

**GENERAL AGREEMENT
ON TARIFFS AND TRADE**

RESTRICTED
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30 May 1994
Special Distribution

(94-0946)

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>UNITED STATES</u>
2.	Agency responsible: Food and Drug Administration (29)
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 (HS Chapter 9018)
5.	Title and number of pages of the notified document: Medical Devices; Performance Standards for Electrode Lead Wires; Requests for Comments and Information; Public Conference (3 pages)
6.	Description of content: The administration is announcing its intent to establish special controls, including the promulgation of performance standards, for medical devices that use electrode lead wires.
7.	Objective and rationale: The administration is taking this action because it has determined that special controls are needed to prevent hazardous electrical connections between patients and electrical power sources.
8.	Relevant documents: 59 FR 26352; 19 May 1994; 21 CFR CH. 1. Will appear in the Federal Register when adopted.
9.	Proposed date of adoption and entry into force: To be determined
10.	Final date for comments: 17 August 1994
11.	Texts available from: National enquiry point [X] or address and telefax number of other body: