logo as well as a CMDCAS recognition statement.

You can find a list of recognized registrars at http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list_liste_regist-eng.php

Along with the ISO 13485:2003 certificate, manufacturers must also submit a completed Class II application form (found at www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/md-im/applic-demande/form/licapp_demhom_cla2-eng.pdf) and fee form (found at www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/md-im/applic-demande/form/md_licapp_demhom-eng.pdf), as well as a copy of the labelling used for their lenses.

You should send your medical device licence application to:

Device Licensing Services Division
Medical Devices Bureau
Therapeutic Products Directorate
Health Canada
11 Holland Avenue
Address locator: 3002A
Ottawa, Ontario K1Y 4T2

For more information on medical device licensing, please visit the medical devices section of Health Canada's website. You can also email device_licensing@hc-sc.gc.ca or call 613-957-7285 with any questions or concerns.

## COMPLIANCE AND ENFORCEMENT

### Transition period for manufacturers

As a manufacturer of decorative contact lenses, you will need to have your licence before you can sell your product in Canada. However, because decorative contact lenses are not considered medical devices until July 16, 2016, any application for licensing you submit before that date will not be accepted by Health Canada. For this reason, all manufacturers are being given a 12-month transition period to get their Class II medical device licence. After July 16, 2017, all manufacturers, importers and distributors who sell decorative contact lenses in Canada may face enforcement action if their lenses are not licensed by Health Canada.

## Requirements for importers and distributors

If you distribute or import medical devices, you do not need a medical devices licence. Instead, you must apply for and obtain a medical device establishment licence (MDEL). In doing so, you are providing assurance that the medical devices you sell or import into Canada meet the safety and effectiveness requirements set out in the Regulations, and that you have procedures in place to protect the public should a problem with a medical device be identified. These should include procedures related to distribution records; complaint handling and recalls; mandatory problem reporting; and the handling, storage, delivery, installation and servicing of any Class II, III or IV devices, where applicable.

For more information about the requirements for obtaining an MDEL, please see *Guidance on Medical Device Establishment Licensing and Medical Device Establishment Licence Fees* (GUI-0016), which can be downloaded from the Health Canada website.

## Health Canada's role in regulating decorative contact lenses

Health Canada regulates the safety, efficacy and quality of health products, including decorative contact lenses. We do so by reviewing and evaluating health products against quality and efficacy standards, conducting post-market surveillance of health products once they are on the market, and taking compliance and enforcement actions to ensure health products' compliance with the *Food and Drugs Act* and its associated regulations.

## Approach for Health Canada to respond to non-compliance

Health Canada uses a number of methods to verify the compliance of health products, including responding to complaints, monitoring international information, conducting inspections and market surveys, and examining products at the border.

When a potential non-compliance is identified, we can take a range of compliance and enforcement actions to manage the risk to Canadians, including product recalls, import alerts, public communications and product seizures. The scale, scope and intensity of our actions are proportional to the risk posed. However, compliance is normally achieved through a cooperative approach between Health Canada and the regulated party before such actions are required.

For more information, please see our *Compliance and Enforcement Policy* (POL-0001), which is available on the Health Canada website.