**NOTIFICATION**

The following notification is being circulated in accordance with Article 10.4

1. Party to Agreement notifying: **SWEDEN**

2. Agency responsible:
   Ministry of Health and Social Affairs/Commission for Medical Technical Safety

3. Notified under Article 2.5.2 [ ] 2.6.1 [x] 7.3.2 [ ] 7.4.1 [ ] Other:

4. Products covered (CCCN where applicable, otherwise national tariff heading):
   Medical Technical Products (ex CCCN Chapter 90 and 30)

5. Title:

6. Description of content:
   The report contains a draft Act concerning control of medical technical products. Producers, importers, retailers and other suppliers of these products will be affected. Medical technical products include apparatus, instruments, implants and sterilized disposable items and other products which in health- and medical service or dental service, are intended to be used for the examination and treatment of patients or for the examination of tests from patients. Drugs and herb medicines are not included.

   The proposed control program consists of certification of conformity and inspection initiated by the supervising authority. In the report the commission also suggests (although not yet expressed as draft regulations) that medical technical products should be classified into three control categories. The basic requirements for categories 2 and 3 are that the products shall be of high and uniform quality in accordance with a quality assurance system (Good Manufacturing Practice, GMP). As to products in category 3 type approval, clinical testing and inspection of other nature can be required.

   More detailed regulations will be issued by the Government and the appointed supervising authority.

7. Objective and rationale:
   Protection for human health and safety

8. Relevant documents:
   Will be published in the Swedish Code of Statute and the statute-book of the supervising authority

9. Proposed date of adoption and entry into force:
   Will be decided later

10. Final date for comments: 4 December 1987

11. Texts available from: National enquiry point [x] or address of other body