

**The Act on Medical Devices
(Medical Devices Act)**

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Part One
The purpose and scope of the Act, definition of terms

Section 1
The purpose of the Act

The purpose of the present Act is to regulate the trade in medical devices and, by doing so, to guarantee the safety, suitability and performance levels of medical devices as well safeguard the health and ensure the necessary protection of patients, users and other persons.

Section 2
The scope of the Act

(1) The present Act shall apply to medical devices and their accessories. Accessories are treated as medical devices in their own right.

(2) The present Act shall also apply to the use, operation and maintenance of devices which are not placed on the market as medical devices but are used with the intended purpose of a medical device within the meaning of Annexes 1 and 2 of the Ordinance on Operators of Medical Devices. These are deemed to be medical devices within the meaning of the present Act.

(3) The present Act shall also apply to medical devices which are intended for the administration of drugs within the meaning of Section 2, sub-section 1 of the German Medicinal Products Act (*Arzneimittelgesetz*). If the medical devices referred to in sentence 1 are placed on the market in such a way that the medical device and the drug form a single, integral device which is intended exclusively for use in the given combination and cannot be re-used, the present Act shall apply only in so far as the medical device in question must fulfil the essential requirements contained in Section 7 relating to safety and performance-related device functions. In other respects, the provisions of the German Medicinal Products Act shall apply.

(4) The present Act shall be without prejudice to the provisions contained in the Atomic Energy Act (*Atomgesetz*), the X-ray Ordinance (*Röntgenverordnung*) and the Radiation Protection Ordinance (*Strahlenschutzverordnung*), the Chemicals Act (*Chemikaliengesetz*), the Dangerous Substances Ordinance (*Gefahrstoffverordnung*) as well as the legal provisions on secrecy and data protection.

(4a) The present Act shall also apply to devices intended by the manufacturer for use according to the Regulations on personal protective equipment covered by Council Directive 89/686/EEC of 21st December 1989 to approximate the laws of the Member States on personal protective equipment (OJ L 399 of 30.12.1989, p. 18) as well as Council Directive 93/42/EEC of 14th June 1993 on medical devices (OJ L 169 of 12.7.1993, p. 1).

(5) The present Act shall not apply to:

1. drugs within the meaning of Section 2, sub-section 1, no. 2 of the Drug Law,
2. cosmetic products within the meaning of Section 2 (5) of the German Commodities, Food and Feed Code,
3. human blood, human blood products, human plasma or blood cells of human origin or products which, at the time when they are placed on the market, contain blood products, blood plasma or blood cells of this type, provided that these do not constitute medical devices pursuant to Section 3, no. 3 or Section 3, no. 4,
4. transplants or tissues or cells of human origin and products which contain tissues or cells of human origin or have been derived from such tissues or cells, provided that these do not constitute medical devices pursuant to Section 3, no. 4,
5. transplants or tissues or cells of animal origin, unless a product is manufactured using animal tissue which is rendered non-viable or non-viable products derived from animal tissue or unless medical devices pursuant to Section 3, no. 4 are concerned.

Section 3

Definition of terms

1. Medical devices are all instruments, apparatus, appliances, software, substances or preparations made from substances or other articles, used alone or in combination, including the software intended by the manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for the medical device's proper application, intended by the manufacturer to be used for human beings, by virtue of their functions, for the purpose of

- a) diagnosis, prevention, monitoring, treatment or alleviation of disease,
- b) diagnosis, monitoring, treatment, alleviation or compensation of injuries or handicaps,
- c) investigation, replacement or modification of the anatomy or of a physiological process or,
- d) control of conception,

and which do not achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which might be assisted in their function by such means.

- 2. Medical devices are also products under number 1, containing a substance or preparation made from substances or coated by the same and which, when used separately, can be considered to be medicinal products within the meaning of Section 2, sub-section 1 of the Medicinal Products Act and which, in complementing the functions of the product, can have an action on the human body.
- 3. Medical devices are also products under number 1, which contain as one of their ingredients a substance which, when used separately, is regarded as an ingredient of a medicinal product or a medicinal product made from human blood or blood plasma within the meaning of Article 1 of Directive 2001/831/EC of the European Parliament and of the Council of 6th November 2001 on the Community Code relating to Medicinal Products for Human Use (OJ L 311 of 38.11.2001, p. 67), last amended by Regulation (EC) No. 1394/2007 (OJ L 324 of 10.12.2007, p.121) and which, complementing the product, can have an action on the human body.
- 4. An *in vitro* diagnostic medical device is a medical device which is intended to be used, alone or in combination with others, as a reagent, reagent device, calibrator material, control material, kit, instrument, apparatus, equipment or system, according to the intended purpose specified by the manufacturer, for the *in vitro* examination of specimens derived from the human body, including blood and tissue donations, purely or mainly with a view to providing information
 - a) on physiological or pathological conditions,
 - b) congenital abnormalities, or
 - c) to investigate the safety of or tolerance by potential recipients, or

- d) to monitor therapeutic measures.

Specimen containers shall be regarded as *in vitro* diagnostic medical devices. Specimen containers are either evacuated medical devices or others which are specially prepared by their manufacturer to receive specimens derived from the human body immediately after their removal and store them for the purpose of *in vitro* diagnostic examination. Devices for general laboratory use are not considered to be *in vitro* diagnostic medical devices unless, due to their features, they are to be used specifically for *in vitro* diagnosis in accordance with the manufacturer's intended purpose.

- 5. An *in vitro* diagnostic medical device for self-testing is an *in vitro* diagnostic medical device which, according to the intended purpose specified by the manufacturer, can be used by lay-persons at home.
- 6. Within the meaning of this Act, an *in vitro* diagnostic medical device is new if:
 - a) such a medical device for the corresponding analyte or other parameter had not been available within the European Economic Area continuously over the previous three years, or
 - b) the procedure uses an analysis technique, which had not been used within the European Economic Area continuously over the previous three years for the given analyte or other parameter.
- 7. Substances, materials and articles which are intended by their manufacturer to be used as calibration and control materials for the comparison of measurement data, or for testing the performance features of an *in vitro* diagnostic medical device with respect to its use in accordance with its intended purpose, are regarded as calibration and control materials. Certified international reference materials and materials used for external quality assessment programmes are not *in vitro* diagnostic medical devices within the meaning of this Act.
- 8. A custom-made device is a medical device which is especially manufactured according to a written prescription and with specific design features and intended for the exclusive use of a patient designated by name. Mass-produced medical devices which need to be adapted to suit the specific requirements of the physician, dentist or other professional user, are not regarded as custom-made medical devices.

9. Accessories for medical devices are articles, substances and preparations made from substances which do not in themselves constitute medical devices according to number 1, but are intended by the manufacturer to be used in combination with a medical device so as to enable the latter to be used for its intended purpose as specified by the manufacturer. Invasive medical devices intended for use in taking samples from human bodies for *in vitro* testing as well as medical devices intended for sample removal, which come into direct contact with the human body, are not deemed to be accessories for *in vitro* diagnostic medical devices.
10. The intended purpose is the use for which the medical device is intended according to the data provided by the group of persons referred to under number 15 in the labelling, the instructions for use or promotional materials.
11. Placing on the market is any act of supplying medical devices to others, either free of charge or in exchange for payment. First placing on the market is the first making available of a new or fully reprocessed medical device to others in the European Economic Area. The following is not considered to be placing on the market for the purposes of this Act:
 - a) the making available of medical devices for the purpose of clinical investigation,
 - b) the making available of *in vitro* diagnostic medical devices for performance evaluation studies,
 - c) the renewed making available of a medical device to others after it has been put into service, unless it has been fully reprocessed or substantially modified.

The reprocessing of a medical device for another party and then returning it to them is not considered to be making available to others.
12. Putting into service is the point at which the medical device is placed at the disposal of the end user as a device which can be used for the first time in the European Economic Area in accordance with its intended purpose. In the case of active implantable medical devices, the making available of the medical device to medical personnel for the purpose of implantation is considered to be putting into service.
13. Putting on exhibition means the exhibiting or demonstration of medical devices for promotional purposes.

14. The reprocessing of medical devices which, according to their indented purpose, are to be used in a practically germ-free or sterile condition consists of the cleaning, disinfection and sterilisation, including related procedures, as well as the testing and restoration of the technical and functional safety, carried out on a medical device after it has been put into service for the purpose of re-use.
15. The manufacturer is the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a medical device with a view to its placing on the market for the first time under his own name, regardless of whether those operations are carried out by that person himself or on his behalf by a third party. The obligations incumbent on manufacturers under the present Act also apply to the natural or legal person who assembles, packages, processes, fully reprocesses and/or labels one or more prefabricated medical devices or is responsible for assigning to them their intended purpose as medical devices with a view to their placing on the market for the first time under his name. This does not apply to natural or legal persons who – while not manufacturers within the meaning of sentence 1 – assemble or adapt medical devices already on the market for a specific, named patient in accordance with their intended purpose.
16. The authorised representative is the natural or legal person established in the European Economic Area, who has been explicitly designated by the manufacturer, to act on his behalf with a view to his obligations under this Act and to be at the disposal of the authorities and competent bodies.
17. Experts are members of the health professions, the health industry or institutions active in the field of health as well as other persons who manufacture or test medical devices or, in the exercise of their profession, place medical devices on the market, implant, put into service, operate or use them.
18. Harmonised standards are those standards of States Party to the Agreement on the European Economic Area which correspond to standards the source references of which have been published in the Official Journal of the European Union as "harmonised standards" for medical devices. The source references of the corresponding standards are published by the Federal Institute for Drugs and Medical Devices in the Federal Gazette (*Bundesanzeiger*). The standards referred to in sentences 1 and 2 are equivalent to the European Pharmacopoeia Monographs relating to medical devices whose source references are published in the Official Journal of the European Union and are published in the Federal Gazette as monographs of the European Pharmacopoeia, Official German Edition.

19. Common technical specifications are those specifications which refer to the *in vitro* diagnostic medical devices contained in Annex II, lists A and B of the Directive 98/79/EC of the European Parliament and the Council of 27th October 1998 on *in vitro* diagnostic medical devices (OJ EC No. L 331, p. 1) in the valid version in each case and the source references of which have been published in the Official Journal of the European Union and promulgated in the Federal Gazette. These specifications establish the criteria for the evaluation and re-evaluation of performance, batch release criteria, reference methods and reference materials.
20. A notified body is a body designated to conduct tests and issue certificates in connection with conformity assessment procedures in accordance with the ordinance referred to in Section 37, sub-section 1 and of which the Commission of the European Union and the States Party to the Agreement on the European Economic Area have been notified by a State Party to the Agreement on the European Economic Area.
21. Medical devices from own production are medical devices including accessories manufactured and used in a health facility without being placed on the market or fulfilling the prerequisites of a custom-made device pursuant to number 8.
22. *In vitro* diagnostic medical devices from own production are *in vitro* diagnostics medical devices which are manufactured in the laboratories of health facilities and used in these laboratories or in their direct proximity, without being placed on the market. In the case of *in vitro* diagnostic medical devices which are manufactured industrially, the provisions governing own production shall not be applicable. Sentences 1 and 2 shall be applied *mutatis mutandis* to *in vitro* medical devices manufactured in blood establishments which serve to test blood preparations in so far as they are subject to testing by the competent federal authority within the framework of the marketing authorisation for medicinal products.
23. A sponsor is a natural or legal person who assumes the responsibility for commissioning, organising and financing a clinical trial on humans being or a performance evaluation study of *in vitro* diagnostic medical devices.
24. An investigator is generally a physician responsible for the conduct of a clinical trial in humans at a trial site or, in justified exceptional cases, another person whose profession, owing to the scientific requirements and the experience in the care of patients which it

calls for qualifies him/her to conduct research on human beings. If a clinical trial is being conducted by several investigators at one site, the sponsor shall appoint a chief investigator. Sentences 1 to 3 shall apply to such performance evaluation studies of *in vitro* diagnostic medical devices as require an authorisation.

25. 'Clinical data' are safety or performance information that is generated from the use of a device. Clinical data are sourced from:
- a) clinical investigations of the device concerned or
 - b) clinical investigations or other studies, reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or
 - c) published or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated.
26. 'Importer', within the meaning of the present Act is any natural or legal person domiciled in the European Community who places a medical device from a third country on the market in the European Community.

Part Two

Requirements for medical devices and their operation

Section 4

Prohibitions to ensure the protection of patients, users and other persons

(1) It is prohibited for medical devices to be placed on the market, installed, put into service, operated or used if:

- 1. there are grounds to suspect that the safety and health of patients, users or third persons could be compromised, directly or indirectly, to a degree which exceeds tolerable limits according to medical scientific knowledge when properly operated, maintained and used in accordance with their intended purpose, or
- 2. the date up until which safe use could be proven has elapsed.

(2) Moreover, it is prohibited for medical devices to be placed on the market if they bear misleading names, particulars or presentations. Deception is said to exist, in particular, in cases where:

1. claims are made to the effect that a medical device has a performance characteristic, which it does not possess,
2. the erroneous impression is given that the treatment with the medical device is certain to be successful or that no harmful effects can be expected when used in accordance with its intended purpose or over a prolonged period,
3. names, particulars or presentations are used which, having an influence on the evaluation of the medical device, are likely to mislead others with regard to the device characteristics laid down in the essential requirements according to Section 7.

Section 5

Person responsible for the first placing on the market

The person responsible for the first placing on the market of the device is the manufacturer or his/her authorised representative. If medical devices are not being imported into the European Economic Area under the responsibility of the authorised representative, the importer shall be the person responsible. The name or the firm and the address of the person responsible must appear on the label or in the instructions for the use of the medical devices.

Section 6

Prerequisites for placing on the market and putting into service

(1) With the exception of custom-made devices and medical devices manufactured in-house, medical devices pursuant to Section 11, sub-section 1, as well as medical devices intended for clinical investigation, or in vitro diagnostic medical devices intended for performance evaluation, medical devices may only be placed on the market or put into service if they bear the CE marking in compliance with the stipulations contained in sub-section 2, sentence 1 and sub-section 3, sentence 1. This shall be without prejudice to provisions which affect the operation or use of medical devices and which go beyond the requirements regarding the properties of the medical device.

(2) Medical devices may only bear the CE marking if the essential requirements according to Section 7 which are applicable to them, taking into consideration their intended purpose, are fulfilled and the conformity assessment procedure prescribed for the medical device in question according to the ordinance pursuant to Section 37, sub-section 1 has been conducted. Intermediate devices, which are intended by the manufacturer specifically as a component of custom-made devices, may be affixed with the CE marking if the conditions contained in sentence 1 have been fulfilled. If the manufacturer does not have his/her registered place of business in the European Economic Area, the medical device may, in addition to sentence 1, only be affixed with the CE marking if the manufacturer has designated a single authorised representative responsible for the individual medical device in the European Economic Area.

(3) If other legal provisions other than those contained in the present Act apply to the medical device, and if their observance is confirmed by affixing the CE marking, the manufacturer of the medical device may only affix the CE marking if these other legal provisions are also observed. If, in a transition period, owing to the existence of one or more additional legal provisions, the manufacturer is allowed to choose which regulations shall apply, affixing the CE marking would indicate that the medical device in question only fulfils the requirements of the legal provisions applied. In such a case, the manufacturer must include, in the accompanying documents, information or instructions, the numbers under which the Council Directives corresponding to the legal provisions which he has applied are published in the Official Journal of the European Union. In the case of sterile medical devices, these documents, information or instructions must be accessible without having to destroy the packaging which guarantees the sterility of the medical device.

(4) The execution of conformity assessment procedures shall be without prejudice to the liability, under civil and penal law, of the person responsible pursuant to Section 5.

Section 7

Essential requirements

(1) The essential requirements for active implantable medical devices, are the requirements contained in Annex 1 to Council Directive 90/385/EEC of 20th June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189 of 20.7.1990, p. 17), last amended by Article 1 of Directive 2007/47/EC (OJ L 247 of 21.9.2007, p. 21), for *in vitro* diagnostic medical devices the requirements contained in Annex I to Directive 98/79/EC and, for other medical devices, the requirements contained in Annex I to

Council Directive 93/42/EEC of 14th June 1993 on medical devices (OJ L 169 of 12.7.1993, p. 1), last amended by Article 2 of Directive 2007/47/EC (OJ L 247 of 21.9.2007, p. 21), in the valid version in each case.

(2) If a pertinent risk exists, medical devices which are also machines within the meaning of Article 2, letter a of Directive 2006/42/EC of the European Parliament and of the Council of 17th May 2006 on machinery (OJ L 157 of 9.6.2006, p. 24) shall also fulfil the essential health and safety requirements pursuant to Annex I of the above-mentioned directive, in so far as these essential health and safety requirements are more specific than the essential requirements pursuant to Annex 1 of Directive 93/42/EEC or pursuant to Annex 1 of Directive 90/385/EEC.

(3) In the case of products which are intended for use not only as medical devices but also for use according to the regulations governing personal protective equipment contained in Directive 89/686/EEC, the relevant essential health and safety requirements contained in this directive shall also be fulfilled.

Section 8

Harmonised standards, common technical specifications

(1) If medical devices conform to harmonised standards or equivalent European Pharmacopoeia monographs or common technical specifications relating to the specific medical device, it shall be presumed in this respect that they conform to the provisions contained in the present Act.

(2) As a rule, compliance with the common technical specifications is required. If, with sufficiently good reason, the manufacturer does not comply with these specifications, he/she must choose solutions of a level which is at least equivalent to that of the specifications.

Section 9

The CE marking

(1) The CE marking shall be used for active implantable medical devices according to the stipulations contained in Annex 9 to Directive 90/385/EEC, for *in vitro* diagnostic medical devices according to Annex X to Directive 98/79/EC, and for the other medical devices according to Annex XII to Directive 93/42/EEC. Marks and inscriptions which are likely to mislead third parties with regard to the meaning or graphic design of the CE marking may not be used. All

other marks may be affixed to the medical device, the packaging or the instructions for use provided that the visibility, legibility and significance of the CE marking are not reduced as a result.

(2) The CE marking must be affixed by the person specified in the provisions governing the conformity assessment procedures in accordance with the ordinance issued under Section 37, sub-section 1.

(3) The CE marking pursuant to sub-section 1, sentence 1 must appear in a clearly visible, legible and indelible form on the medical device and, where applicable, on the sales packaging and instructions for use. It is not necessary for the CE marking to appear on the medical device if the latter is too small, its nature does not allow for it or if it is not appropriate. The CE marking must be accompanied by the identification number of the relevant notified body which was involved in the conformity assessment procedure pursuant to Annexes 2, 4 and 5 to Directive 90/385/EEC, Annexes II, IV, V and VI to Directive 93/42/EEC, as well as Annexes III, IV, VI and VII to Directive 98/79/EC, which resulted in the right to affix the CE marking. In the case of medical devices which have to bear a CE marking and which are placed on the market in a sterile condition, the CE marking must appear both on the sterile packaging and on the sales packaging where appropriate. Where a conformity assessment procedure which is not to be conducted by a notified body is stipulated for a medical device, the CE marking may not be accompanied by the identification number of a notified body.

Section 10

Prerequisites for the first placing on the market and the putting into service of systems and procedure packs as well as for the sterilisation of medical devices

(1) Medical devices which bear a CE marking and have been put together in keeping with their intended purpose, within the limits of use specified by the manufacturer for the first placing on the market in the form of a system or procedure pack, do not have to be subjected to a conformity assessment procedure. The person who is responsible for putting the system or procedure pack together must draw up a declaration in such a case according to the ordinance pursuant to Section 37, sub-section 1.

(2) Where the system or procedure pack incorporates medical devices or other devices which do not bear the CE marking in accordance with the present Act, or where the chosen combination of medical devices is no longer compatible with their original intended purpose, the

system or procedure pack must be subjected to a conformity assessment procedure according to the ordinance pursuant to Section 37, sub-section 1.

(3) Any person who sterilises, for the purpose of placing on the market for the first time, systems or procedure packs referred to in sub-section 1 or 2 or other medical devices bearing the CE mark intended by their manufacturer to be sterilised before use must, in accordance with the ordinance provided for in Section 37, sub-section 1, conduct a conformity assessment procedure and draw up a declaration. This applies accordingly in cases where medical devices which are used in a sterile condition are reprocessed and supplied to others after they have been placed on the market for the first time.

(4) Medical devices, systems and procedure packs referred to in sub-sections 1 and 3 are not to be affixed with an additional CE marking. Any person who puts together the systems or procedure packs referred to in sub-section 1 or sterilises these as well as the medical devices referred to in sub-section 3, shall ensure that, in keeping with Section 7, the medical device is accompanied by the information required under numbers 11 to 15 of Annex 1 to Directive 90/385/EEC, under numbers 13.1, 13.3, 13.4 and 13.6 of the Annex I to Directive 93/42/EEC or numbers 8.1, 8.3 to 8.5 and 8.7 of Annex I to Directive 98/79/EC including the information delivered by the manufacturer of the devices put together to form the system or procedure pack.

Section 11

Special regulations regarding placing on the market and putting into service

(1) By way of derogation from the provisions contained in Section 6, sub-sections 1 and 2, the competent higher federal authority may authorise for a limited period of time, on duly justified application, the first placing on the market or putting into service in Germany, of individual medical devices for which the procedures according to the ordinance pursuant to Section 37, sub-section 1, have not been carried out if their use is in the interest of the protection of health. The authorisation may be prolonged in response to a well-founded application.

(2) Medical devices may only be supplied to users if the information destined for their use is written in the German language. In justified cases, another language which is easily understood by the user of a medical device can be envisaged or provisions can be made to ensure that the user is informed by other means. However, in such a case, the information bearing on safety must be present in German or in the language of the user.

(3) Regulations governing the prescription requirement for medical devices may be laid down by means of ordinances pursuant to Section 37, sub-section 2, regulations governing the distribution channels of medical devices, by means of ordinances pursuant to Section 37, sub-section 3.

(3a) *In vitro* diagnostic medical devices for the diagnosis of HIV infections may be made available only to:

1. physicians,
2. out-patient and in-patient facilities of the health care system, wholesale establishments and pharmacies,
3. the health authorities of the Federal Government, the *Laender*, municipalities and associations of municipalities.

(4) Regulations governing establishments and facilities which place medical devices on the market or store them in Germany can be issued by means of ordinances pursuant to Section 37, sub-section 4.

Section 12

Custom-made devices, medical devices manufactured in-house, medical devices intended for clinical investigation, performance evaluation or exhibition

(1) Custom-made devices may only be placed on the market or put into service if they meet the essential requirements pursuant to Section 7 which are applicable to them taking account of their intended purpose, and if the conformity assessment procedure required for them according to the ordinance pursuant to Section 37, sub-section 1, has been carried out. The person responsible under Section 5 is obliged to submit a list of the custom-made devices to the competent authority upon request. With respect to the putting into service of medical devices manufactured in-house pursuant to Section 3, nos. 21 and 22, the provisions contained in sentence 1 shall apply correspondingly.

(2) Medical devices which are intended for clinical investigations may only be supplied for this purpose to physicians, dentists or other persons whose professional qualifications authorise them to conduct such investigations if, in the case of active implantable medical de-

vices, the requirements of number 3.2, sentences 1 and 2 of Annex 6 to Directive 90/385/EEC, and in the case of other medical devices, the requirements contained in number 3.2 of Annex VIII to Directive 93/42/EEC have been fulfilled. The sponsor of a clinical investigation shall keep the documentation referred to in number 3.2 of the Annex 6 to Directive 90/385/EEC for at least 15 years and the documentation referred to under number 3.2 of Annex VIII to Directive 93/42/EEC for at least five and, in the case of implantable medical devices, at least 15 years after completion of the investigation.

(3) *In vitro* diagnostic medical devices for performance evaluation purposes may only be supplied for this purpose to physicians, dentists or other persons whose professional qualifications authorise them to conduct such studies if the requirements pursuant to number 3 of Annex VIII to Directive 98/79/EC have been met. The sponsor of the performance evaluation study must keep the documentation pursuant to number 3 of Annex VIII to Directive 98/79/EC for at least five years after completion of the study.

(4) Medical devices which do not meet the prerequisites laid down in Section 6, subsections 1 and 2 or Section 10, may only be exhibited if a visible sign clearly indicates that such devices do not conform to the prerequisites and cannot be purchased until they have been made to comply. In the case of demonstrations, the necessary precautions for the protection of persons must also be taken. *In vitro* medical devices exhibited on the basis of sentence 1, may not be used on specimens obtained from a visitor to the exhibition.

Section 13

Classification of medical devices, differentiation from other devices

(1) Medical devices with the exception of *in vitro* medical devices and active implantable medical devices shall be divided into classes. The classification shall take place according to the classification rules contained in Annex IX to Directive 93/42/EEC.

(2) In the event of a difference of opinion between the manufacturer and the notified body regarding the application of the afore-mentioned rules, the notified body shall refer the matter for decision to the competent higher federal authority.

(3) Furthermore, the competent higher federal authority shall decide on the classification of individual medical devices and the differentiation of medical devices from other devices, when requested to do so by a competent authority.

(4) The competent authority shall transmit all decisions on the classification of medical devices and on the differentiation of medical devices from other products to the German Institute for Medical Documentation and Information (DIMDI) for central processing and use pursuant to Section 33, sub-section 1, sentence 1. This shall apply *mutatis mutandis* to decisions taken by the competent higher federal authority pursuant to sub-sections 2 and 3.

Section 14

Installation, operation, use and maintenance of medical devices

Medical devices may only be installed, operated, used and maintained in accordance with the ordinance issued under Section 37, sub-section 5. They may not be operated and used if they exhibit defects which could place patients, employees or third persons at risk.

Part Three

Notified bodies and certificates

Section 15

Designation and supervision of bodies, approval and subcontracting to testing laboratories

(1) The Federal Ministry of Health shall inform the Federal Ministry of Economic Affairs and Technology of the notified bodies designated by the competent authority to carry out tasks in connection with the conformity assessment procedure pursuant to the ordinance referred to in Section 37, sub-section 1 and of their area of responsibility, and the Federal Ministry of Economic Affairs and Technology shall pass on this information to the Commission of the European Communities and the other States Party to the Agreement on the European Economic Area. An application for designation as a notified body can be placed with the competent authority. The prerequisite for the designation of such a body is that its competence and compliance with the criteria in Annex 8 to Directive 90/385/EEC, Annex XI to Directive 93/42/EEC or Annex IX to Directive 98/79/EC, depending on the procedure for which it is to be designated, is confirmed by the competent authority in a designation procedure. Those bodies that meet the criteria laid down in the individual national standards adopted pursuant to the relevant harmonised standards are presumed to meet the relevant criteria. The designation can be issued subject to conditions and is to be granted for a limited period. The Federal Ministry of Health must be notified immediately of the issue, termination, withdrawal, revocation or expiry of the designation.

(2) The competent authority shall monitor compliance with the obligations and requirements for notified bodies laid down in sub-section 1. It shall give instructions for the removal of any defects found or for the prevention of future infringements. The monitoring of notified bodies who participate in the execution of conformity assessment procedures for medical devices, which emit ionising radiation or contain radioactive substances, shall be carried out by the *Laender* on behalf of the Federal Government. The competent authority can request information and other assistance required in fulfilment of its monitoring tasks from the notified body and its staff designated for the management and execution of specialist tasks; it is authorised to accompany the notified body during inspections. Its officers are authorised to enter and inspect property and business premises as well as testing laboratories during operating and business hours and to request to see documents relating to the issue of certificates and providing evidence of fulfilment of the requirements contained in sub-section 1, sentence 2. The right of entry extends to the manufacturer's property provided the monitoring takes place there. Section 26, sub-sections 4 and 5 apply accordingly.

(3) Bodies about which the Commission of the European Communities and the other Member States of the European Community have been notified based on a legal instrument of the Council of the European Union or the European Commission by a State Party to the Agreement on the European Economic Area, are on a par with notified bodies pursuant to sub-section 1.

(4) An announcement regarding the German notified bodies as well as their specific tasks and their identification number shall be made by the competent authority on its website.

(5) If a notified body subcontracts its tasks to testing laboratories, it must ensure that the latter comply with the criteria in Annex 8 to Directive 90/385/EEC, Annex XI to Directive 93/42/EEC or Annex IX to Directive 98/79/EC required for the procedures they are to be subcontracted to carry out. The fulfilment of the minimum requirements is to be verified by the competent authority through an approval procedure.

Section 15a

Designation and supervision of conformity assessment bodies for third countries

(1) With the designation as a conformity assessment body for third countries, a natural or legal person or a partnership with legal capacity is authorised to conduct tasks related to the conformity assessment of medical devices for the named third country or countries within the framework of the specific agreement of the European Communities with third states or organisa-

tions pursuant to Article 228 of the EC Treaty (third-country agreements). Section 15, sub-sections 1 and 2 shall apply *mutatis mutandis*.

(2) The basis for the designation as a conformity assessment body for third countries is a designation procedure conducted by the competent authority to establish the body's competence to conduct its tasks in keeping with the corresponding sectoral requirements of the individual agreement.

(3) The designation as a conformity assessment body for third countries can be granted with conditions and shall be limited in time. The Federal Ministry of Health and the institutions named in the individual agreements shall be notified immediately of the issuing, termination, withdrawal, revocation and expiry of the designation.

Section 16

Expiry, withdrawal, revocation and suspension of the designation

(1) The designation shall end on the expiry date if the notified body ceases to operate or relinquishes the designation. The competent authority shall be notified immediately of the cessation or relinquishment.

(2) The competent authority shall withdraw the designation if it subsequently becomes known that a notified body, at the time of its designation, did not comply with the conditions for designation; it shall revoke the designation if the conditions for the designation subsequently cease to exist. The suspension of the designation can be ordered instead of the revocation.

(3) In the case of sub-sections 1 and 2, the previous notified body is obliged to make available all relevant information and documents to the notified body appointed by the manufacturer to continue the conformity assessment procedures.

(4) The competent authority shall inform the Federal Ministry of Health and the other competent authorities in Germany immediately of the expiry, withdrawal or revocation stating the reasons and the measures deemed necessary. The Federal Ministry of Health shall immediately inform the Federal Ministry of Economic Affairs and Technology which then immediately informs the Commission of the European Communities and the other States Party to the Agreement on the European Economic Area. The competent authority shall announce the expiry, withdrawal or revocation of a designation on its website.

(5) Sub-sections 1, 2 and 4 shall apply *mutatis mutandis* to conformity assessment bodies for third countries.

Section 17

Duration of the validity of certificates issued by notified bodies

(1) In cases where the certificates issued by the relevant notified body within the context of a conformity assessment procedure on the basis of the ordinance referred to in Section 37, sub-section 1, is of limited validity, such certificates may, upon application, be prolonged for an additional period of five years at maximum in each case. Should the notified body in question no longer exist, or should other grounds require a switch to a different notified body, the application may be made to another notified body.

(2) The application for a prolongation shall be accompanied by a report containing information about whether and, if so, to what degree the criteria used for the conformity assessment have changed since the issuing or prolongation of the certificate of conformity. Failing any other arrangement with the notified body, the application must be submitted no later than six months before expiration of validity.

Section 18

Restriction, suspension and withdrawal of certificates, notification obligations

(1) If a notified body determines that the conditions for issuing a certificate are not or are no longer fulfilled by the manufacturer, or that the certificate should not have been issued, it shall, taking into consideration the principle of proportionality, restrict, suspend or withdraw the certificate unless the person responsible ensures compliance with the conditions through appropriate remedial action. The notified body shall take the necessary measures immediately.

(2) Before taking a decision on a measure pursuant to sub-section 1, the notified body shall consult the manufacturer unless such a consultation is not possible owing to the urgency of the required decision.

(3) The notified body shall inform:

1. the German Institute for Medical Documentation and Information immediately of all certificates issued, amended and supplemented and, stating the grounds, of all certificates re-

fused, restricted, withdrawn, suspended and reinstated; Section 25, sub-sections 5 and 6 shall apply accordingly,

2. its competent authority, immediately, in cases where an intervention by the competent authority could prove necessary,
3. the other notified bodies or competent authorities of all its certificates, on request, and shall make additional information available, if required, on request,
4. at the request of third parties, regarding information in certificates which have been issued, modified, supplemented, suspended or withdrawn.

(4) The German Institute for Medical Documentation and Information shall notify the authority in charge of the person responsible pursuant to Section 5, as well as the competent federal authority, the Commission of the European Communities, the other States Party to the Agreement on the European Economic Area, electronically, of restricted, refused, suspended, reinstated or withdrawn certificates and shall grant the notified bodies access to this information.

Part Four

Clinical evaluation, performance evaluation, clinical investigation, performance evaluation studies

Section 19

Clinical evaluation, performance evaluation

(1) Evidence of the suitability of medical devices for the specified intended purpose shall be provided through a clinical evaluation based on clinical data pursuant to Section 3, number 25, unless, in exceptional cases with good reason, other data are sufficient. The clinical evaluation shall include the evaluation of adverse effects, as well as the acceptability of the risk-benefit balance mentioned in the basic requirements contained in Directive 90/385/EEC and Directive 93/42/EEC. The clinical evaluation shall be conducted on the basis of a defined and methodologically impeccable procedure and shall, if necessary, take relevant, harmonised standards into account:

(2) Evidence of the suitability of *in vitro* diagnostic medical devices for the specified intended purpose should be provided through performance evaluation based on appropriate data. The performance evaluation should be based on:

1. data from scientific literature which cover the intended use of the medical device and the techniques involved in its use as well as a written report containing a critical evaluation of these data or
2. the results of all performance evaluation studies or other appropriate tests.

Section 20

General prerequisites for clinical investigations

(1) Clinical investigations of medical devices may only be commenced in Germany, if the responsible ethics committee has issued a favourable opinion on the clinical investigation pursuant to Section 22 and the competent higher federal authority has authorised it pursuant to Section 22a. In the case of clinical investigations of medical devices with a negligible safety risk, the competent higher federal authority can waive the need for an authorisation. Details of this procedure are regulated in an ordinance pursuant to Section 37, sub-section 2a. Clinical investigations of medical devices may only be performed on human beings if and as long as:

1. the risks to the person on whom they are to be performed are medically justifiable when weighed against the medical device's potential significance for medicine,
 - 1a. a sponsor or his/her representative whose registered place of business is in a Member State of the European Union or in another State Party to the Agreement on the European Economic Area, is present,
2. the person on whom they are to be performed has granted consent after having been informed of the nature, significance and implications of the clinical investigation by a physician or by a dentist, in the case of medical devices intended for use in dentistry, and with this consent at the same time declares that he/she agrees with the recording of health-related data within the framework of the clinical investigation and with the inspection of such data for the purpose of verifications by the sponsor's representative or the competent authority,
3. the person on whom they are to be performed has not been committed to an institution by virtue of an order issued either by the courts or by an authority,
4. the clinical investigation is conducted in a suitable facility and by an appropriately qualified investigator and under the responsibility of either an appropriately qualified and special-

ised physician, also by a dentist in the case of medical devices destined for use in dentistry, or by a person who is otherwise qualified and authorised for this purpose and able to prove at least two years' experience in the clinical investigation of medical devices,

5. where appropriate, biological safety testing reflecting the latest scientific knowledge or any other test deemed necessary in the light of the medical device's intended purpose has been conducted,
6. where necessary, the technical safety of the medical device with regard to its use has been proven, taking into consideration the state of the art as well as provisions in the field of occupational safety and accident prevention,
7. the investigators have been informed of the results of the biological safety tests and the technical safety tests as well as the potential risks associated with the clinical investigation,
8. an investigational plan reflecting the latest scientific knowledge exists, and
9. in the event that a person is killed or a person's body or health is harmed or impaired in the course of the clinical investigation, an insurance policy, which also provides benefits when no one else accepts liability for the damage, exists in accordance with the provisions contained in sub-section 3.

(2) Consent pursuant to sub-section 1, number 2, is only valid if the person granting it is:

1. capable of contracting and of understanding the nature, risks, significance and implications of the clinical investigation and able to form a rational intention in the light of these facts, and
2. has granted consent personally and in writing.

Consent may be revoked at any time.

(3) The insurance pursuant to sub-section 1, number 9, must be taken out with an insurance carrier authorised to conduct business in Germany, with the person affected by the clinical investigation as beneficiary. Its size must be commensurate with the risks associated with the clinical investigation and must be concluded, on the basis of the risk assessment, in such a way that in every case of death or permanent disablement of a participant in a clinical investigation,

it provides a minimum coverage of 500,000 Euro. In so far as compensation is paid by the insurance, the right to damages shall expire.

(4) Sub-sections 1 to 3 shall apply to a clinical investigation performed on minors subject to the following proviso:

1. The medical device must be intended for the detection or prevention of diseases in minors.
2. The use of the medical device must be indicated in accordance with scientific medical knowledge for the purpose of detecting disease in the minor or protecting the minor from disease.
3. Clinical investigations performed on adults cannot be expected to produce satisfactory test results according to scientific medical knowledge.
4. Consent is granted by the minor's legal representative or person having the care of the minor. It is only valid if they have been informed by a physician, or in the case of medical devices intended for use in dentistry also by a dentist, about the nature, significance and implications of the clinical investigation. If the minor is capable of understanding the nature, significance and implications of the clinical investigation and able to form a rational intention in the light of these facts, his/her written consent is also necessary.

(5) In the case of clinical investigations involving pregnant women or nursing mothers, sub-sections 1 to 4 shall apply with the following proviso: the clinical investigation may only be performed if:

1. the medical device is intended for the purpose of preventing, detecting, treating or alleviating diseases among pregnant women, nursing mothers or unborn children,
2. the use of the medical device is indicated, according to scientific medical knowledge, for the purpose of detecting diseases or the course of diseases among pregnant women, nursing mothers and unborn children, of treating or alleviating the same or protecting pregnant women, nursing mothers and unborn children against disease,
3. according to scientific medical knowledge, performing the clinical investigation is not expected to expose the unborn child to any unacceptable risks, and

4. according to scientific medical knowledge, satisfactory test results can only be expected if the clinical investigation is performed on pregnant women or nursing mothers.

Section 21

Special prerequisites for clinical investigations

The conduct of clinical investigations on persons suffering from a disease in the cure of which the investigational device is intended to be used is subject to Section 20, sub-sections 1 to 3, under the following proviso:

1. The clinical investigation may only be conducted if the use of the device under investigation is indicated according to medical scientific knowledge in order to save the patient's life, to restore him or her to health or to alleviate his or her suffering.
2. The clinical investigation may also be performed on a person who is legally incapacitated or whose capacity to contract is limited. It requires the consent of the person's legal representative. In addition to this, the consent of the person represented is also necessary if he or she is capable of understanding the nature, significance and implications of the clinical investigation and able to form a rational intention in the light of these facts.
3. The consent of the legal representative is only valid if the latter has been informed by a physician or, in the case of medical devices intended for use in dentistry, also by a dentist, regarding the nature, significance and implications of the clinical investigation. Section 20, sub-section 2, sentence 2 shall apply to the revocation of consent. The consent of the legal representative is not required in cases where it is necessary to treat the patient without delay to save his or her life, restore him or her to good health or to alleviate suffering and where a declaration of consent cannot be procured.
4. The consent of the patient or the patient's legal representative is also valid if it is given orally, either to the attending physician or, in the case of medical devices intended for use in dentistry, also to the dentist in attendance in the presence of a witness who was also included in the process by which the affected person was informed. The witness may not be a person employed at the investigation site, nor may he/she be a member of the investigation team. Consent granted orally must be documented in writing, dated and signed by the witness.

Section 22

Procedure regarding the ethics committee

(1) The favourable opinion of the ethics committee required pursuant to Section 20, sub-section 1, sentence 1 shall be applied for, by the sponsor, from the independent, interdisciplinary ethics committee that is responsible for the investigator under Land law. If the clinical investigation is conducted by several investigators, the application has to be made to the independent, interdisciplinary ethics committee responsible for the principal investigator or the chief investigator. In the case of multi-centre clinical investigations, one opinion is sufficient. Further details concerning the setting up, composition and financing of the ethics committee shall be determined on the basis of Land law. The sponsor shall submit to the ethics committee, all the information and documents which the latter needs for the evaluation. For the purpose of evaluating the documents, the ethics committee may use its own scientific findings, invite experts or solicit expert opinions. It must invite experts or solicit expert opinions in the case of a clinical investigation on minors if it does not possess its own specialist knowledge in the area of paediatrics, including the ethical and psychological questions of paediatrics. Further details regarding the procedure shall be regulated in an ordinance pursuant to Section 37, sub-section 2a.

(2) The task of the ethics committee shall be to discuss and examine the investigational plan and the required documents, especially from an ethical and legal perspective, as to whether the preconditions pursuant to Section 20, sub-section 1, sentence 4, numbers 1 to 4 and 7 to 9, as well as sub-sections 4 and 5 and pursuant to Section 21, are fulfilled.

(3) The favourable opinion may only be refused, if:

1. the submitted documents remain incomplete, even after an appropriate deadline, granted to the sponsor for the purpose of completion, has expired,
2. the documents submitted, including those referring to the investigational plan, the investigator's brochure and the modalities for the choice of clinical investigation participants, do not correspond to the current state of scientific knowledge, in particular if the clinical investigation is unsuitable for proving the safety, performance levels or functioning of the medical device, or
3. the requirements contained in Section 20, sub-section 1, sentence 4, numbers 1 to 4 and 7 to 9, as well as sub-sections 4 and 5 and the requirements contained in Section 21 are not fulfilled.

(4) The ethics committee shall communicate a decision on the application pursuant to sub-section 1 within a deadline of 60 days after submission of the necessary documents. It shall, additionally, inform the competent higher federal authority of its decision.

Section 22a

Authorisation procedure at the competent higher federal authority

(1) The necessary authorisation pursuant to Section 20, sub-section 1, sentence 1 shall be applied for, by the sponsor, at the competent higher federal authority. The application must contain, in each case with the exception of the opinion of the relevant ethics committee, in the case of active implantable medical devices, the information pursuant to number 2.2 of Annex 6 of Directive 90/385/EEC and, in the case of other medical devices, the information pursuant to number 2.2 of Annex VII of Directive 93/42/EEC. In addition, the sponsor shall submit all of the information and documents which the competent higher federal authority requires for its assessment. The opinion of the ethics committee shall be submitted subsequently. Further details regarding the procedure shall be regulated in an ordinance pursuant to Section 37, sub-section 2a.

(2) The competent higher federal authority is responsible for examining the investigational plan and the required documents, particularly from the scientific and technical perspective, and for determining whether the prerequisites pursuant to Section 20, sub-section 1, sentence 4, numbers 1, 5, 6 and 8 are being fulfilled.

(3) The authorisation may only be refused if:

1. the documents submitted remain incomplete, even after an appropriate deadline, granted to the sponsor for the purpose of completion,
2. the medical device or the submitted documents, especially the information on the investigational plan, including the investigator's brochure, do not correspond to the latest scientific knowledge, and the clinical investigation, in particular, is not suited to proving the safety, performance characteristics or effect of the medical device on patients, or
3. the requirements listed in Section 20, sub-section 1, sentence 4, numbers 1, 5, 6 and 8 have not been fulfilled.

(4) The authorisation shall be deemed granted if the competent higher federal authority fails to communicate to the sponsor any objections together with the grounds therefor, within 30 days subsequent to the submission of the application documents. If the sponsor fails to modify the application to meet the reasoned objections within a deadline of 90 days, the application shall be deemed to be refused.

(5) Subsequent to a decision by the competent higher federal authority on the authorisation application, or after the deadline pursuant to sub-section 4, sentence 2 has elapsed, it shall no longer be possible to submit documents to correct flaws.

(6) The competent higher federal authority shall inform the competent authority of authorised and refused clinical investigations and the opinions of the ethics committees and shall inform the competent authorities of the other States Party to the Agreement on the European Economic Area and the European Commission of refused clinical investigations. The information shall take place automatically via the information system of the German Institute for Medical Documentation and Information. Section 25, sub-sections 5 and 6 shall apply *mutatis mutandis*.

(7) The competent higher federal authority responsible for authorising a clinical investigation shall inform the competent ethics committee if it is in possession of information on other clinical investigations which are of significance for the opinion of the ethics committee on the clinical investigation at hand; this applies in particular to information on aborted or otherwise prematurely discontinued investigations. In such instances, no transmission of personal data shall take place; furthermore, business and company secrets shall remain confidential. Section 6, sentences 2 and 3 shall apply *mutatis mutandis*.

Section 22b

Withdrawal, revocation and suspension of the authorisation or of the favourable opinion

(1) The authorisation pursuant to Section 22a shall be withdrawn if it becomes known that one of the grounds for refusal pursuant to Section 22a, sub-section 3 existed at the time of issuance. It shall be revoked, if facts subsequently arise which would justify refusal pursuant to Section 22a, sub-section 3, number 2 or 3. In the cases referred to in sentence 1, the suspension of the authorisation may also be ordered for a limited period of time.

(2) The competent higher federal authority may withdraw the authorisation if the conditions surrounding the clinical investigation do not correspond to the information contained in the authorisation application or if facts give reason to doubt the safety or the scientific basis of the clinical investigation. In such a case, the suspension of the authorisation can also be ordered for a limited period of time.

(3) Before a decision pursuant to sub-sections 1 and 2 is taken, the sponsor shall be allowed a deadline of one week to submit a statement. Section 28 sub-section 2 number 1 of the Administrative Procedures Act shall apply *mutatis mutandis*. In the event that the competent higher federal authority orders the immediate withdrawal, revocation or suspension of the clinical investigation, it shall inform the sponsor immediately of this order. The lodging of an objection and action to rescind the revocation, the withdrawal or the order to suspend the authorisation shall have no suspensive effect.

(4) If the authorisation to conduct a clinical investigation is withdrawn, revoked or suspended, the clinical investigation may not be continued.

(5) The favourable opinion by the competent ethics committee shall be withdrawn if the ethics committee subsequently becomes aware that grounds for a refusal pursuant to Section 22, sub-section 3 existed at the time; it shall be revoked if the ethics committee subsequently becomes aware of the fact that:

1. the requirements regarding the suitability of the investigator or of the investigation site are not fulfilled,
2. the clinical investigation participants are not properly insured,
3. the modalities for selecting clinical investigation subjects do not correspond to the current state of medical knowledge and, in particular, the clinical investigation is unsuitable for proving the safety, performance and functioning of the medical device,
4. the prerequisites for the inclusion of persons pursuant to Section 20 sub-section 4 or Section 21 are not fulfilled.

Sub-sections 3 and 4 shall apply *mutatis mutandis*. The competent ethics committee shall inform the competent higher federal authority and the other authorities responsible for surveillance immediately, stating the grounds.

(6) If the authorisation to conduct a clinical investigation is withdrawn, revoked or suspended, the competent higher federal authority shall inform the competent authorities and the authorities of the other affected Member States of the European Economic Area about the measures taken and the grounds therefor. Section 22a, sub-section 6, sentences 2 and 3 shall apply *mutatis mutandis*.

Section 22c

Changes subsequent to the authorisation of a clinical investigation

(1) The sponsor shall notify the competent higher federal authority of any changes in the documentation.

(2) Should the sponsor intend to make any essential change subsequent to the authorisation of the clinical investigation, he/she shall apply, stating the contents and the grounds for the change:

1. to the competent higher federal authority, for an assessment, and
2. to the competent ethics committee, for an opinion of the notified changes.

(3) Essential changes are changes which could:

1. have an effect on the safety of the clinical investigation participants,
2. influence the interpretation of the documents on which the conduct of the clinical investigation is based, or
3. influence the other requirements assessed by the ethics committee.

(4) The ethics committee shall arrive at a decision on the application to make changes with 30 days of its submission. Section 22, sub-section 4, sentence 2 shall apply *mutatis mutandis*.

(5) If the ethics committee approves the application and if the competent higher federal authority raises no objections within 30 days after submission of the application to make changes, the sponsor is authorised to conduct the clinical investigation according to the modified investigational plan. If conditions are imposed, the sponsor shall observe these and adapt

the documentation accordingly, or withdraw his/her application for changes. Section 22a, sub-section 6 shall apply *mutatis mutandis*. In the case of the withdrawal, revocation or suspension of the authorisation by the competent higher federal authority pursuant to sentence 1, Section 22b shall apply *mutatis mutandis*.

(6) If essential changes have to be made to a clinical investigation on the basis of measures taken by the competent higher federal authority, the competent higher federal authority shall inform the competent authorities and the competent authorities of the other affected States Party to the Agreement on the European Economic Area about the measures taken and the grounds therefor. Section 22a, sub-section 6, sentences 2 and 3 shall apply *mutatis mutandis*.

Section 23

Execution of clinical investigations

In addition to Sections 20 to 22c, the provisions contained in number 2.3 of Annex 7 to Directive 90/385/EEC shall also apply to the execution of clinical investigations regarding active implantable medical devices and, in the execution of clinical investigations regarding other medical devices, the provisions contained in number 2.3 of Annex X to Directive 93/42/EEC.

Section 23a

Announcements regarding completion or early termination of clinical investigations

(1) Within 90 days after the completion of a clinical investigation, the sponsor shall inform the competent higher federal authority of the completion of the clinical investigation.

(2) In the case of the early termination of the clinical investigation, this period shall be reduced to 15 days. The announcement shall contain all of the grounds for the early termination.

(3) The sponsor shall submit the final report to the competent higher federal authority within 12 months following the early termination or the completion of the clinical investigation.

(4) In the event that the clinical investigation is terminated early for safety reasons, the competent higher federal authority shall inform all competent authorities, the authorities of the Member States of the European Economic Area and the European Commission. Section 22a, sub-section 6, sentences 2 and 3 shall apply *mutatis mutandis*.

Section 23b

Exceptions to the provisions governing clinical investigations

Sections 20 to 23a shall not apply where the clinical investigation is conducted using devices which are authorised in accordance with Sections 6 and 10 to bear the CE marking unless the aim of the investigation is to use the device for a different intended purpose or additional invasive or other stressful examinations are to be carried out.

Section 24

Performance evaluation studies

Sections 20 to 23b shall apply *mutatis mutandis* to performance evaluation studies of *in vitro* diagnostic medical devices if:

1. invasive sampling is conducted either exclusively or to a considerably higher degree to obtain a specimen for the purpose of a performance evaluation of an *in vitro* diagnostic medical device, or
2. in the context of the performance evaluation study, additional invasive or other stressful examinations are conducted, or
3. the results obtained in the context of the performance evaluation are to be used for diagnostic purposes without it being possible to confirm them by means of established procedures.

In the remaining cases, the consent of the person from whom the specimen is to be taken is necessary, in so far as this person's personal rights or commercial interests are affected.

Part Five

Supervision and protection from risks

Section 25

General obligation to notify

(1) A person responsible within the meaning of Section 5, sentences 1 and 2, who has his/her registered place of business in Germany and places medical devices, with the exception of those referred to in Section 3, no. 8, on the market for the first time, must notify the competent authority thereof before commencing activities, giving his/her address. This also applies to

companies and facilities which reprocess medical devices which are intended for use in a practically germ-free or sterile condition, exclusively for others.

(2) Any person who assembles systems or procedure packs pursuant to Section 10, sub-section 1 or sterilises these as well as medical devices pursuant to Section 10, sub-section 3 and has his/her registered place of business in Germany, shall notify the competent authority, giving his/her address, the name and, in the case of systems or procedure packs, the description of the medical devices in question before commencing with such activities.

(3) Any person responsible under Section 5, sentences 1 and 2 who has his/her registered place of business in Germany and places *in vitro* diagnostic medical devices on the market for the first time, shall notify the competent authority of the following, giving his/her address, before commencing activities:

1. information relating to the reagents, reagent products and calibration and control materials in terms of the common technological characteristics and analytes as well as the appropriate information regarding other *in vitro* diagnostic medical devices,
2. in the case of *in vitro* diagnostic medical devices, pursuant to Annex II to Directive 98/79/EC and *in vitro* diagnostic medical devices for self-testing, all information which enables the identification of these *in vitro* diagnostic medical devices, the analytical and, if necessary, diagnostic parameters pursuant to Annex I, Section A, no. 3 to Directive 98/79/EC, the results of the performance evaluation as well as details regarding certificates,
3. in the case of a “new *in vitro* diagnostic medical device” within the meaning of Section 3, no. 6, in addition, the information that it consists of a “new *in vitro* diagnostic medical device”.

(4) Changes made to the particulars referred to in sub-sections 1 to 3 thereafter, as well as the cancellation of the placing on the market, must also be communicated without delay to the competent authority.

(5) The competent authority shall transmit the data referred to in sub-sections 1 to 4 to the German Institute for Medical Documentation and Information (DIMDI) for central processing and use in accordance with Section 33. The latter shall inform the Commission of the European

Communities and the other States Party to the Agreement on the European Economic Area, upon request, about the notifications referred to in sub-sections 1 to 4.

(6) Further details regarding sub-sections 1 to 5 are regulated in the ordinance provided for in Section 37, sub-section 8.

Section 26

The conduct of supervision

(1) Enterprises and facilities with their registered places of business in Germany on whose premises medical devices are manufactured, clinically investigated, subjected to performance evaluation studies, packaged, exhibited, placed on the market, installed, operated and used, or in which medical devices intended for use in a practically germ-free or sterile condition are reprocessed, are, in this respect, subject to supervision by the competent authority. This also applies to sponsors and persons who pursue the activities referred to in sentence 1 on a professional basis as well as persons and associations of persons who collect medical devices for others.

(2) The competent authority shall take the necessary measures to remedy violations found or to prevent future violations. It shall examine to an appropriate degree, taking into account possible risks, whether the prerequisites have been fulfilled for the placing on the market, putting into service, installing, operating and use of the medical device. Should there be sufficient indications of the unlawful use of the CE marking or a risk emanating from the medical device, it can demand that the person responsible under Section 5 have the medical device checked by an expert. Sentence 2 shall apply *mutatis mutandis* to the supervision of clinical investigations, performance evaluation studies and the reprocessing of medical devices which are intended for use in a practically germ-free or sterile condition. In the case of an *in vitro* diagnostic medical device pursuant to Section 3, no. 6, it can at any time within the two year period following the notification referred to in Section 25 sub-section 3, and with sufficient justification, require the submission of a report on the experience gathered with the new *in vitro* diagnostic medical device since the first placing on the market.

(2a) The competent authorities must have at their disposal the personnel and equipment needed to fulfil their tasks and shall ensure regular further training for the supervisory personnel, which meets the generally recognised scientific and technical standards.

(2b) The details regarding sub-sections 2 and 2a, in particular those referring to the implementation and quality assurance of the supervisory activities shall be regulated by a general administrative regulation pursuant to Section 37a.

(3) Persons charged with supervisory functions are authorised to:

1. enter upon and inspect, at normal hours of business, land, business premises, factory premises, motor vehicles and, to avert imminent danger to public safety and order, even dwellings in which activities of the sort mentioned in sub-section 1 are carried out; the basic constitutional right of the inviolability of the home (Article 13 of the Basic Law (*Grundgesetz*)) shall be limited in this respect,
2. inspect and examine medical devices and, in particular, have these put into service for this purpose or take samples,
3. inspect documentation on the development, manufacture, testing and clinical investigation, performance evaluation studies or the acquisition, reprocessing, storage, packaging, placing on the market and other whereabouts of the medical devices or on the promotional materials currently in circulation and to make copies or photocopies thereof in duly justified cases,
4. demand all the necessary information, especially about the operations referred to in number 3.

Appropriate compensation is to be paid for samples not taken from persons responsible under Section 5, unless the right to such compensation is expressly waived.

(4) Any party subject to supervision pursuant to sub-section 1 is bound by law to tolerate the measures contained in sub-section 3, sentence 1, nos. 1 to 3 and to support the persons charged with supervisory functions as well as all other persons involved in the supervision in the performance of their duties. This includes, especially the obligation to allow such persons access to the medical devices, to permit the necessary tests, to make available the necessary staff and aids, and to furnish the relevant information and documents.

(5) The party obligated in the context of supervision can refuse to answer such questions if he/she has reason to fear that answering them could expose him/her or one of the relatives

specified in Section 383, sub-section 1, nos. 1 to 3 of the German Code of Civil Procedure (*Zivilprozeßordnung*) to the danger of prosecution under criminal law or a lawsuit according to the Regulatory Offences Act (*Gesetz über Ordnungswidrigkeiten*).

(6) Experts who conduct examinations in the context of sub-section 2, must possess the necessary expertise to do so. Proof of such expertise may also take the form of a certificate from a body accredited by the competent authority.

(7) Upon request, the competent authority shall inform the Federal Ministry for Health as well as the competent authorities of the other States Party to the Agreement on the European Economic Area about inspections conducted, their results as well as the measures taken.

Section 27

Procedures in the event of the unlawful and wrongful affixing of the CE marking

(1) If the competent authority establishes that the CE marking has been unlawfully affixed to a medical device, the responsible person within the meaning of Section 5 shall be obliged to fulfil the requirements for the lawful affixing of the CE marking in accordance with the instructions of the competent authority. If the responsible person fails to fulfil said requirements, the competent authority shall restrict the placing on the market of the medical device in question, make its placing on the market contingent on the fulfilment of certain conditions, prohibit the same or have the medical device withdrawn from the market. It shall inform the other competent authorities in Germany and the Federal Ministry for Health of any such acts and the latter shall, in turn, inform the Commission of the European Communities and the other States Party to the Agreement on the European Economic Area thereof.

(2) If a device wrongfully bears the CE marking indicating it to be a medical device, the competent authority shall take the necessary measures pursuant to sub-section 1, sentence 2. Sub-section 1, sentence 3 shall apply *mutatis mutandis*.

Section 28

Procedures for the protection against risks

(1) The competent authority pursuant to this Act shall take all necessary measures to protect the health or the safety of the patient, users and other persons from dangers arising from medical devices unless the Atomic Energy Act or an ordinance based on it for medical devices which emit ionising radiation or contain radioactive substances, provides corresponding powers for the relevant competent authority.

(2) The competent authority is, in particular, authorised to issue orders, including those regarding the closure of the enterprise or facility if necessary to avert imminent danger to public health, safety and order. It can prohibit, limit or make contingent upon specific conditions the placing on the market, putting into service, operating and use of medical devices as well as the commencement or continuation of the clinical investigation or the performance evaluation study, or order the recall or seizure of the medical device. It shall inform the other competent authorities in Germany, the competent higher federal authority and the Federal Ministry for Health of such action.

(3) If the competent authority determines that a CE-marked medical device or custom-made device is able to endanger the health or safety of patients, users or third-parties or their property, even when properly installed, maintained or used in accordance with their intended purpose, and should it take measures aimed at removing the medical device from the market or prohibiting or limiting the placing on the market or putting into service, it shall inform the Federal Ministry for Health without delay, giving the reasons for the action, to enable the initiation of a safeguard clause procedure pursuant to Article 7 of Directive 90/385/EEC, Article 8 of Directive 93/42/EEC or Article 8 of Directive 98/79/EC. The reasons should state, in particular, whether the non-compliance with the provisions of this Act are to be attributed to:

1. the non-fulfilment of the essential requirements,
2. the inadequate application of harmonised standards or common technical specifications, if such application is claimed, or
3. a deficiency in the harmonised standards or common technical specifications themselves.

(4) The competent authority can have all persons who could be exposed to danger arising from a medical device informed in due time in an appropriate manner of this danger. An official warning to the public at large is admissible in cases of imminent danger where other equally effective measures cannot be taken or cannot be taken in time.

(5) The measures referred to in Article 14b of Directive 93/42/EEC and Article 13 of Directive 98/79/EC shall be taken by the Federal Ministry for Health by means of an ordinance pursuant to Section 37, sub-section 6.

Section 29

Medical Devices Vigilance System

(1) In so far as competence does not lie with one of the highest federal authorities pursuant to the Atomic Energy Act or the ordinances issued on the basis thereof, the competent higher federal authority – in order to avert danger to the health and safety of patients, users or other parties – shall ensure the central collection, analysis and evaluation of the risks arising from the use or application of medical devices, in particular, adverse effects, interactions with other substances or products, contra-indications, falsifications, operational defects, malfunctions and technical defects. It shall co-ordinate the necessary measures to be taken especially as regards all serious, adverse events during clinical investigations or performance evaluation studies of *in vitro* diagnostic medical devices or the following incidents:

1. any operational problem, any failure or change in the characteristics or performance of a medical device as well as any inaccuracies in the labelling or instructions for use which has led, or could have led, directly or indirectly, to the death or serious deterioration in the state of the health of a patient, user or another person,
2. any technical or medical reason, which, as a result of the causes mentioned in number 1, is related to the characteristics and performance of the medical device and has led to the systematic recall of medical devices of the same type by the manufacturer.

Section 26, sub-section 2, sentence 3 applies accordingly. The competent higher federal authority shall inform the competent authority of the result of the evaluation and the latter shall decide on the necessary measures. The competent higher federal authority shall transmit data resulting from the observation, collection, analysis and evaluation of risks in connection with medical devices, to the German Institute for Medical Documentation and Information (*DIMDI*) for central processing and use pursuant to Section 33. Further details shall be regulated in the ordinance referred to in Section 37, sub-section 8.

(2) The name, address and date of birth of patients, users and other persons may be transmitted to the competent authorities, in so far as this is necessary for the fulfilment of the tasks referred to in sub-section 1. The competent authority under sub-section 1 may, upon request, inform the authority competent under Land law about the cases which it has notified and the information gathered in respect of personal data. In the context of collaboration under sub-section 3, none of the patient's personal data may be transmitted. Sentence 3 also applies to the transmission of data to the information system referred to in Section 33.

(3) In fulfilling the tasks referred to in sub-section 1, the authority under sub-section 1 shall collaborate with: the authorities of the other States Party to the Agreement on the European Economic Area, and the Commission of the European Communities; the World Health Organization; the authorities of other countries responsible for public health as well as occupational safety and health; the authorities of the Laender responsible for public health, occupational safety and health, radiation protection, and metrology and other higher federal authorities which are concerned from a technical viewpoint; notified bodies in Germany; the competent occupational accident insurance funds; the medical advisory service of the Central Federal Association of the health insurance funds; the pertinent professional societies; the manufacturers and distributors; as well as other bodies which compile data on risks associated with medical devices in the fulfilment of their tasks. If any incident is suspected to have been caused by an electromagnetic interaction with any device other than a medical device, then the Federal Office for Posts and Telecommunications shall be involved.

(4) Details regarding the execution of the tasks contained in Section 29 shall be regulated by the safety plan referred to in Section 37, sub-section 7.

Section 30

Safety officer for medical devices

(1) The person responsible according to Section 5, sentences 1 and 2 and who has his/her registered place of business in Germany shall, immediately upon commencement of his/her activities, appoint a person who is sufficiently reliable and possesses the expert knowledge necessary for the fulfilment of his/her functions as the safety officer for medical devices.

(2) If the person responsible according to Section 5, sentences 1 and 2 is not exclusively placing medical devices pursuant to Section 3, no. 8 on the market for the first time, he/she shall notify the competent authority immediately of the name of the safety officer as well as of any changes thereto. The competent authority shall transmit the data referred to in sentence 1 to the German Institute for Medical Documentation and Information (*DIMDI*) for central processing and use pursuant to Section 33.

(3) Proof of the necessary expert knowledge qualifying the person in question for the post of safety officer shall be provided in the form of:

1. a certificate testifying to a completed course of natural science, medical or technical university studies, or
2. any other course of training which qualifies such person to fulfil the tasks set forth under sub-section 4,

as well as at least two years' professional experience. Upon demand by the competent authority, proof of the relevant expert knowledge shall be adduced.

(4) The safety officer for medical devices shall collect and evaluate existing information concerning risks connected to medical devices and shall co-ordinate the necessary measures. He/she is responsible for the fulfilment of reporting obligations in so far as they concern risks related to medical devices.

(5) The safety officer for medical devices shall suffer no disadvantage by executing the tasks entrusted to him/her.

Section 31

Medical devices consultant

(1) Any person who provides technical information to experts or instructs them in the proper handling of medical devices on a professional basis (medical devices consultant), may only carry out such an activity if he/she possess, for the specific medical device, the requisite expert knowledge as well as the experience needed to provide information and, where necessary, instruction in the handling of specific medical devices. The first sentence shall also apply to information given by telephone.

(2) The following shall be deemed to have the necessary expert knowledge:

1. any person who has successfully completed a course of studies in a natural science, medical or a technical profession and has received training on specific medical devices, or
2. any person who, for a period of at least one year, in justified cases also for a shorter period of time, has gained the necessary experience in informing and, where necessary, instructing others in the handling of specific medical devices.

(3) The medical devices consultant shall furnish the competent authority, upon request, with proof of his/her expert knowledge. The medical devices consultant shall have up-to-date knowledge of the specific medical devices so as to be able to provide competent advice. The sponsor shall ensure that the medical devices consultant receives regular training.

(4) The medical devices consultant shall take written record of reports from experts bearing on adverse effects, interactions, malfunctions, technical defects, contra-indications, falsifications or other risks associated with medical devices and transmit them in writing without delay to the person responsible according to Section 5, sentences 1 and 2 or that person's safety officer for medical devices.

Part Six

Competent authorities, ordinances, miscellaneous provisions

Section 32

Tasks and competences of the higher federal authorities in the field of medical devices

(1) The Federal Institute for Drugs and Medical Devices is particularly responsible for:

1. the tasks pursuant to Section 29, sub-sections 1 and 3,
2. the evaluation of the technical and medical requirements and the safety of medical devices, unless otherwise provided for in the present Act or unless competence lies with other higher federal authorities,
3. the authorisation of clinical investigations and performance evaluation studies pursuant to Sections 22a and 24,
4. decisions regarding the differentiation and classification of medical devices pursuant to Section 13, sub-sections 2 and 3,
5. special marketing authorisations pursuant to Section 11, sub-section 1, and
6. advising the competent authorities, the person responsible pursuant to Section 5, sponsors and notified bodies.

(2) The Paul Ehrlich Institute is responsible for the tasks contained in sub-section 1, in so far as *in vitro* diagnostic medical devices mentioned in Annex II to Directive 98/79/EC are con-

cerned which are intended for testing the safety or compatibility of blood or tissue donations or are related to infectious diseases. A technically independent testing laboratory can be set up at the Paul Ehrlich Institute which can collaborate with the notified bodies and other organisations.

(3) The *Physikalisch-Technische Bundesanstalt* is responsible for ensuring the uniformity of metrology in medicine and shall:

1. perform expert evaluations of medical devices with measuring functions and, in so far as it is designated for that purpose pursuant to Section 15, carry out type examinations,
2. develop and, upon request, test reference measuring procedures, standard measuring devices and testing aids,
3. furnish scientific advice to the competent authorities and notified bodies.

Section 33

Database-supported information system, European database

(1) The German Institute for Medical Documentation and Information (*Deutsches Institut für medizinische Dokumentation und Information*) shall set up an information system on medical devices to support the enforcement of the present Act and shall make available the information required for this purpose to the federal and Land authorities responsible for medical devices. It shall make available the necessary data for the European database referred to in Article 10b of Directive 90/385/EEC, Article 14a of Directive 93/42/EEC and Article 12 of Directive 98/79/EC. The making available of such information to non-public bodies is admissible insofar as this is provided for in the ordinance referred to in Section 37, sub-section 8. The Institute may charge for its services. Such charges are to be specified in a catalogue of charges subject to the approval of the Federal Ministry of Health.

(2) The institute referred to in sub-section 1 shall have the following principal tasks within the meaning of said sub-section:

1. the central processing and use of information pursuant to Section 25, sub-section 5, also in conjunction with Section 18, sub-section 3, Sections 22a to 23a and 24,
2. the central processing and use of basic information concerning the medical devices already on the market,

3. the central processing and use of data compiled from the observation, recording, analysis and evaluation of risks in connection with medical devices,
4. the acquisition of information and the transmission of data to databases in other Member States and institutions of the European Communities and the other States Party to the Agreement on the European Economic Area, especially in the context of the detection and prevention of risks connected with medical devices,
5. the establishment and maintenance of access to databases, which have a connection with medical devices.

(3) The institute specified in sub-section 1 shall take the necessary measures so that data is transmitted only to authorised persons or that only such persons have access to the same.

Section 34

Export

(1) Upon application by the manufacturer or his/her authorised representative, the competent authority shall issue a certificate stating that the medical device in question is marketable in Germany.

(2) Medical devices which are subject to a prohibition as referred to in Section 4, sub-section 1, may only be exported if the competent authority of the country of destination has authorised the import after having been informed by the competent authority regarding the reasons for the prohibition.

Section 35

Costs

Payment (fees and outlays) shall be required for official acts pursuant to the present Act and the ordinances issued for the purpose of the implementation of the present Act as prescribed in Section 37, sub-section 9. In so far as the Federal Ministry for Health fails to make use of the empowerment, the Land governments shall be empowered to issue corresponding statutory provisions. The Administrative Costs Act (*Verwaltungskostengesetz*) shall be applicable.

Section 36

**Co-operation between the authorities and notified bodies in the
European Economic Area and the European Commission**

The authorities and notified bodies responsible for the implementation of the legislation on medical devices shall co-operate with the competent authorities and notified bodies of the other States Party to the Agreement on the European Economic Area and the European Commission and will furnish one another with the necessary information to ensure uniform application of the provisions adopted to implement Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

Section 37

Delegated powers to issue ordinances

(1) The Federal Ministry for Health is empowered to issue ordinances which stipulate the prerequisites for issuing conformity certificates, the conduct of conformity assessment procedures and the assignment of medical devices to classes as well as special procedures for systems and procedure packs for the purpose of implementing legal instruments of the European Communities.

(2) The Federal Ministry for Health is empowered to issue ordinances stipulating prescription-only status for medical devices which:

1. could directly or indirectly endanger human health, even when used in accordance with their intended purpose, if used without the supervision of a physician or dentist,
2. are used often and to a considerable extent in a manner which is not in accordance with their intended purpose if this poses a direct or indirect threat of human health.

Additional supply restrictions may be specified in the ordinance referred to in sentence 1.

(2a) The Federal Ministry of Health is empowered to issue ordinances containing regulations on the proper conduct of the clinical investigation and the performance evaluation study requiring an authorisation, as well as the obtention of documents which meet scientific standards. The ordinance may contain, in particular, regulations concerning:

1. the tasks and responsibilities of the sponsor, the investigators or other persons who conduct or supervise the clinical investigation including obligations to notify, to document and to report, in particular on serious adverse events occurring during the clinical investigation which could compromise the safety of the study participants or the conduct of study itself,

2. the tasks of and procedure within the ethics committee, including the documents to be submitted, including information on the adequate participation of men and women as participants in the clinical investigation, the interruption, prolongation or reduction of the processing deadline and the special requirements placed on the ethics committee in the case of clinical investigations pursuant to Section 20, sub-sections 4 and 5, as well as Section 21,
3. the tasks of the competent authorities and the official authorisation procedure, including the documents to be submitted together with information on the adequate participation of women and men as participants in the study and the interruption, prolongation or reduction of the processing deadline, the procedure for the inspection of documents in enterprises and facilities, as well as the prerequisites and the procedure for the withdrawal, revocation and suspension of the authorisation or the disallowance of a clinical investigation,
4. the requirements on the testing facility and the keeping and storage of protocols,
5. the transmission of the name and address of the sponsor and the responsible investigator and non-personalised information on the clinical investigation by the competent authority to a European database,
6. the manner in which documents and copies of the decisions are to be transmitted to the competent authorities and the appointment of the ethics committees responsible for the investigator,
7. special regulation for medical devices with a minor safety risk.

(3) The Federal Ministry for Health is empowered to issue ordinances specifying distribution channels for medical devices where considered necessary to maintain the necessary quality of the medical device or to fulfil the necessary conditions for the safety of patients, users and other persons in the supply and use of medical devices.

(4) The Federal Ministry for Health is empowered to issue ordinances containing regulations for enterprises or facilities (internal regulations), which place medical devices on the market or store them in Germany, where necessary to ensure proper operation and the required quality, safety and performance of the medical devices and to avoid endangering the safety and health of patients, users and other persons. The ordinance can lay down, in particular, regula-

tions concerning storage, purchase, distribution, information and advice as well as instruction on the operation of medical devices including performance tests after installation, and the use of medical devices. The regulations can also be issues for persons who exercise the activities in question on a professional basis.

(5) The Federal Ministry for Health is empowered to issue ordinances:

1. stipulating requirements for the installation, operation, use and maintenance of medical devices, adopting regulations governing the training of operators and users, technical safety controls, performance tests, notification obligations, and details of notification obligations concerning incidents and risks, the inventory list and medical devices log book and other requirements where necessary to ensure the safe operation and safe use or the proper maintenance of medical devices,
 - 1a. stipulating requirements on the safe reprocessing of medical devices intended for use in a practically germ-free or sterile condition and drawing up regulations on:
 - a) additional regulations on reprocessors who reprocess medical devices, which are subject to especially high reprocessing requirements,
 - b) the certification of reprocessors pursuant to letter a,
 - c) the requirements to be placed on conformity assessment bodies, recognised by the competent authority, which conduct the certification pursuant to letter b,
2.
 - a) stipulating requirements regarding the quality assurance system in operating and using *in vitro* diagnostic medical devices,
 - b) drawing up regulations concerning:
 - aa) the fixing and application of quality assurance standards, the procedure for drawing up guidelines and recommendations, the scope, content and responsibilities, the participation of the affected persons as well as
 - bb) the scope, frequency and inspection procedures, as well as the requirements to be placed on the bodies responsible for the inspection and the procedure for appointing them, and

- c) laying down that the standards, guidelines and recommendations or their references are to be published by the Federal Ministry for Health in the Federal Gazette,
- 3. guaranteeing the measuring accuracy of medical devices with a measuring function, determining which medical devices with a measuring function are to be subject to measurement-related controls and determining that the operator, an appropriate body or the competent authority must conduct measurement-related tests as well as enacting provisions on the scope, frequency and the procedure to be applied in measurement-related controls, the prerequisites, the scope of and the procedure for recognition and monitoring the bodies responsible for conducting measurement-related controls as well as the obligations of the operator of a medical device with a measuring function to co-operate in measurement-related controls.

(6) The Federal Ministry for Health is empowered to issue ordinances to prohibit or limit the availability of a specific medical device or a group of medical devices or subject them to special conditions for reasons of health protection and safety or in the interest of public health pursuant to Article 30 of the EC Treaty.

(7) The Federal Ministry for Health is empowered to issue ordinances to set up a safety plan to fulfil the tasks connected with the medical devices vigilance system pursuant to Section 29. In this ordinance, in particular, the tasks of and co-operation between the participating authorities and bodies as well as the involvement of the manufacturers and their authorised representatives, importers, the persons responsible for placing on the market, other traders, the uses and operators, the Commission of the European Communities as well as other States Party to the Agreement on the European Economic Area, will be regulated in greater detail and the measures to be taken, in each case, determined. Moreover, in the safety plan, details can be regulated concerning risk assessment and its conduct, the obligation to co-operate of those responsible according to Section 5, sentences 1 and 2, other traders, users, operators, persons responsible for maintenance, details of the notification procedure, and its publication, notification, reporting, recording and retention obligations, tests and production monitoring, details regarding the implementation of measures to avert risk and their monitoring as well as information obligations, methods and channels. Furthermore, the safety plan can include regulations on personal data in so far as they are recorded, processed and used in the context of risk prevention.

(8) The Federal Ministry for Health is empowered to regulate, by means of ordinances, further details including those relating to the type and scope of as well as the requirements to be

placed on such data in order to ensure the proper collection, processing and use of data pursuant to Section 33, sub-sections 1 and 2. Such an ordinance may also contain provisions stipulating the fees to be charged by the institute mentioned therein for its services.

(9) The Federal Ministry for Health is empowered to determine, by ordinance, the elements liable to a fee pursuant to Section 35 and, in the process, specify fixed rates and ranges. The fees shall be calculated in such a way as to cover the personnel and material costs associated with the official acts. The ordinance may contain provisions to the effect that a fee may also be charged for an official act which has not been completed if the fault lies with the person who instigated said official act.

(10) The Federal Ministry for Health is empowered to issue ordinances enacting provisions to fulfil the obligations arising out of inter-State agreements or to implement legal acts of the Council or the Commission of the European Communities which affect the fields to which this Act applies especially safety and medical requirements, the manufacture and other prerequisites of the placing on the market, operation, use, exhibiting, especially tests, production monitoring, certificates, labelling, storage and notification obligations official measures, as well as requirements on the designation and supervision of notified bodies.

(11) The ordinance pursuant to sub-sections 1 to 10 shall be issued with the consent of the *Bundesrat*, in agreement with the Federal Ministry of Economics and Technology. They shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, in so far as protection from radiation is concerned or in the case of medical devices in the manufacture of which ionising radiation is used and in agreement with the Federal Ministry of Labour and Social Affairs where safety at work is concerned and in agreement with the Federal Ministry of the Interior, in so far as data protection is concerned.

(12) The ordinances pursuant to sub-sections 6 and 10 do not require the consent of the *Bundesrat* in cases of imminent danger or if their immediate entry into force is necessary to implement legal acts of the bodies of the European Community. The ordinances pursuant to sub-sections 1 to 3 can be issued without the consent of the *Bundesrat* if unforeseen dangers to health so require. In so far as the ordinance pursuant to sub-section 9 affects costs of federal authorities, it does not require the consent of the *Bundesrat*. The ordinances pursuant to sentences 1 and 2 do not require the agreement of the individual federal ministries involved. They shall expire at the latest six months after entry into force. The duration of their validity can only be prolonged with the consent of the *Bundesrat*. This shall be without prejudice to the provisions contained in sub-section 11 in so far as radiation protection is concerned.

Section 37a

General administrative ordinances

The Federal Government shall issue, with the consent of the *Bundesrat*, the general administrative ordinances necessary for the implementation of the present Act, in particular those regarding the conduct and quality assurance of the supervision, the expert knowledge of the persons entrusted with the supervision, the equipment, the exchange of information and the co-operation among authorities.

Part Seven

Special regulations applying to the Federal Armed Forces

Section 38

Application and enforcement of the Act

(1) The present Act shall be applicable *mutatis mutandis* to such facilities as supply the German Federal Armed Forces (*Bundeswehr*) with medical devices.

(2) In the sphere of responsibility of the German Federal Armed Forces, the enforcement of the present Act and the pertinent supervision shall be incumbent on the competent agencies and experts of the German Federal Armed Forces.

Section 39

Exceptions

(1) In cases where the essential requirements referred to under Section 7 provide for a statement regarding the expiry date, an exception may be made for medical devices supplied to the German Federal Armed Forces. The Federal Ministry of Defence shall take measures to ensure that the quality, performance and the safety of the medical devices are guaranteed. Sentence 1 shall apply *mutatis mutandis* to medical devices which are supplied to the competent authorities of the Federal Government or the Federal Laender for the purpose of civil protection and disaster control. The competent authorities shall ensure that the quality, performance and safety of the medical devices are guaranteed.

(2) The Federal Ministry of Defence may permit exceptions to the present Act and to such ordinances as have been issued under the authority of the present Act, for its own sphere of responsibility, with the agreement of the Federal Ministry for Health and, in so far as safety at

work is affected, with the Federal Ministry of Labour and Social Affairs, in individual cases, provided that they do not conflict with legal instruments of the European Communities, are justified by reason of the special tasks to be performed and are compatible with the protection of health.

Part Eight

Criminal provisions and regulatory fining provisions

Section 40

Criminal provisions

(1) Any person who:

1. violates the provisions of Section 4, sub-section 1, no. 1 by placing a medical device on the market or installing, putting into service, operating or using the same,
2. violates the provisions of Section 6, sub-section 1, sentence 1 by placing on the market or putting into service any medical device which is subject to the provisions of the Radiation Protection Ordinance or the X-ray Ordinance or in the manufacture of which ionising radiation has been used,
3. violates the provisions of Section 6, sub-section 2, sentence 1 in conjunction with an ordinance pursuant to Section 37, sub-section 1 by affixing the CE marking to any medical device which is subject to the provisions of the Radiation Protection Ordinance or the X-ray Ordinance or in the manufacture of which ionising radiation has been used, or
4. violates the provisions of Section 14, sentence 2, by operating or using a medical device,

shall be imprisoned for up to three years or shall be fined.

(2) The attempt to commit such acts is punishable.

(3) In especially serious cases, such acts shall be punishable by imprisonment for a period of one to five years. A case shall be deemed to be especially serious, as a rule, if, by committing one of the acts referred to in sub-section 1, the offender:

1. endangers the health of a large number of persons,

2. exposes another person to the risk of death or to the risk of serious injury to that person's body or health, or
3. out of gross self-interest, acquires large amounts of property for personal profit or the profit of another.

(4) If in the cases referred to in sub-section 1, the offender is guilty of negligence, he/she shall be imprisoned for a period of up to one year or fined.

Section 41 Criminal provisions

Any person who:

1. violates the provisions of Section 4, sub-section 2, sentence 1 in conjunction with sentence 2 by placing a medical device on the market,
2. violates the provisions of Section 6, sub-section 1, sentence 1 by placing on the market or putting into service any medical device which is not subject to the provisions of the Radiation Protection Ordinance or the X-ray Ordinance or in the manufacture of which ionising radiation has not been used,
3. violates the provisions of Section 6, sub-section 2, sentence 1 in conjunction with an ordinance pursuant to Section 37, sub-section 1, by affixing the CE marking to a medical device which is not subject to the provisions of the Radiation Protection Ordinance or the X-ray Ordinance or in the manufacture of which ionising radiation has not been used,
4. violates the provisions of Section 20, sub-section 1, sentence 1 or sentence 4, numbers 1 to 6 or number 9, in each case also in conjunction with Section 20, sub-section 4 or sub-section 5, or Section 21, number 1 or contravenes Section 22b, sub-section 4 by beginning a clinical investigation, conducting a clinical investigation or continuing a clinical investigation,
5. violates the provisions of Section 24, sentence 1, in conjunction with Section 20, sub-section 1, sentence 1 or sentence 4, numbers 1 to 6 or number 9, in each case, also in conjunction with Section 20, sub-section 4 or sub-section 5, or violates Section 24, sentence 1, in conjunction with Section 22b, sub-section 4, by beginning a performance

evaluation study, conducting a performance evaluation study, continuing a performance evaluation study, or

6. fails to comply with the provisions of an ordinance pursuant to Section 37, sub-section 2, sentence 2 in so far as it refers to these criminal provisions in connection with a specific offence,

shall be imprisoned for a period of up to one year or fined.

Section 42

Regulatory fining provisions

(1) An administrative offence shall be deemed to be committed by any person who negligently perpetrates one of the acts referred to in Section 41.

(2) An administrative offence shall be deemed to be committed by any person who wilfully or negligently:

1. violates the provisions of Section 4, sub-section 1, no. 2 by placing on the market, putting into service, operating or using a medical device,
2. violates the provisions of Section 9, sub-section 3, sentence 1, by failing to affix the CE marking or to affix it properly in the stipulated manner,
3. violates the provisions of Section 10, sub-section 1, sentence 2 or sub-section 3, sentence 1, also in conjunction with sentence 2 and, in each case in conjunction with an ordinance pursuant to Section 37, sub-section 1 by failing to issue a notification or by failing to do so properly, completely or on time,
4. violates the provisions of Section 10, sub-section 4, sentence 2, by not causing a medical device to be accompanied by information,
5. violates the provisions of Section 11, sub-section 2, sentence 1 or sub-section 3a, by supplying a medical device,

6. violates the provisions of Section 12, sub-section 1, sentence 1, in conjunction with an ordinance pursuant to Section 37, sub-section 1, by placing a custom-made device on the market or putting the same in service,
7. violates the provisions of Section 12, sub-section 2, sentence 1 or by supplying a medical device,
8. violates the provisions of Section 12, sub-section 4, sentence 1 by placing a medical device on exhibition,
9. violates the provisions of Section 12, sub-section 4, sentence 3 by using an *in vitro* diagnostic medical device,
10. violates the provisions of Section 20, sub-section 1, sentence 4, no. 7 or 8 in each case also in conjunction with Section 21, no. 1 by conducting a clinical investigation,
11. violates the provisions of Section 25, sub-section 1, sentence 1, sub-section 2, 3 or 4 or Section 30, sub-section 2, sentence 1, by not giving notice, or by not giving notice properly, completely or on time,
12. violates the provisions of Section 26, sub-section 4, sentence 1 by failing to tolerate a measure or support a person,
13. violates the provisions of Section 30, sub-section 1 by failing to appoint a safety officer or failing to do so in time,
14. violates the provisions of Section 31, sub-section 1, sentence 1, also in conjunction with sentence 2 by engaging in an activity,
15. violates the provisions of Section 31, sub-section 4 by failing to record information, or failing to record it properly, completely or in the stipulated manner or by failing to transmit the same or to transmit it on time,
16. fails to comply with an ordinance pursuant to Section 37, sub-sections 1, 2a, 3, 4, sentence 1 or 3, sub-section 5, nos. 1, 2, letter a or b, double letter bb or no. 3, sub-section 7 or 8, sentence 1 or an enforceable ruling based on such an ordinance, in so far as such ordinance refers to the present regulatory fining provision for a specific case.

(3) An administrative offence shall be punishable with a fine of up to twenty-five thousand euros.

Section 43 Confiscation

Objects implicated in a criminal offence pursuant to Section 40 or Section 41 or an administrative offence pursuant to Section 42, can be confiscated. Section 74a of the Criminal Code (*Strafgesetzbuch*) and Section 23 of the Act on Administrative Offences (*Gesetz über Ordnungswidrigkeiten*) shall be applicable.

Part Nine Transitional provisions

Section 44 Transitional provisions

(1) Medical devices with an expiry date before 30th June 2007, which had been supplied to the competent authorities of the Federal Government or the Federal Laender for the purpose of civil protection or disaster control or to the Federal Armed Forces for the fulfilment its special tasks may continue to be used even after the expiry date has passed. The competent authorities shall ensure that the quality, performance and safety of the medical devices are guaranteed.

(2) The provisions contained in the present Act shall become applicable to medical devices within the meaning of Section 3, no. 3 as of 13th June 2002. Medical devices pursuant to Section 3, no. 3 may still be placed on the market in Germany for the first time until 13th December 2005 pursuant to the regulations in force in Germany on 13th December 2000. The further placing on the market and the putting into service of the medical devices placed on the market for the first time pursuant to the above, shall be admissible until 13th December 2007.

(3) The provisions contained in Section 14 as well as the ordinance pursuant to Section 37, sub-section 5 shall apply irrespective of the provisions pursuant to which the medical devices were first placed on the market.

(4) For clinical investigations pursuant to Section 20 and performance evaluation study pursuant to Section 24 of the Medical Devices Act which were commenced prior to 20th March

2010, Sections 19 to 24 of the Medical Devices Act in the version published on 7th August 2002 (Federal Law Gazette I, p. 3146), last amended by Article 1 of the Act of 14th June 2007 (Federal Law Gazette I, p. 1066) shall continue to apply.

(5) For clinical investigations and performance evaluation studies pursuant to subsection 4, the Medical Devices Safety Plan Ordinance of 24th June 2002 (Federal Law Gazette I, p. 2131), last amended by Article 3 of the Act of 14th June 2007 (Federal Law Gazette I, p. 1066) shall apply from 21st March 2010 in the version valid in each case resulting from Article 3 of the Act of 29th July 2009 (Federal Law Gazette I, p. 2326).