

# GENERAL AGREEMENT ON

RESTRICTED

TBT/Notif.92.386

9 December 1992

# TARIFFS AND TRADE

Special Distribution

Committee on Technical Barriers to Trade

## NOTIFICATION

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

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| 1. Party to Agreement notifying: <u>EUROPEAN COMMUNITY</u>   |
| 2. Agency responsible: Commission of the European Community  |
| 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):<br>Medical devices, HS Chapter 90  |
| 5. Title and number of pages of the notified document: Amended Proposal for a Council Directive Relating to Medical Devices (18 pages)   |
| 6. Description of content: Amendments to the earlier proposal concerning harmonization of Community legislation with regard to medical devices on the basis of Article 100A of the EEC Treaty, in order to remove and prevent technical barriers to trade.   |
| 7. Objective and rationale: The purpose of this amended proposal for a directive is to ensure the safety and protection of patients and users, following a uniform sectorial approach, and to provide an appropriate and favourable framework for the technological development of the products concerned. |
| 8. Relevant documents: Official Journal of the European Communities, No. C251 of 28 September 1992, pages 40-50 amended document 92/C251/02 with reference to original notified document 91/C237/03  |
| 9. Proposed date of adoption and entry into force:<br>Date of adoption: mid 1993<br>Entry into force: in 1995  |
| 10. Final date for comments: 30 January 1993   |
| 11. Texts available from: National enquiry point [X] or address of other body:   |