

**GENERAL AGREEMENT
ON TARIFFS AND TRADE**

RESTRICTED
TBT/Notif.94.409
31 October 1994
Special Distribution

(94-2276)

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.4.

1.	Party to Agreement notifying: <u>CANADA</u>
2.	Agency responsible: Department of National Health and Welfare
3.	Notified under Article 2.5.2 [X], 2.6.1 [], 7.3.2 [], 7.4.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Medical devices
5.	Title and number of pages of the notified document: Proposed Amendment to the Medical Devices Regulations
6.	<p>Description of content: Part V of the Medical Devices Regulations provides for the pre-market review of new devices prior to sale in Canada. The Table to Part V lists devices that are considered new devices for the purposes of this Part. Contact lenses designed or represented for prolonged wear were recently removed from the Table. Since extended wear contact lenses have been on the market since the 1970s, the technology has stabilized, and it is no longer necessary to designate these lenses as a new device. However, labelling requirements are necessary to promote safe use of contact lenses.</p> <p>This amendment puts in place specific labelling requirements for all contact lenses, in addition to the general labelling requirements in section 6 of the Medical Devices Regulations.</p>
7.	Objective and rationale: Protection of health
8.	Relevant documents: Canada Gazette, Part I, 15 October 1994, pages 4246-4249
9.	Proposed date of adoption and entry into force: 1 December 1995
10.	Final date for comments: 29 December 1994
11.	Texts available from: National enquiry point [X] or address and telefax number of other body: