NOTIFICATION

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

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

2. Agency responsible: Electrical Inspectorate

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):
   
   Medical equipment

5. Title: Circular KL 160-91; Mandatory Type Testing and Control of Medical Equipment (available in Finnish and English, 6 pages)

6. Description of content: Electromedical equipment is defined in this circular as equipment intended to diagnose, treat and monitor the patient under medical supervision of the doctor and which makes physical or electrical contact with the patient and/or transfers energy to or from the patient and/or detects such energy transfer to or from the patient.

   The sale, conveyance or use of electromedical equipment listed in this circular is prohibited in Finland before they have been duly inspected and SETI has approved them.

   Compared with the old requirements (KL 118-86) some pieces of equipment are left out of the list and some equipment is transferred from "complete test" category to "limited test" category.

   Furthermore there is a possibility to give exemption or permission to use if, for example:

   - amount of equipment is small;
   - imperfections noticed in equipment are slight;
   - so called limited testing of equipment has been done;
   - equipment is only on exhibition.

7. Objective and rationale: Safety
8. Relevant documents:

9. Proposed date of adoption and entry into force:
   
   Entry into force: 1 July 1991

10. Final date for comments: 14 June 1991

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