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

1. **Party to Agreement notifying:** FEDERAL REPUBLIC OF GERMANY

2. **Agency responsible:** Federal Ministry for Youth, Family Affairs and Health

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

4. **Products covered (CCCN where applicable, otherwise national tariff heading):**
   - Drugs and objects which are considered to be drugs, such as sterile medical disposable devices

5. **Title:** Draft of the Second Law on the Amendment of the Drug Law

6. **Description of content:**
   - Subjection of the sterile medical disposable devices to the requirements of the Drug Law on safety, prevention of fraud, proper manufacturing and control,
   - possibility of reference to the test results of a former applicant,
   - embodiment of the Basic Standards of Good Laboratory Practice.

7. **Objective and rationale:** Improvement of health protection (drug safety)

8. **Relevant documents:** Drug Law of 24 August 1976 (BGB. I pages 2445, 2448), amended by the First Law on the Amendment of the Drug Law

9. **Proposed dates of adoption and entry into force:** Promulgation of the Law in the second half of the year 1986, entry into force at the beginning of 1987 and/or at the beginning of 1988

10. **Final date for comments:** 16 June 1986

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