COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

on in vitro diagnostic medical devices

Draft
DECISION OF THE EEA JOINT COMMITTEE

amending Annex II, technical regulations, standards, testing and certification, to the Agreement on the European Economic Area

- Draft common position of the Community -

(presented by the Commission)

EXPLANATORY MEMORANDUM

I. GENERAL CONTEXT

As part of the programme to complete the internal market, the rules for placing medical devices on the market are being harmonized throughout the Community to protect patients, users and third parties. Most medical-devices are covered already by the Directives on active implantable medical devices (90/385/EEC)[1] and on medical devices (93/42/EEC).[2]

In vitro diagnostic medical devices were defined as medical devices in Directive 93/42/EEC but, in view of their special nature, were excluded from the abovementioned Directives. They are covered by this proposal. "In vitro diagnostic medical device" means, essentially, reagents, instruments and equipment for examining tissues or substances from the human body for medical purposes.

Unlike medicinal products, which are administered to the human body, in vitro diagnostic devices are used outside the human body for medical examinations of samples taken from the patient. These devices are therefore important tools for diagnosing illnesses, monitoring patients' state of health, checking the progress of courses of treatment and a whole series of other medical applications (for example, AIDS, hepatitis and glucose tests, pregnancy tests, tests for congenital abnormalities, etc.). Any malfunctioning of these devices could lead to misdiagnosis, in some cases with grave consequences for the health and treatment of the patients or for third parties who could be infected by contagious diseases.

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1 OJ No L 189, 20.7.1990, p. 17.

2 OJ No L 169, 12.7.1993, p. 1.

These devices are used mainly by medical laboratories, doctors and pathologists. A growing proportion, however, are intended to be used by the patients themselves (for example, glucose or pregnancy tests).

The public interest covered by this proposal concerns the reliability, performance and precision of the devices in their medical application. In addition, the Directive provides protection for the health and safety of professional or private users and third parties against the risks inherent in the devices.

Unlike the other medical devices already covered by Directives 90/385/EEC and 93/42/EEC, in vitro diagnostic devices do not usually enter into contact with the patient. To take account of this unique feature and of the different risks posed compared with other medical devices, this Directive covers such devices to complement the existing legislation in this sector.

This proposal for a Directive is based on Article 100a of the Treaty. Furthermore, it takes into account Article 129 of the Treaty which stipulates that Community action shall be directed towards the prevention of diseases and that health protection requirements shall form one constituent part within other Community policies.

It applies the principles of the new approach to technical harmonization. The proposal lays down the essential requirements which devices placed on the market must meet and the conformity assessment procedures with which manufacturers must comply.

Before drafting this proposal, the Commission ordered a comparative study of the national legislation on such devices (cf. Section III). Its findings, together with the broad-based consultations held since 1991 with experts from the Member States, industrial circles and users, confirmed the need for this Directive and paved the way for drafting it.

II. ECONOMIC IMPORTANCE OF THE SECTOR

Estimates put total worldwide production of medical devices, of which in vitro diagnostic devices are one subsector, at ECU 80 billion in 1993 (source: Health Industry Manufacturers' Association, HIMA). In 1993 the breakdown of production by country of origin was as follows: USA 52%; EC + EFTA 28% (EC 26%); Japan 18%. Since 1990 consumption has grown by 6% per year in the Community (by 7% in the USA in 1993 and by 6% in Japan).

Some 50% of the Community market is supplied by the Community's own producers, 43% by US makers and 5% by Japanese manufacturers. In 1993 the estimated number of jobs provided by this industry in the EC stood at over 240 000.

Research is particularly important to the performance of this sector. According to sources in the industry, an average of 5.9% of its turnover is invested in research (EC 5%; USA 6.7%; Japan 6%).

The in vitro diagnostic medical device subsector covered by this proposal accounts for between 16% and 18% of the total medical device market. This amounted to a total world market in these devices of some ECU 12.2 billion in 1992 (source: European Diagnostics Manufacturers' Association, EDMA). In 1992 the EC/EFTA took ECU 4.6 billion of this market, giving them a world market share of 38% (USA 39%; Japan 12%).

European industry is highly developed in this subsector. It holds an extremely competitive position on the world market. An estimated 400 or so businesses, most of them medium-sized, are active in this field in the EC and EFTA countries. Germany is the largest producer in Europe. France, the United Kingdom, Italy, Belgium and the Netherlands also have major industries.

In vitro diagnostic medical device technology has developed rapidly over the last thirty years.

The success of the technology is due, in particular, to the progress made with the development of scientific methods of analysis in the fields of chemistry, biochemistry and immunology, to the increase in the biological parameters available and to the combination of these data and methods with microelectronics, automation and information technology. Research activity in this industry is above average for the sector. Research accounts for between 15 and 20% of the jobs in this subsector.

III. LEGISLATION ON IN VITRO DIAGNOSTIC MEDICAL DEVICES AND EVALUATION OF THE NEED FOR LEGISLATION

1. Existing legislation

Before starting the harmonization work, in 1991 the Commission conducted a study to compare and analyse several Member States' national legislation on this subject. This revealed that the Member States' legislation differed not only in terms of the products covered but also on the detailed rules and the level of protection. Moreover, most of the legislation did not cover all the reagents, instruments, equipment and complete complex systems used for biomedicine, for which legislation is needed to provide an appropriate level of protection of health and safety.

Based on the abovementioned study, the current situation as regards the Member States' legislation can be summed up as follows:

* Some Member States have no legislation specifically on in vitro diagnostic devices, except on selected products which are particularly sensitive from the public health point of view. This is the case in the United Kingdom, Spain, Italy and the Netherlands where, in essence, tests to detect AIDS (HIV), tests on blood intended for transfusions or a few other specific reagents are monitored by the public authorities or subjected to special regulatory procedures before they can be placed on the market.

* France recently adopted new legislation introducing a registration procedure to check the performance of reagents before they are placed on the market. Further inspections are required for certain categories of devices such as HIV tests, tests to determine blood groups and radioimmunoassays.

* Belgium applies some of the rules for medicinal products to in vitro reagents too.

* In Germany the devices in question are governed by various regulations which call for stringent monitoring of some of them. Reagents are classified as medicinal products and are subject to controls calling for the application of good manufacturing practice. Several other groups of tests (immunological tests, particularly HIV tests, tests for hepatitis and tests for venereal diseases) have to pass an authorization procedure before they can be placed on the market. In addition, laboratory instruments and equipment used in this field are covered by the legislation on metrology and product safety.

In conclusion, the study revealed big differences between the requirements imposed on the devices by the national regulatory systems, particularly with regard to labelling, authorization or registration procedures and production control.

In the USA, the Community's leading trading partner and the biggest producer, in vitro diagnostic devices (reagents, laboratory instruments and equipment for biomedicine) have been governed by the legislation on medical devices since 1976. A series of special rules on, for example, labelling, manufacturing, etc. take account of the specific nature of these devices. The rules on good manufacturing practice are compulsory.

2. *European standardization*

Work already done by the European standardization bodies CEN/CENELEC will smooth the way for implementation of the future Community legislation. A number of "horizontal" standards on medical devices in general also apply to in vitro diagnostic devices and more specific work has been carried out on, for example, the information which must be supplied to users or on laboratory equipment. Some of this work has already been started in anticipation of this Directive.

3. *Evaluation of the need for harmonization*

There is a danger that the current differences between the national regulatory systems could deepen in the future. In particular, several Member States have already begun to legislate on in vitro diagnostic devices, notably when reorganizing their national legislation to implement Directives 90/385/EEC and 93/42/EEC on medical devices.

This has been confirmed by the cases of application or non-application of Directive 83/189/EEC on the notification of draft technical regulations.[3] Under this procedure the Commission has received notification of several national regulations concerning, in particular, the introduction of monitoring arrangements for HIV and hepatitis tests or for other tests (immunological and cancer tests). In one case the Commission had to apply Directive 83/189/EEC to block a draft national technical regulation for one year pending this proposal.

The current disparities between the national systems, plus those which would follow with the adoption of further national legislation in the absence of European harmonization, create barriers to the free movement of these devices in the Community. The diverging requirements applied with regard to the devices covered and the monitoring procedures make it virtually impossible to establish any equivalence between the various national provisions in terms of health protection. For this reason, application of the principles of mutual recognition based on Article 30 of the Treaty will be insufficient and inappropriate for removing and preventing barriers in this sector. Establishment of European standards by the CEN/CENELEC alone, without a regulatory framework, will not be enough to remedy the situation described above, given the voluntary nature of the standards. Consequently, harmonization of the legislation is the most appropriate means of ensuring free trade, all the more so since such Community legislation already exists for most other medical devices.

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[3] OJ No L 109, 26.4.1983, p. 8, as last amended by Directive 94/10/EC of the European Parliament and the Council, OJ No L 100, 19.4.1994, p. 30.

From the economic point of view, there is a danger that the lack of harmonized legislation could hamper the development of this industry in the Community. The diverging regulations force manufacturers to adapt their products to the situation on the individual national markets. They are therefore unable to benefit from the Community market as their internal market. By contrast, harmonized conditions for placing products on the market would enable them to achieve economies of scale. Also, once manufacturers have adapted their products and processes to the Community legislation, they can expect the harmonization of legislation to cut the costs of complying with the regulations which are higher at the moment because of the need to comply with the varying national systems and procedures.

The introduction of Community legislation taking account of the specific nature of the devices in question will generate added value for the development of the European industry and enable it to benefit more fully from the dimension of the internal market. In contrast to the current situation, such legislation will create stable, foreseeable regulatory conditions and at the same time encourage the industry to proceed with research and make the necessary investments. In this way, it will contribute towards making the European industry more competitive on the world market.

Finally, the Community legislation will have an impact on trading relations with non-Community countries. Once this proposed Directive has been adopted, the Community will be able to use it in its international negotiations to improve access for the European industry to markets in third countries.

Since 1991 the Commission has organized several meetings to consult experts from the Member States, the industry and users on the results of the comparative analysis of the legislative systems in a number of Member States and the evaluation of the need for harmonization of the legislation and the content thereof. The conclusions drawn confirmed the Commission's view that, in view of the big differences between the national systems, of the obstacles to free trade and of their negative impact on industrial activity on the European market, harmonization of the legislation is necessary and will provide added value, both for protecting health and for the activities of the European industry concerned. In particular, all concerned have recognized the need for harmonization of the legislation. The consultations also showed that, as far as possible, this harmonization must complement and follow the same lines as the harmonization already completed for other medical devices.

IV. JUSTIFICATION IN THE LIGHT OF THE SUBSIDIARITY PRINCIPLE

1. What are the objectives of the proposed action in relation to the Community's obligations?

As explained in Section III, the objective of this proposal for a Directive is:

* to ensure free movement of in vitro diagnostic medical devices by harmonizing the national legislation on protection of the health and safety of patients, users and third parties;

* to complete the existing Community legislation provided by Directives 90/385/EEC and 93/42/EEC on medical devices and to apply the same principles to in vitro diagnostic devices;

* to create a favourable environment with uniform conditions of competition to enable the industry to benefit from the scale of the European Economic Area and to help make European industry more competitive.

2. *Does competence for the planned activity lie solely with the Community?*

Exclusive competence, under Article 100a in conjunction with Article 7a of the Treaty.

3. *What forms of action are available to the Community?*

In view of the objectives of removing the barriers created by the diverging regulatory systems, of preventing new barriers and of establishing a uniform, stable and foreseeable legal framework to protect the public interests concerned, the introduction of Community legislation is necessary. It must cover the manufacturing conditions, the protection requirements imposed on the devices, the conformity assessment procedures and the arrangements for monitoring the market. A Directive is the most appropriate instrument. As far as possible, the Directive will have to follow the principles already adopted for the rest of the industry in Directives 90/385/EEC and 93/42/EEC.

4. *Is it necessary to have a uniform regulation or is a Directive setting out the general objectives sufficient, leaving implementation at the level of the Member States?*

A new approach Directive is proposed. It is confined to laying down the essential safety and performance requirements to be met by devices placed on the market and refers to voluntary European standards to be established by the CEN/CENELEC for technical formulation of these requirements. At the administrative level, implementation is reserved for the Member States. They will be responsible for monitoring the market and cooperating with the authorities in the other Member States. They will also appoint the certification bodies (notified bodies), depending on the availability of suitably qualified bodies, and monitor their activities.

V. CONTENT OF THE PROPOSAL

1. Scope

This proposal for a Directive governs the conditions for placing in vitro diagnostic medical devices on the market. It lays down the essential requirements in terms of the reliability of the devices, bearing in mind their intended purpose as tools for diagnostics and medical monitoring, and in terms of protection of users and third parties. The Directive also harmonizes the conformity assessment procedures to be applied by manufacturers before placing the devices on the market. The CE marking must be affixed to devices conforming with the requirements, which will be allowed to move freely throughout the internal market.

In vitro diagnostic medical devices are a subcategory of medical devices, as already defined in Directive 93/42/EEC. They are devices used in medicine for the in vitro analysis of specimens from the human body. The medical applications include analyses of state of health (cholesterol or pregnancy tests), of diseases or congenital abnormalities, monitoring progress with a course of treatment (for example, dose and effect of medicinal products) or the establishment of compatibility in cases of organ or blood donations (for example, HIV and hepatitis tests).

The vast majority of the products covered are intended for professional users, i.e. reagents, kits, instruments and equipment specifically for medical laboratories. The Directive also includes devices for self-testing which are used by patients or consumers in the home environment, for which it lays down special requirements to ensure that these devices can be easily used correctly by users with no particular knowledge of biological analysis.

Control material and calibrators intended for use in combination with the abovementioned reagents and equipment are also considered to be in vitro diagnostic devices.

The Directive will cover laboratory equipment only where it is specifically intended for use in medical laboratories conducting in vitro examinations.

The proposal does not apply to devices, in particular reagents, manufactured by laboratories for their own needs without any transaction with other users. It is left to the discretion of the Member States whether to require the appropriate monitoring for such activities.

2. *Essential requirements*

Devices placed on the market must comply with the essential requirements set out in Annex 1 to ensure a high level of protection of health and safety. They must be designed and manufactured to achieve the performances stated by the manufacturer and for use for the intended medical purpose, taking account of the generally acknowledged state of the art. The essential requirements are also designed to protect users and third parties in particular against the risks posed by the physical and chemical properties of the devices and against the biological, mechanical, thermal, electrical and radiation risks posed by any energy source with which they are equipped. Devices for self-testing must be designed taking into account the skills and means available to users. Particular attention must be paid to the clarity of the information and instructions accompanying the devices.

3. *Conformity assessment procedures*

The conformity assessment procedures are based on Council Decision 90/683/EEC,[4] as amended by Council Decision 93/465/EEC.[5] The proposal is aligned on the wording for these procedures in Directive 93/42/EEC, taking account of the specific nature of in vitro diagnostic medical devices and of manufacture thereof.

(a) Devices placed on the market solely on the manufacturer's responsibility

For an extremely large proportion of these devices, Article 9 and Annex 3 of the proposal provide for the design and manufacture stages to be monitored on the manufacturer's responsibility, without the intervention of any third party. In view of the requirements imposed in order to control production and obtain products of reliable quality, manufacturers must follow the principles of quality assurance as appropriate for the devices manufactured. In addition, the technical documentation provided by the manufacturer must contain, inter alia, proof of the manufacturer's evaluation of the performance.

(b) Devices requiring the intervention of a notified body

Provision is made for the intervention of a notified body before devices for self-testing (Annex 3, point 6) and various categories of devices specified in Annex 2 are placed on the market.

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4 OJ No L 380, 31.12.1990, p. 13.

5 OJ No L 220, 30.8.1993, p. 23.

In the case of devices for self-testing, the intervention of a notified body is necessary as these devices are normally intended for persons with no experience of using them. For this reason, the notified body must concentrate on verification and on the performance of the devices under the conditions in which they would normally be used, taking account of the intended users.

For the categories specified in Annex 2, i.e. tests for blood grouping and for the detection of HIV and hepatitis, Article 9 and Annexes 4, 5, 6 and 7 provide for procedures requiring the intervention of a notified body. The notified bodies will certify the design and manufacture of such devices. In accordance with Decision 90/683/EEC on the certification modules, manufacturers may choose between product certification (Annexes 5 and 6), evaluation of the full quality assurance system (Annex 4) or an approach combining a type examination with a certified production quality assurance system (Annexes 5 and 7).

These stringent procedures are warranted by the fact that the tests in question are used particularly in the context of blood transfusions or organ transplants. Consequently, strict controls on these devices are essential to ensure reliable diagnosis. Moreover, HIV tests are targeted on AIDS, which must be combated with the most appropriate, effective means available in the interest of public health.

(c) Classification and reclassification of devices

The proposal allows amendment of the list of devices in Annex 2, with the assistance of a regulatory committee (cf. Article 12). This reclassification procedure could prove necessary, particularly where devices for new uses cannot provide sufficient guarantees of the reliability of their performance. In such cases, verification by a third party could be necessary on health protection grounds.

For this reason, depending on their intended medical use, performance or characteristics, certain categories of device could, if necessary, be subjected to the appropriate conformity assessment procedures within the framework of this proposal. The rules on the conformity assessment procedures are a balanced reflection of the existing national legislation in this field. By reserving conformity assessment for a large proportion of devices for the manufacturers, the proposal takes account of the fact that these devices are intended for professional users. In addition, in most Member States medical laboratories in turn are subject to outside quality assurance systems which will offer added controls.

Finally, the proposal provides for mechanisms to monitor the market, notably via vigilance procedures. If application of these mechanisms indicates a need to tighten up the controls before certain devices are placed on the market, reclassification may be decided following the committee procedures.

4. *Registration of manufacturers and vigilance procedure*

Article 10 of the proposal requires all manufacturers to inform the competent authorities of the Member State where they have their registered place of business of the categories of devices which they market. Manufacturers not established in the Community must designate an authorized representative to carry out the abovementioned notification. Notification is also required for new devices, as specified in the proposal. These rules enable the authorities to monitor the market and to take any measures necessary to protect the public interest. A network linking the authorities will therefore have to be established to make it easier to exchange data. Just as for the other medical devices covered by Directives 90/385/EEC and 93/42/EEC, this proposal introduces a vigilance procedure (Article 11). Under these rules, manufacturers will have to give notification of any malfunction of the devices which could affect patients' and users' health. The objective of this vigilance system is to prevent devices from remaining in circulation on the Community market if they display faults which could lead to the wrong medical decisions. This system reinforces the monitoring methods at the disposal of the competent authorities and encourages manufacturers to conduct the requisite investigations and make the necessary corrections to the devices concerned. Close cooperation between the national administrations will be essential in this system.

5. *Special arrangements for devices for performance evaluation*

Article 9(3) of the proposal makes special arrangements for in vitro diagnostic medical devices for performance evaluation. These apply to

devices intended for medical use of which the precise performance has yet to be verified and confirmed. In view of the objective of the evaluations, there is no need for such devices to comply with all the essential requirements. The status of these devices must be indicated on the label and the manufacturer must follow a special conformity procedure.

6. *Amendments to Directive 93/42/EEC concerning medical devices*

These amendments (Article 19(1)) concern the definition of "in vitro diagnostic medical device" in Directive 93/42/EEC. They would also extend the scope of Directive 93/42/EEC by adding devices incorporating tissues of human origin. At the time of the adoption of the Directive concerning medical devices, the Council asked the Commission to reexamine the situation with these devices and to propose the measures to be taken. Preparatory work on this subject has revealed that, at national level, either there is no legal cover for such devices or that they are governed by diverging classifications which could impair free movement. In view of the current legal uncertainty and of the inherent health hazards posed by these devices, the majority of the national experts recognize the need to make such devices subject to Directive 93/42/EEC. However, Directive 93/42/EEC will apply only to devices incorporating tissues which have been rendered non viable. The proposal will apply without prejudice to the national regulations relating to the ethics of collecting and using tissues of human origin, thereby taking account of the concerns expressed during the consultation phase.

Similar problems with the inclusion of devices incorporating tissues of human origin also arise in the case of in vitro diagnostic devices (including in the form of control materials in kits). Consequently, the proposed amendment to Directive 93/42/EEC will result in uniform rules for the entire sector.

VI. RELEVANCE TO THE EUROPEAN ECONOMIC AREA

This proposal falls into the field covered by the Agreement on the European Economic Area. The consultations included experts from the EFTA countries in the EEA. The proposal for a decision by the EEA Joint Committee extending the proposal for a Directive to the EEA is included in this dossier.

PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND THE COUNCIL

ON IN VITRO DIAGNOSTIC MEDICAL DEVICES

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the Economic and Social Committee[2],

Acting in accordance with the procedure referred to in Article 189B of the Treaty establishing the European Community,

Whereas measures should be adopted for the progressive establishment of the internal market; whereas the internal market is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas the content and scope of the laws, regulations and administrative provisions in force in the Member States with regard to the safety, health protection and performance characteristics and authorization procedures for in vitro diagnostic medical devices are different; whereas the existence of such disparities constitute barriers to trade and the need to establish harmonised rules was confirmed by a comparative survey of national legislations carried out on behalf of the Commission;

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Whereas the harmonization of national legislations is the only means of removing these barriers to free trade and preventing new barriers; whereas this objective cannot be achieved in a satisfactory manner at another level by the individual Member States; whereas this Directive only lays down necessary and sufficient requirements for the free circulation of the in vitro diagnostic medical devices to which it is applicable;

Whereas the harmonized provisions must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices; whereas, therefore, the provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with;

Whereas in vitro diagnostic medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive;

Whereas, in accordance with the principles set out in the Council resolution of 7 May 1985 concerning a new approach to technical harmonization and standardization[3], rules regarding the design and manufacture of relevant products must be confined to the provisions required to meet the essential requirements; whereas, because they are essential, such requirements should replace the corresponding national provisions; whereas the essential requirements, including requirements to minimize and reduce risks, should be applied with discretion, taking into account the technology and practice at the time of design and of technical and economic considerations compatible with a high level of protection of health and safety;

Whereas the major part of medical devices are covered by Council Directive 90/385/EEC relating to active implantable medical devices[4] and Council Directive 93/42/EEC relating to all other medical devices[5] with the exclusion of in vitro diagnostic medical devices; the present Directive shall extend the harmonization to in vitro diagnostic medical devices; whereas, in the interest of uniform Community rules, this Directive is based largely on the provisions of Directives 90/385/EEC and 93/42/EEC;

Whereas certified international reference materials and materials used for external quality assessment schemes are not covered by this Directive, calibrators and control materials needed by the user to establish or verify performances of devices are in vitro diagnostic medical devices;

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3 OJ No.C 136, 4.6.1985, p.1

4 OJ No L 189, 20.7.1990, p.17

5 OJ No. L 169, 12.7.1993, p. 1

Whereas reagents produced within user laboratories and which are not subject to commercial transactions, taking account of the principle of subsidiarity, are not included in this Directive;

Whereas the electromagnetic compatibility aspects form an integral part of the essential requirements of this Directive, the Council Directive 89/336/EEC of 3 May 1989 relating to electromagnetic compatibility [6] shall not apply;

Whereas, in order to ease the task of proving conformity with the essential requirements and to enable conformity to be verified, it is desirable to have harmonized standards in respect of the prevention of risks associated with the design, manufacture and packaging of medical devices; whereas such harmonized standards are drawn up by private-law bodies and should retain their status as non-mandatory texts; whereas, to this end, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines on cooperation between the Commission and these two bodies signed on 13 November 1984;

Whereas, for the purpose of this Directive, a harmonized standard is a technical specification (European standard or Harmonization Document) adopted, on a mandate from the Commission, by either or both of these bodies in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations[7], and pursuant to the abovementioned general guidelines;

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6 OJ No. L 139, 23.5.1989, p. 19. Directive last amended by Directive 93/68/EEC (OJ No. L 220, 30.8.1993, p. 1)

7 OJ No. L 109, 26.4.1983, p. 8. Directive last amended by Directive 94/10/EC of the European Parliament and the Council (OJ No. L 100, 19.4.1994, p. 30)

Whereas, in Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives[8], the Council has laid down harmonized conformity assessment procedures; whereas the details added to these modules are justified by the nature of the verification required for in vitro diagnostic medical devices and by the need for consistency with the previous directives on medical devices;

Whereas it is necessary, essentially for the purpose of the conformity assessment procedures, to group in vitro diagnostic medical devices into two product classes; whereas, since the large majority of such devices do not constitute a direct risk to patients and are used by competently trained professionals, and the results obtained can often be confirmed by other means, the conformity assessment procedures can be carried out, as a general rule, under the sole responsibility of the manufacturer; whereas, taking account of existing national regulations and of notifications received following the procedure of Directive 83/189/EEC, the intervention of notified bodies is needed only for defined devices, the correct performance of which is essential to medical practice and the failure of which can cause a serious risk to health;

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8 OJ No. L 380, 31.12.1990, p. 13, as last amended by Decision 93/465/EEC, OJ No. L 220, 30.8.1993, p. 23

Whereas the list of in vitro diagnostic medical devices to be subjected to third party conformity assessment needs updating, taking account of technological progress and of evolution in the domain of protection of health; whereas such updating measures must be taken in line with the procedure IIIa as laid down in the Council Decision 87/373/EEC[9]; whereas a system of adverse incident reporting (vigilance) constitutes a useful tool for the surveillance of the market, including the performance of new devices; whereas information obtained from vigilance as well as from external quality assessment schemes becomes useful for decision-making on classification of devices;

Whereas medical devices should, as a general rule, bear the CE marking to indicate their conformity with the provisions of this Directive to enable them to move freely within the Community and to be put into service in accordance with their intended purpose;

Whereas manufacturers shall have the possibility, when the intervention of a notified body is required, to choose amongst those bodies published by the Commission; whereas the Member States do not have an obligation to designate such notified bodies, they must ensure however that bodies designated as notified bodies comply with the assessment criteria laid down in this directive;

Whereas the competent authorities in charge of market surveillance must be able, particularly in emergencies, to contact the manufacturer or his authorized representative established in the Community; whereas cooperation and exchange of information between Member States are necessary in view of uniform application of this Directive, in particular for the purpose of market surveillance;

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[9] OJ no. L 197, 18.7.1987, p. 23

Whereas this Directive includes in vitro diagnostic medical devices incorporating substances derived from the human body, it does not affect national regulations relating to the ethics of use of such substances; whereas for the purpose of overall consistency between medical devices directives, the Directive 93/42/EEC needs to be amended accordingly;

HAVE ADOPTED THIS DIRECTIVE :

Article 1

Scope, Definitions

1. This Directive shall apply to in vitro diagnostic medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as in vitro diagnostic medical devices in their own right. Both in vitro diagnostic medical devices and accessories shall hereinafter be termed devices.

2. For the purpose of this Directive, the following definitions shall apply :

   (a) **"medical device"** means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of :

   - diagnosis, prevention, monitoring, treatment or alleviation of disease,
   - diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,
   - investigation, replacement or modification of the anatomy or of a physiological process,
   - control of conception

   and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

(b) **"in vitro diagnostic medical device"** means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological state, state of health or disease or congenital abnormality or to determine the safety and compatibility with potential recipients.
For the purpose of this directive, a specimen receptacle, whether evacuated or not, specifically intended by its manufacturer to contain a specimen for the purpose of in vitro diagnostic examination is considered to be a device;

Products for general laboratory use are not devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;

(c) **"accessory"** means an article which, whilst not being a device in the meaning of paragraph 2(b), is intended specifically by its manufacturer to be used together with a device to enable this device to be used in accordance with its intended purpose;

(d) "Device **for self-testing"** means any device intended by the manufacturer to be used in the home environment;

(e) "Device for performance evaluation" means any device intended by the manufacturer to be subject to one or more performance evaluation studies in clinical laboratories or in other appropriate environments outside his own premises;

(f) **"manufacturer"** means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name;

(g) **"authorized representative"** means the natural or legal person established within the Community who, being explicitely designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community in substitution for the manufacturer with regard to the latter's obligations in accordance with this Directive.

(h) **"intended purpose"** means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use and/or in promotional materials;

(i) **"placing on the market"** means the first making available in return for payment or free of charge of a device with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

(j) **"putting into service"** means the stage at which a device is ready for use on the Community market for the first time for its intended purpose;

(k) **"calibrator"**, "control material" mean any substance, material or article intended by its manufacturer to establish and/or verify performance characteristics of a device in conjunction with the use of that device;

3. Where a device incorporates tissues or substances of human origin, this directive shall not affect national regulations relating to the ethics of the collection of tissues or substances of human origin as well as any regulations relating to the ethics governing distribution of given types of devices of such origin.

4. This Directive shall not apply to devices manufactured and used only within the same institution and on the premises of their manufacture. This does not affect the right of Member States to subject such activities to appropriate protection requirements.

5. This Directive is a specific directive within the meaning of Article 2(2) of the Directive 89/336/EEC[10].

Article 2

Placing on the market and putting into service

Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they comply with the requirements laid down in this Directive when properly installed, maintained and used in accordance with their intended purpose.

Article 3

Essential requirements

Devices must meet the essential requirements set out in Annex 1 which apply to them, taking account of the intended purpose of the devices concerned.

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10 Council Directive 89/336/EEC relates to electromagnetic compatibility. OJ No. L 139, 23.5.1989, p. 19; as last amended by Directive 93/68/EEC (OJ no L 220, 30.8.1993, p. 1)

Article 4

Free movement

1. Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE-marking provided for in article 14 or labelled as devices for performance evaluation if these devices have been the subject of an assessment of their conformity in accordance with the provisions of article 9.

2. At trade fairs, exhibitions, demonstrations, Member States shall not create any obstacle to the showing of devices which do not conform to this Directive, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply.

3. Member States may require, when a device reaches the final user, information, as referred to in Annex 1 point 13, to be in their national language(s) or in other Community language(s) to the extent that it is needed for safe and correct use of the device. In the application of this provision Member States shall take into account the principle of proportionality and in particular whether information can be provided by recognised symbols or codes and whether the device is intended for use by trained professionals.

4. Where the devices are subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the devices also fulfil the provisions of the other Directives.
However, should one or more of these directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate that the devices fulfil the provisions only of those directives applied by the manufacturer. In this case, the particulars of these directives, as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by the directives and accompanying such devices.

Article 5

Reference to standards

1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards which transpose the harmonized standards the reference of which have been published in the Official Journal of the European Communities; Member States shall publish the references of such national standards

2. If the Member State or the Commission considers that the harmonized standards do not entirely meet the essential requirements referred to in Article 3, the measures to be taken with regard to these standards and the publication referred to in paragraph 1 of this Article shall be adopted by the procedure defined in Article 6(2)

Article 6

Committee on Standards and Technical Regulations

1. The Commission shall be assisted by the Committee set up by Article 5 of Directive 83/189/EEC.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

   The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

   The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account.

Article 7

Committee on Medical Devices

1. The Commission shall be assisted by the Committee set up by Article 6(2) of Directive 90/385/EEC.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referal to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission

3. The Committee referred to in paragraph 1 may examine any question connected with the implementation of this Directive.

Article 8

Safeguard clause

1. Where a Member State ascertains that the devices referred to in Article 4(1), when correctly installed, maintained and used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, and the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

   (a) failure to meet the essential requirements referred to in Article 3;

   (b) incorrect application of the standards referred to in Article 5, in so far as it is claimed that the standards have been applied;

   (c) shortcomings in the standards themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that:

- the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the parties concerned, bring the matter before the committee referred to in Article 6(1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the procedures referred to in Article 6;
- the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorized representative established within the Community.

3. Where a non-complying device bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the marking and shall inform the Commission and the other Member States thereof.

4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

Article 9

Conformity assessment procedures

1. For all devices other than those covered by Annex 2 and devices for performance evaluation, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex 3 and draw up the EC declaration of conformity required before placing the devices on the market.

For all devices for self-testing the manufacturer shall, prior to the drawing up of the aforementioned declaration of conformity, fulfil the supplementary requirements set out in Annex 3 point 6. Instead of applying this procedure, the manufacturer may also follow the procedure referred to in paragraph 2.

2. For all devices covered by Annex 2 other than those intended for performance evaluation, the manufacturer shall, in order to affix the CE-marking either :

   (a) follow the procedure relating to the EC declaration of conformity set out in Annex 4 (full quality assurance) or

   (b) follow the procedure relating to EC type examination set out in Annex 5 coupled with :

      (i) the procedure relating to EC verification set out in Annex 6, or

      (ii) the procedure relating to the EC declaration of conformity set out in Annex 7 (production quality assurance)

3. In the case of devices for performance evaluation, the manufacturer shall follow the procedure referred to in Annex 8 and draw up the statement set out in that Annex before placing such devices on the market.

4. During the conformity assessment procedure for a device, the manufacturer and, if involved, the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate stage of manufacture.

5. The manufacturer may instruct his authorized representative established in the Community to initiate the procedures provided for in Annexes 3, 5, 6 and 8.

6. The manufacturer must keep the declaration of conformity, the technical documentation referred to in Annexes 3 to 8, as well as the decisions, reports and certificates established by notified bodies, and make it available to the national authorities for inspection purposes for a period ending five years after the last product has been manufactured. Where the manufacturer is not established in the Community, the obligation to make the aforementioned documentation available on request applies to his authorized representative established within the Community.

7. Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorized representative established in the Community, may apply to a body of his choice within the framework of the tasks for which the body has been notified.

8. The notified body may require, where duly justified, any information or data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

9. Decisions taken by the notified bodies in accordance with Annexes 3, 4 and 5 shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of five years.

10. The records and correspondence relating to the procedures referred to in paragraphs 1 to 3 shall be in one of the official languages of the European Community and in the case of involvement of a notified body in a Community language acceptable to the notified body.

11. By derogation from paragraphs 1 to 3, the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 to 3 have not been carried out and the use of which is in the interest of protection of health.

Article 10

Registration of manufacturers

1. Any manufacturer, who places devices on the market under his own name, shall notify the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business, the categories of devices as defined in terms of common characteristics of technology and/or analytes and of any significant change thereto. The before mentioned notification shall also include any new device as referred to in Article 11(4).

2. Where a manufacturer, who places devices on the market under his own name, does not have a registered place of business in a Member State, he shall designate an authorized representative established in the Community. The authorized representative shall inform the competent authorities of the Member State, in which he has his registered place of business, of all particulars as referred to in paragraph 1.

3. The Member States shall on request inform the other Member States and the Commission of the details referred to in paragraphs 1 and 2. The procedures implementing the present Article shall be adopted in accordance with the procedure referred to in Article 7(2).

Article 11

Vigilance

1. Member States shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Directive, regarding the incidents mentioned below involving devices bearing CE marking is recorded and evaluated centrally :

   (a) any malfunction, failure or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

   (b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a), leading to systematic recall of devices of the same type by the manufacturer.

2. Where a Member State requires medical practitioners, the medical institutions or the organizers of external quality assessment schemes to inform the competent authorities of any incidents referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorized representative established in the Community, is also informed of the incident.

3. After carrying out an assessment, if possible together with the manufacturer, Member States shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of the incidents referred to in paragraph 1 for which relevant measures have been taken or are contemplated.

4. Where, in the context of notification referred to in Article 10, a device notified, bearing a CE marking, is a "new" product, the manufacturer shall indicate this fact on his notification. The competent authority so notified may at any time within the following two years and on justified grounds, require the manufacturer to submit a report relating to the experience with the device subsequent to its being placed on the market. For this purpose, a device is "new" if :

   (a) such a device, for the relevant analyte or other parameter, has not been continuously available on the Community market during the previous three years,

   (b) the procedure involves analytical technology not used in connection with a given analyte or other parameter on the Community market continuously during the previous three years.

5. The Member States shall on request inform the other Member States of the details referred to in paragraphs 1 and 4. The procedures implementing the present Article shall be adopted in accordance with the procedure referred to in Article 7(2).

Article 12

Modification of Annex 2, derogation clause

1. Where a Member State considers that :

   (a) the list of devices covered by Annex 2 should be modified or extended, or

   (b) the conformity of a device or a category of devices should be established by way of derogation from the provisions of Article 9, by applying one or several alternative given procedures taken from amongst those referred to in Article 9,

   it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. The measures shall be adopted in accordance with Article 7(2).

2. When a measure is to be taken in accordance with paragraph 1, due consideration shall be given :

   (a) to any relevant information available from the vigilance procedures and from external quality assessment schemes as referred to in Article 11

   (b) to the following criteria

      (i) whether total reliance has to be put on the result obtained with a given device, having a direct impact on the subsequent medical action, and

(ii) whether an action taken on the basis of an incorrect result obtained using a given device could prove to be hazardous to the patient or third party as a consequence of false positive or false negative results, and

(iii) whether the involvement of a notified body is appropriate and justified.

3. The Commission shall inform the Member States of the measures taken and, where appropriate, publish these measures in the Official Journal of the European Communities.

Article 13

Notified bodies

1. Member States shall notify the Commission and other Member States of the bodies which they have designated for carrying out the tasks pertaining to the procedures referred to in Article 9 and the specific tasks for which the bodies have been designated. The Commission shall assign identification numbers to these bodies, hereinafter referred to as "notified bodies".

The Commission shall publish a list of the notified bodies, together with the identification numbers it has allocated to them and the tasks for which they have been notified, in the Official Journal of the European Communities. It shall ensure that the list is kept up to date.

2. Member States shall apply the criteria set out in Annex 9 for the designation of bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonised standards shall be presumed to meet the relevant criteria.

3. A Member State that has notified a body shall withdraw that notification if it finds that the body no longer meets the criteria referred to in paragraph 2. It shall immediately inform the other Member States and the Commission of any withdrawal of notification for the aforementioned or any other reason.

4. The notified body and the manufacturer, or its authorized representative established in the Community, shall lay down, by common accord, the time limits for completion of the assessment and verification operations referred to in Annexes 3 to 7.

5. The notified body must make available to the other notified bodies and the competent authority, on request, all relevant information concerning approvals and certificates issued, refused or withdrawn.

Article 14

CE-marking

1. Devices, other than devices for performance evaluation, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market.

2. The CE-marking of conformity, as shown in Annex 10, must appear in a visible, legible and indelible form on the device, where practicable and appropriate, and on the instructions for use. Where applicable the CE marking of conformity must also appear on the sales packaging. The CE marking shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes 4, 6 and 7.

3. It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking. Any other mark may be affixed to the device, to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not thereby reduce.

Article 15

Unduly affixed CE marking

Without prejudice to Article 8 :

(a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to end the infringement under conditions imposed by the Member State

(b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 8.

Article 16

Decisions in respect of refusal or restriction

1. Any decision taken pursuant to this Directive :

   (a) to refuse or restrict the placing on the market or the putting into service of a device or

   (b) to withdraw devices from the market

shall state the exact grounds on which it is based. Such decisions shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the national law in force in the Member State in question and of the time limits to which such remedies are subject.

2. In the event of a decision as referred to in paragraph 1, the manufacturer, or his authorized representative established in the Community, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken.

Article 17

Confidentiality

Without prejudice to the existing national provisions and practices on medical secrets, Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to information obtained in carrying out their tasks. This does not affect the obligations of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

Article 18

Cooperation between Member States

Member States shall take appropriate measures to ensure that competent authorities charged with the implementation of the present Directive cooperate with each other and convey to each other the information necessary to ensure compliance with the provisions of this Directive.

Article 19

Amendment of Directives

1. Directive 93/42/EEC is hereby amended as follows :

a) Article 1(2) c) shall read as follows :

"(c) in vitro diagnostic medical device means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological state, state of health or disease or congenital abnormality or to determine the safety and compatibility with potential recipients".

b) Article 1(5)f shall read as follows :

"(f) transplants or tissues or cells of human origin, unless a device is manufactured utilizing tissues or substances derived from such tissues which are non viable or rendered non viable. In this case, the directive shall not affect national regulations relating to the ethics of the collection of tissues or substances of human origin, as well as any regulations relating to the ethics governing distribution of given types of devices of such origin."

c) Annex I, paragraph 8.2, shall read as follows :

"8.2. Where a device is manufactured utilizing human tissues or substances derived from human tissues, the use of such tissues or substances must be subject to the relevant validated selection and screening procedures, including traceability as appropriate in relation to the inherent risk.
Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.

Processing, preservation, testing and handling of tissues, cells and substances of human or animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed as appropriate by implementation of validated methods of elimination or inactivation of such viruses or other transmissible agents in the course of the manufacturing process, taking into account the sourcing and control methods applied."

d) Annex I paragraph 13.3 shall be completed by the following subparagraph :

"n) in the case of devices incorporating tissues of human origin or substances derived from such tissues, a statement indicating that the device incorporates tissue or substances derived from tissue of human origin as appropriate"

e) In annex II paragraph 3.2c) and annex III paragraph 3 the following indent shall be included as third last indent :

"in the case of devices incorporating tissues of human or animal origin, information on the selection and origin"

f) Annex IX, section III, paragraph 4.5 : the following sub-paragraph shall be added :

"All devices manufactured utilizing human tissues or substances derived from such tissues are in class III."

2. In Directive 89/392/EEC, the text of Article 1(3), second indent " machinery for medical use, used in direct contact with patients" is replaced by the following text :

"- medical devices"

Article 20

Implementation, transitional provisions

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 April 1998. They shall immediately inform the Commission thereof.

   The Standing Committee referred to in Article 7 may assume its tasks from the date of notification of this Directive. The Member States may take the measures referred to in Article 13 on notification of this Directive.

   When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such a reference at the time of their official publication. The procedures for such reference shall be adopted by Member States.

   Member States shall apply these provisions with effect from 1 July 1998.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

3. Member States shall take the necessary action to ensure that the notified bodies which are responsible pursuant to Article 9 for conformity assessment take account of any relevant information regarding the characteristics and performance of such devices, including in particular the results of any relevant tests and verification already carried out under pre-existing national law, regulations or administrative provisions in respect of such devices.

4. Member States shall accept during a period of four years following adoption of the present Directive the placing on the market and putting into service of devices which conform to the rules in force in their territory on the date of adoption of this Directive.

Article 21

This Directive shall enter into force the twentieth day after its publication.

Article 22

This Directive is addressed to the Member States.

Annex 1

ESSENTIAL REQUIREMENTS

I. GENERAL REQUIREMENTS

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, ~~or~~ the safety and health of users and, where applicable, other persons, and the safety of property. Any risks, which may be associated with their use, must be acceptable when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

   In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order :

   - eliminate or reduce risks as far as possible (inherently safe design and construction);
   - where appropriate take adequate protection measures in relation to risks that cannot be eliminated;
   - inform users of the residual risks due to any shortcomings of the protection measures.

3. The devices must be designed and manufactured in such a way that they are suitable for the purposes referred to in Article 1(2)(b), as specified by the manufacturer, taking account of the generally acknowledged state of the art. They must achieve the performances in particular in terms of analytical sensitivity, specificity, accuracy, repeatability, reproducibility and limits of detection stated by the manufacturer.

   The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of higher order.

4. The characteristics and performances referred to in Sections 1 and 3 must not be adversely affected to such a degree that the health or the safety of the patient or the user and, where applicable, of other persons, are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subject to the stresses which can occur during normal conditions of use. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected in the storage and transport conditions (temperature, humidity, ...) taking account of the instruction and information provided by the manufacturer.

II. REQUIREMENTS REGARDING DESIGN AND MANUFACTURING

6. Chemical and physical properties

6.1. The devices must be designed and manufactured in such a way as to achieve the characteristics and performances referred to in Section I on the "General Requirements". Attention must be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the samples (such as biological tissues, cells, body fluids and micro-organisms) intended to be used with the device, taking account of its intended purpose.

6.2. The devices must be designed, manufactured and packed in such a way as to reduce as far as possible the risk posed by leakage products, contaminants and residues to the persons involved in the transport, storage and use of the devices, taking account of the intended purpose of the products.

7. Infection and microbial contamination

7.1. The devices must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or other persons. The design must allow easy handling and, where necessary, reduce as far as possible contamination of and leakage from the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes.

7.2. Where a device incorporates biological substances, the risks of infection must be reduced as far as possible by selecting appropriate donors, appropriate substances and using appropriate inactivation, conservation, test and control procedures.

7.3. Devices labelled either as "STERILE", or, as having a special microbiological state must be designed, manufactured and packed in an appropriate pack, according to procedures suitable to ensure that they remain in the microbiological state indicated on the label when placed on the market, under the storage and transport conditions as laid down by the manufacturer, until the protective packaging is damaged or opened.

7.4. Devices labelled either as "STERILE", or, as having a special microbiological state must have been processed by an appropriate, validated method.

7.5. Packaging systems for devices other than those referred to in section 7.3 must keep the product without deterioration at the level of cleanliness, if any, as indicated by the manufacturer and, if the devices are to be sterilized prior to use, reduce as far as possible the risk of microbial contamination.

Steps shall be taken to reduce microbial contamination during selection and handling of raw materials, manufacture, storage and distribution where the performance of the device can be adversely affected by such contamination.

8. Construction and environmental properties

8.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label and/or in the instructions for use.

8.2 Devices must be designed and manufactured in such a way as to remove or reduce as far as possible :

- the risk of injury, in connection with their physical features, including aspects of volume x pressure, dimensional and where appropriate ergonomic features;
- risks connected with reasonably foreseeable external influences, such as magnetic fields, external electrical effects, electrostatic discharge, pressure, temperature or variations in pressure or acceleration.

Devices must be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity from electromagnetic disturbance to enable them to operate in accordance with their intended purpose.

8.3. Devices must be designed and manufactured in such a way as to reduce as far as possible the risks of fire or explosion during normal use. Particular attention must be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.

8.4. Devices must be designed and manufactured in such a way as to facilitate the management of safe waste disposal.

8.5 The measuring, monitoring or display scale (including colour change and other visual indicators) must be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.

9. Devices which are instruments or apparatus with a measuring function

9.1. Devices which are instruments or apparatus having a primary analytical measuring function must be designed and manufactured in such a way as to provide adequate stability and accuracy of measurement within appropriate accuracy limits, taking into account the intended purpose of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits have to be specified by the manufacturer.

9.2. When values are expressed numerically, they must be given in legal units conforming to the provisions of Council Directive 80/181/EEC [11]

10. Protection against radiation

10.1 Devices shall be designed and manufactured in such a way that exposure of users and other persons to the emitted radiation is reduced as far as possible.

10.2 When devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be :

- designed and manufactured in such a way as to ensure that the quality and quantity of radiation emitted can be adjusted and controlled;
- fitted, where practicable, with visual displays and/or audible warnings of such emissions.

10.3 The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.

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[11] OJ Nr. L 39, 15.02.1980, p. 40, directive as last amended by Directive 89/617/EEC, OJ Nr. L 357, 07.12.1989, P. 28.

11. Requirements for medical devices connected to or equipped with an energy source

11.1 Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use.

11.2 Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.

11.3 Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained correctly.

11.4 Protection against mechanical and thermal risks

11.4.1 Devices must be designed and manufactured in such a way as to protect the user against mechanical risks connected with, for example, resistance, stability and moving parts. Annex 1, sections 1.3 and 1.4 of Directive 89/392/EEC [12] shall apply, were appropriate.

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[12] Council Directive 89/392/EEC, OJ Nr. L 183, 29.6.1989, as last amended by Council Directive 93/68/EEC, OJ Nr. L 220, 30.8.1993, p. 1

11.4.2 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

11.4.3 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

11.4.4 Terminals and connectors to electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and manufactured in such a way as to minimize all possible risks.

11.4.5 Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.

12. Requirements for devices for self-testing

Devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in users' technique and environment. The information and instructions provided by the manufacturer should be easily understood and applied by the user.

12.1 Devices for self-testing must be designed and manufactured in such a way as to reduce as far as practicable the risk of user's error in handling and in interpretation of the result.

12.2 Devices for self-testing must, where reasonably possible, include a method of user control, i.e. a procedure by which the user can reasonably verify that, at the time of use, the product will perform as intended.

13. Information supplied by the manufacturer

13.1 Each device must be accompanied by the information needed to use it properly, taking account of the training and knowledge of the potential users and to identify the manufacturer.

This information comprises the data on the label and in the instructions for use.

As far as practicable and appropriate, the information needed to use the device properly must be set out on the device itself and/or on the packaging or, where appropriate, on the sales packaging. If individual full labelling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with one or more devices.

Instructions for use must accompany or be included in the packaging of one or more devices.

By way of exception, no such instructions for use are needed for a device if it can be used properly and safely without them.

13.2 Where appropriate, this information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours as used must be described in the documentation supplied with the device.

13.3 In the case of devices containing a substance or being a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant danger symbols and labelling requirements of Directive 67/548/EEC and Directive 88/379/EEC shall apply. Where there is insufficient space to put all information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the instructions for use.

The provisions of the aforementioned directives on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.

13.4 The label must bear the following particulars which may take the form of symbols as appropriate:

a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorized representative of the manufacturer established within the Community;

b) the details strictly necessary for the user to identify the device and the contents of the packaging.

c) where appropriate, the word "STERILE" or a statement indicating any special microbiological state or state of cleanliness;

d) where appropriate, the batch code, preceded by the word "LOT", or the serial number;

e) where appropriate, an indication of the date by which the device or part of it should be used, expressed as the year, the month and, where relevant, the day;

f) in cases of devices for performance evaluation, the words "for performance evaluation only";

g) where appropriate, a statement indicating the in vitro nature of the device;

h) any special storage and/or handling conditions;

i) where applicable any special operating instructions;

j) appropriate warnings and/or precautions to take;

k) if the device is intended for self-testing, this fact should be clearly stated.

l) In the case of devices incorporating tissues of human origin or substances derived from such tissues, a statement indicating that the device incorporates tissues or substances derived from tissue of human origin.

13.5 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label.

13.6 Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.

13.7 Where appropriate, the instructions for use must contain the following particulars :

a) the details referred to in Section 13.4, with exception of points d) and e);

b) composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement that the device contains other ingredients influencing the measurement;

c) the storage conditions and shelf life following the first opening of the immediate container, together with the storage conditions and stability of working reagents;

d) the performances referred to in Section 3;

e) a statement of any special materials required including information necessary to enable those special materials to be identified for proper use;

f) the type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions;

g) a detailed description of the procedure to be followed in using the device;

h) the measurement procedure to be followed with the device including as appropriate :

- the principle of the method;
- the specific analytical performance characteristics (e.g. analytical sensitivity, specificity, accuracy, repeatability, reproducibility and limits of detection), limitations of the method and information about the use of available reference measurement procedures and materials by the user;
- the details of any further procedure or handling needed before the device can be used (for example reconstitution, incubation, dilution, instrument checks, etc);
- the indication whether any particular training is required;

i) the mathematical approach upon which the calculation of the analytical result is made;

j) measures to be taken in the event of changes in the analytical performance of the device;

k) information appropriate to users on :

- internal quality control including specific validation procedures,
- the traceability of the calibration of the device;

l) the reference intervals for the quantities being determined;

m) if the device must be used in combination with or installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination;

n) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely; information about safe waste disposal;

o) the necessary instructions in the event of damage to the sterile protective packaging and details of appropriate methods of resterilization or decontamination;

p) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and resterilization or decontamination, and any restriction on the number of reuses;

q) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;

r) precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures; where the device includes substances of human or animal origin, attention shall be drawn to their potential infectious nature;

s) specifications for devices for self-testing :

- the results need to be expressed and presented in a way that is readily understood by a non-professional person; information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result) and on the possibility of false positive or false negative result;
- specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to know how to use the device and to understand the result(s) produced by the device;
- the information provided must include a statement clearly directing that the user should not take any decision of medical relevance without first consulting his or her medical practitioner;

t) date of issue or last revision of the instructions for use.

Annex 2

LIST OF DEVICES REFERRED TO IN ARTICLE 9(2)

1. Reagents and reagent products for blood grouping (A B O system and Rh$_o$/D)

2. Reagents and reagent products for the detection in human specimens of markers of HIV infection, Hepatitis B and C .

Annex 3

EC DECLARATION OF CONFORMITY

1. The EC declaration of conformity is the procedure whereby the manufacturer or his authorized representative established in the Community who fulfils the obligations imposed by Sections 2 to 5 and additionally, in the case of devices for self-testing, the obligations imposed by Section 6, ensures and declares that the products concerned meet the provisions of this Directive which apply to them. The manufacturer must affix the CE marking in accordance with Article 14.

2. The manufacturer must prepare the technical documentation described in Section 3 and ensure that the manufacturing process follows the principles of quality assurance as set out in section 4.

3. The technical documentation must allow assessment of the conformity of the product with the requirements of the Directive. It must include in particular :

- a general description of the product, including any variants planned;
- the documentation of the quality system;
- design information, including performance characteristics and limitation, methods of manufacture and, in the case of instruments, design drawings, diagrams of components, sub-assemblies, circuits, etc.;
- the descriptions and explanations necessary to understand the abovementioned characteristics, drawings and diagrams and the operation of the product;
- the results of the risk analysis, where appropriate, and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full;
- in the case of sterile products or products with a special microbiological state or state of cleanliness, a description of the procedures used;
- the results of the design calculations and of the inspections carried out, etc...
- if the device is to be combined with other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when combined with any such device(s) having the characteristics specified by the manufacturer;
- the test reports;

- adequate performance evaluation data, supported by a reference measurement system (when available), originated from studies in a clinical or other appropriate environment or resulting from available literature; this applies in particular to biological materials, culture media and devices using a new technology;
- the labels and instructions for use.

4. The manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured.

The system shall address :

- the organizational structure and responsibilities,
- the manufacturing processes and systematic quality control of production;
- the means to monitor the performance of the quality system;

5. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. He shall notify the competent authorities of the following incidents immediately on learning of them :

(i) any malfunction, failure or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(ii) any technical or medical reason connected with the characteristics or the performance of a device for the reasons referred to in subparagraph (i) above leading to systematic recall of devices of the same type by the manufacturer.

6. For devices for self-testing the manufacturer shall lodge an application for examination of the design with a notified body.

6.1 The application shall enable the design of the device to be understood and shall enable conformity with the design-related requirements of the directive to be assessed.

It shall include :

- test reports including, where appropriate, results of studies carried out with lay persons;
- data showing the handling suitability of the device in view of its intended purpose for self-testing;
- the information to be provided with the device on its label and its instructions for use.

6.2 The notified body shall examine the application and, if the design conforms to the relevant provisions of this Directive shall issue the applicant with an EC design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the design-related requirements of the Directive. The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design and, where appropriate, a description of the intended purpose of the product.

6.3 The applicant shall inform the notified body which issued the EC designed-examination certificate of any significant change made to the approved design. Changes to the approved design must receive further approval from the notified body which issued the EC design-examination certificate wherever the changes could affect conformity with the essential requirements of the Directive or with the conditions prescribed for use of the product. This additional approval shall take the form of a supplement to the EC design-examination certificate.

Annex 4

EC DECLARATION OF CONFORMITY

(FULL QUALITY ASSURANCE SYSTEM)

1. The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the products concerned, as specified in Section 3, and is subject to audit as laid down in section 3.3 and to the EC surveillance as specified in Section 4.

2. The declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.

   The manufacturer shall affix the CE marking in accordance with Article 14 and shall draw up a declaration of conformity covering the products concerned.

3. Quality system

   3.1 The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

- the name and address of the manufacturer and any additional manufacturing site covered by the quality system;
- adequate information on the product or product category covered by the procedure;
- a written declaration that no such application has been lodged with any other notified body for the same product-related quality system;
- the documentation on the quality system;
- an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved;
- an undertaking by the manufacturer to keep the approved quality system adequate and efficacious;
- an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post production phase and to implement appropriate means to apply any necessary corrective action and notification as referred to in Annex 3, section 5 .

3.2 Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures, such as quality programmes, quality plans, quality manuals and quality records.

It shall include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

- the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned;
- the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform;

(c) the procedures for monitoring and verifying the design of the products and in particular:

- a general description of the product, including any variants planned;
- all documentation referred to in Annex 3, section 3, indents 3 to 11;
- in the case of devices for self-testing, the information referred to in Annex 3, section 6.1;
- the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed;

(d) the inspection and quality assurance techniques at the manufacturing stage and in particular:

- the processes and procedures which will be used, particularly as regards sterilization and purchasing;

- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration of the test equipment adequately.

3.3 The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

The decision shall be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

3.4 The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system or the product-range covered.

The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

4. Surveillance

4.1 The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

4.2 The manufacturer must authorize the notified body to carry out all the necessary inspections and supply it with all relevant information, in particular:

- the documentation on the quality system;
- the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculation, tests, etc.;
- the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3 The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and must supply the manufacturer with an assessment report.

4.4 In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

Annex 5

EC TYPE-EXAMINATION

1. EC type-examination is the part of the procedure whereby a notified body ascertains and certifies that a representative sample of the production envisaged fulfils the relevant provisions of this Directive.

2. The application for EC type-examination shall be lodged by the manufacturer or by his authorized representative established in the Community with a notified body.

   The application shall include:

   - the name and address of the manufacturer and the name and address of the authorized representative if the application is lodged by the representative;
   - the documentation described in Section 3 needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the "type", with the requirements of this Directive. The applicant shall make a "type" available to the notified body. The notified body may request other samples as necessary;
   - a written declaration that no application has been lodged with any other notified body for the same type.

3. The documentation must allow an understanding of the design, the manufacture and the performances of the product. The documentation shall contain the following items in particular:

- a general description of the type, including any variants planned;
- all documentation referred to in Annex 3, section 3, indents 3 to 5, 7, 10 and 11,

4. The notified body shall:

4.1 examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable provisions of the standards referred to in Article 5, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;

4.2 perform or have performed appropriate examinations and the tests necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements of this Directive if the standards referred to in Article 5 have not been applied; if the device is to be combined with other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when combined with any such device(s) having the characteristics specified by the manufacturer;

4.3 carry out or ask for the appropriate examinations and the tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;

4.4 agree with the applicant on the place where the necessary examinations and tests will be carried out.

5. If the type conforms to the provisions of this Directive, the notified body shall issue the applicant with an EC type-examination certificate. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation shall be annexed to the certificate and a copy shall be kept by the notified body.

6. The applicant shall inform the notified body which issued the EC type-examination certificate of any significant change made to the approved product.

Changes to the approved product must receive further approval from the notified body which issued the EC type-examination certificate wherever the changes may affect conformity with the essential requirements or with the conditions prescribed for use of the product. This new approval shall, where appropriate, take the form of a supplement to the initial EC type-examination certificate.

7. Administrative provisions

Other notified bodies may obtain a copy of the EC type-examination certificates and/or the supplements thereto. The annexes to the certificates must be made available to the other notified bodies on reasoned application, after the manufacturer has been informed.

Annex 6

EC VERIFICATION

1. EC verification is the procedure whereby the manufacturer or his authorized representative established in the Community ensures and declares that the products which have been subject to the procedure set out in Section 4 conform to the type described in the EC type-examination certificate and meet the requirements of this Directive which apply to them.

2.1 The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the EC type-examination certificate and to the requirements of the Directive which apply to them. Before the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular as regards sterilization and the suitability of starting materials, where necessary, and define the necessary testing procedures according to the state of the art. All the routine, pre-established provisions must be implemented to ensure homogeneous production and conformity of the products with the type described in the EC type-examination certificate and with the requirements of this Directive which apply to them. The manufacturer must affix the CE marking in accordance with Article 14 and draw up a declaration of conformity covering the products concerned.

2.2 To the extent that for certain aspects the final testing according to section 6.3 is not appropriate, adequate in process testing, monitoring and control methods shall be established by the manufacturer with the approval of the notified body. The provisions of Annex 4 section 4 shall apply accordingly in relation to the above mentioned approved procedures.

3. The manufacturer must undertake to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective and notification action as referred to in Annex 3 section 5.

4. The notified body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Directive either by examining and testing every product as specified in section 5 or by examining and testing products on a statistical basis as specified in section 6, as the manufacturer decides.

In as far as the conduct of examinations and tests on a statistical basis is not appropriate, examinations and tests may be carried out on a random basis provided that such procedure in conjunction with the measures taken in accordance with section 2.2 ensures an equivalent level of conformity.

5. Verification by examination and testing of every product

5.1 Every product is examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out in order to verify the conformity of the products with the EC type described in the type-examination certificate and with the requirements of the Directive which apply to them.

5.2 The notified body must affix, or have affixed, its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.

6. Statistical verification

6.1 The manufacturer must present the manufactured products in the form of homogeneous batches.

6.2 A random sample is taken from each batch. The products which make up the sample are examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in the EC type-examination certificate and with the requirements of the Directive which apply to them in order to determine whether to accept or reject the batch.

6.3 Statistical control of products will be based on attributes, entailing a sampling system ensuring a limit quality corresponding to a probability of acceptance of 5%, with a non-conformity percentage of between 3 and 7%. The sampling method will be established by the harmonized standards referred to in Article 5, taking account of the specific nature of the product categories in question.

6.4 If the batch is accepted, the notified body affixes, or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If a batch is rejected the competent notified body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

The manufacturer may, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

Annex 7

EC DECLARATION OF CONFORMITY

(PRODUCTION QUALITY ASSURANCE)

1. The manufacturer must ensure application of the quality system approved for the manufacture of the products concerned and carry out the final inspection, as specified in Section 3, and is subject to the EC surveillance referred to in Section 4.

2. The declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them.

   The manufacturer must affix the CE marking in accordance with Article 14 and draw up a declaration of conformity.

3. Quality system

3.1 The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

- all documentation and undertakings referred to in Annex 4 section 3.1 and
- the technical documentation on the types approved and a copy of the EC type-examination certificates.

3.2 Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures. This quality system documentation must permit uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records.

It must include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

- the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned;

- the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including control of products which fail to conform;

(c) the inspection and quality assurance techniques at the manufacturing stage and in particular:

- the processes and procedures which will be used, particularly as regards sterilization and purchasing;

- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

(d) the appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment.

3.3 The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

The decision must be notified to the manufacturer after the final inspection and contain the conclusions of the inspection and a reasoned assessment.

3.4 The manufacturer shall inform the notified body which approved the quality system of any plan for substantial changes to the quality system.

The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2.

It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

4. Surveillance

The provision of Annex 4, section 4, shall apply.

Annex 8

STATEMENT AND PROCEDURES CONCERNING DEVICES FOR PERFORMANCE EVALUATION

1. For devices for performance evaluation the manufacturer or his authorized representative established in the Community shall draw up the statement containing the information stipulated in Section 2 of this Annex and ensure that the relevant provisions of this Directive are met.

2. The statement shall contain the following information:

   - the list of laboratories or other institutions taking part in the performance evaluation study;
   - in the case of devices for self-testing, the place, starting date and scheduled duration for the investigations and the number of lay-persons involved.
   - a statement that the device in question conforms to the requirements of the Directive, apart from the aspects covered by the investigation and apart from those specifically itemised in the statement, and that every precaution has been taken to protect the health and safety of the patient, user and third parties.

3. The manufacturer shall also undertake to keep available for the competent national authorities the documentation allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Directive. This documentation must be kept for a period ending at least five years after the end of the performance evaluation.

The manufacturer shall take all the measures necessary for the manufacturing process to ensure that the products manufactured conform to the documentation mentioned in the first paragraph.

Annex 9

CRITERIA FOR THE DESIGNATION OF NOTIFIED BODIES

1. The notified body, its Director and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer or user of the devices which they inspect, nor the authorized representative of any of these persons. They may not be directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This in no way precludes the possibility of exchanges of technical information between the manufacturer and the body.

2. The notified body and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications.

   Should the notified body subcontract specific tasks connected with the establishment and verification of the facts, it must first ensure that the subcontractor meets the provisions of the Directive. The notified body shall keep at the disposal of the national authorities the relevant documents assessing the subcontractor's qualifications and the work carried out by the subcontractor under this Directive.

3. The notified body must be able to carry out all the tasks assigned to such bodies by one of Annexes 3 to 7 and for which it has been notified, whether these tasks are carried out by the body itself or on its responsibility. In particular, it must have the necessary staff and possess the facilities needed to perform properly the technical and administrative tasks entailed in assessment and verification. It must also have access to the equipment necessary for the verifications required.

4. The notified body must have:

- sound vocational training covering all the assessment and verification operations for which the body has been designated;
- satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections;
- the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5. The impartiality of the inspection staff must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of the inspections.

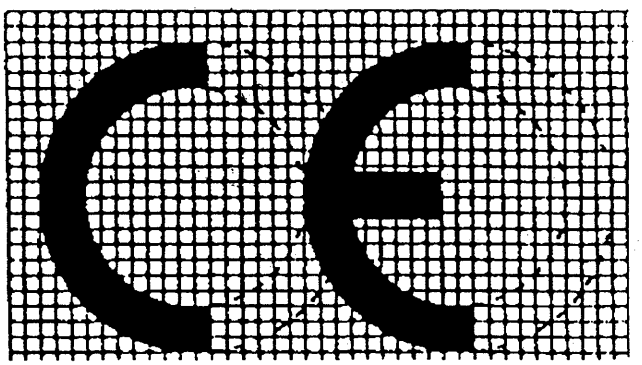
6. The body must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.

7. The staff of the inspection body are bound to observe professional secrecy with regard to all information gained in the course of their duties (except vis-à-vis the competent administrative authorities of the State in which their activities are carried out) under this Directive or any provision of national law putting it into effect.

Annex 10

CE MARKING OF CONFORMITY

The CE conformity marking shall consist of the initials "CE" taking the following form :



- If the marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.

ANNEX

DRAFT

DECISION OF THE EEA JOINT COMMITTEE

No. [.....]

amending Annex II, Technical regulations, standards, testing and certification, to the Agreement on the European Economic Area

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area, as adjusted by the Protocol Adjusting the Agreement on the European Economic Area, hereinafter referred to as the Agreement, and in particular Article 98 thereof;

Whereas Directive ...../...../EEC of ..../...../..... (OJ No. L .....) on in vitro diagnostic medical devices is to be integrated into the Agreement,

HAS DECIDED AS FOLLOWS :

Article 1

The following shall be inserted in Annex II to the Agreement :

Directive ...../...../EC on in vitro diagnostic medical devices

Article 2

The texts of Directive ..../...../.EC in the Finnish, Icelandic, Norwegian and Swedish languages, which are annexed to the respective language versions of this decision, are authentic

Article 3

This Decision shall enter into force on [.....] [.....], provided that all the notifications under Article 103(1) of the Agreement have been made to the EEA Joint Committee

Article 4

This decision shall be published in the EEA Section of, and in the EEA Supplement to, the Official Journal of the European Communities

For the EEA Joint Committee
The President

.....

The Secretaries
to the EEA Joint Committee

....

ANNEX

FINANCIAL STATEMENT

Financial implications (details for publication in the working papers)

1. TITLE OF OPERATION

Proposal for a Directive on in vitro diagnostic medical devices

2. BUDGET HEADING

B5-300 Measures concerning the internal market; Operating appropriations
B5-7210 Development of a data interchange system

3. LEGAL BASIS

Article 100a of the EC Treaty.

4. DESCRIPTION OF OPERATION

4.1 Specific objectives of operation: The specific objective of this operation is to establish the internal market in in-vitro diagnostic medical devices.

This proposal is intended to complement the existing Directives 90/385/EEC (on active implantable medical devices) and 93/42/EEC (on medical devices) by introducing Community legislation governing the placing on the market of in vitro diagnostic medical devices. The Directive aims at ensuring the safety and protecting the health of patients, users of the devices concerned and third parties. Harmonized rules will ensure free movement of the devices and prevent the emergence of new barriers to trade.

Following the principles laid down in the new approach, the Directive provides for harmonization of the essential safety requirements and for the conformity assessment procedures which in vitro diagnostic medical devices must satisfy when they are placed on the market. Effective implementation of this Directive will entail:

- drafting of harmonized standards by the CEN/CENELEC; if these are applied, conformity with the essential requirements in the Directive will be presumed;

- establishment by the parties concerned and submission by the Commission of the guidelines necessary to ensure uniform application of the Directive, on its scope, the principles to be applied, the means to be employed to meet the essential requirements, etc.;

- concertation between the notified bodies on the certification procedures;

- exchanges of information between the Member States concerning application and monitoring of the Directive;

- management by the Commission of the procedures for implementing the safeguard clauses, which will imply seeking the opinion of high-level experts.

4.2 Duration: *Ad hoc* measure.

4.3 Target population: Every citizen in the Community is a potential user of the devices covered by the Directive, since the products are employed in the health care sector.

5. CLASSIFICATION OF EXPENDITURE

5.1 Non-compulsory expenditure.

5.2 Differentiated appropriations.

5.3 No revenue is expected.

6. TYPE OF EXPENDITURE

The expenditure will be on:

(a) standardization: The proposal for a Directive lays down the essential requirements. Article 5 refers to harmonized standards. As with the other new approach Directives, the Commission plans to give the CEN/CENELEC a mandate to draft the relevant harmonized standards. This mandate will cover technical formulation of the essential requirements defined in the proposal. It will be governed by the framework contract of 15 September 1992, which provides for financial support from the Commission.

(b) development of a data interchange system: The registration procedures for manufacturers (Article 10) and the vigilance system (Article 11) involve exchanges of official data between the Member States, the parties concerned and the Commission. The development of a system facilitating data interchange will therefore be essential if the directive is to be fully effective. To this end, the profiles of the data to be exchanged must be established, procedures must be devised and common software must be provided.

6.1 100% subsidy: none.

6.2 Subsidy for joint financing with other sources in the public and/or private sector: none.

6.3 Interest subsidy: none.

6.4 Other: none.

6.5 Should the operation prove an economic success, is there provision for all or part of the Community contribution to be reimbursed? No.

6.6 Will the proposed operation cause any change in the level of revenue? No.

7. FINANCIAL IMPACT

7.1 Method of calculating total cost of operation

7.1.1 Standardization

(a) Estimated cost of:

- drafting the standards: In the order of 25 harmonized standards will have to be drafted.

The funding will depend on the work given to the contractors.

On average, the estimated financial contribution from the Commission for drafting a standard is a flat rate of ECU 50 000. Total expenditure of ECU 1.25 million is expected.

- developing a data interchange system between the Member States.

The cost of a project such as referred to in point 6b, to be carried out in 1996/1997, is estimated at ECU 300 000.

(b) The indicative schedule of appropriations could be as follows

	Commitment appropriations (1.000 ECU	Payment appropriations (1.000 ECU)
1995	750	350
1996	650	500
1997	150	300
1998	-	300
1999	-	100
	1550	1550

7.2 Itemized breakdown of cost

ECU

BREAKDOWN	1994 BUDGET	1995 PRELIMINARY DRAFT BUDGET	PERCENTAGE CHANGE
Standardization (B5-300) * Mandate	-	750 000	-

7.3 Indicative schedule of commitment appropriations

ECU

			INDICATIVE SCHEDULE				
	1994 BUDGET	1995 PRELIMINARY DRAFT BUDGET	1996	1997	1998	1999	2000
Standardization (B5-300) Mandate	-	750 000	500 000	-	-	-	-
Development of a data interchange system between the Member States (B5-7210)	-		150 000	150 000			

8. FRAUD PREVENTION MEASURES

The Commission verifies the subsidies or receipt of the services and preparatory, feasibility or evaluation studies ordered before payment, taking account of the contractual obligations and of the principles of economy and sound financial or general management. All agreements or contracts concluded between the Commission and recipients of payments include fraud prevention clauses (on monitoring, submission of reports, etc.).

9. ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

9.1 Objectives

This new approach Directive is a measure to complete the internal market. The reference to harmonized standards is part of the Commission's multiannual programme to support reinforcement and extension of European standardization.

9.2 Grounds for the operation

The national legislation on in vitro diagnostic medical devices is extremely heterogeneous and takes different approaches to safety which make application of the principle of mutual recognition delicate.

The diverging requirements imposed by the national systems, both on the products and on the procedures for placing them on the market, give rise to enormous wastage of human and financial resources at the expense of the manufacturers and of the Member States.

The Community procedures will avoid multiple repetition with the same objective. In addition, the harmonized requirements will allow industry to make savings on unit production costs.

The harmonization of standards is designed to pool resources and thereby avoid duplication of expenditure by the Member States.

All in all, the resources required from the Community budget are only a small proportion of the total resources which the Member States and parties concerned will release for the common good as a result of the operation.

9.3 Monitoring and evaluation of the operation

9.3.1 Performance indicators selected

- degree of harmonization of standards (number of standards);
- number of certifications carried out;
- number of reports of undesirable incidents;
- number of infringement procedures.

9.3.2 Details and frequency of planned evaluation:

- regular progress reports on standardization under Council Directive 83/189/EEC, at least once a year.

9.4 Coherence with financial programming

9.4.1 The operation is included in DG III's financial programming.

9.4.2 Broader objectives defined in DG III's financial programming: not applicable.

9.4.3 Main factors of uncertainty which could affect the specific results of the operation: not applicable.

10. ADMINISTRATIVE EXPENDITURE (PART A OF THE BUDGET)

10.1 The proposed operation will involve an increase in the number of Commission staff for administration of the Directive.

The procedures concerning the safeguard clauses, monitoring of European standardization and administrative cooperation presuppose the availability of staff capable of administration and evaluation of analyses and technical or legal opinions.

The staff requirements will be covered either by internal redeployment or by a Commission decision allocating resources in the budgetary procedure. It is estimated that Unit III.D.2 will require one grade A official from 1995 on.

FINANCIAL STATEMENT

Financial implications (details for internal information)

10.2 Amount of staff and operating expenditure generated by the proposed operation subject to the outcome of the budgetary procedure and the decision allocating resources

10.2.1 Expenditure on staff covered by the Staff Regulations
Titles A1 and A2 : ECU 90 000 per year
This item should be covered either through redeployment or under the allocation of resources decided each year by the Commission.

10.2.2 Other expenditure from Part A of the budget:
Budget items concerned and type of expenditure

(a) A2500: Meetings of experts: To promote uniform application of the Directive, the Commission plans regular meetings with the experts from the Member States, representatives of the notified bodies and the European federations to coordinate their activities and harmonize their practices.

Estimated annual cost (from 1996 on):
24 experts x 3 meetings per year x ECU 658 per expert per meeting = ECU 47.376 per year.

(b) A1178 Technical assistance

* *Consultants*: In the pre-implementation phase (1996-1997) consultants' fees are estimated to total ECU 25 000 per year.

(c) A 2600* Studies

* *Technical opinions:* The technical opinions required to administer the safeguard clause procedures will be funded by study contracts. ECU 40 000 per year must be earmarked for this purpose from 1998 on.

10.3 Itemized breakdown of cost (Part A of the budget)

ECU

BREAKDOWN	1994 BUDGET	1995 PRELIMINARY DRAFT BUDGET	PERCENTAGE CHANGE
(a) A1, A2	-	90.000	-
(b) A2550: meetings Member States	-	-	-
(c) A1178:* technical assistance (safeguard clauses)	-	25.000	-

* or A1178 according to nomenclature for 1995.

* or A1178 according to nomenclature for 1995.

10.4 Indicative schedule of appropriations

ECU

			INDICATIVE SCHEDULE				
	1994 BUDGET	1995	1996	1997	1998	1999	2000
(a) A1, A2		90.000	90.000	90.000	90.000	90.000	90.000
(b) Meetings with the Member States (A2500)	-	-	47 376	47 376	47 376	47 376	47 376
(c) Studies and consultations							
*. Consultants (A1178)	-	25 000	25 000	25 000	-	-	-
* Technical opinions (A2600)	-	-	-	-	40 000	40 000	40 000
TOTAL	-	115.000	162.376	162.376	177.376	177.376	177.376

IMPACT ASSESSMENT FORM

TITLE OF PROPOSAL:

Proposal for a Directive of the European Parliament and the Council on in vitro diagnostic medical devices.

REFERENCE NUMBER: 2111.2.1.1

1. THE PROPOSAL

This proposal is for a new approach Directive based on Article 100a of the Treaty. It is intended to achieve the following objectives:

- to complete the harmonization started by Directive 90/385/EEC on active implantable medical devices and Directive 93/42/EEC on medical devices for the products concerned;
- to ensure free movement of in vitro diagnostic medical devices by harmonizing the national legislation to protect the health and safety of patients and users;
- to remove the existing barriers created by the diverging regulations and prevent the emergence of new barriers. This proposal is essential to prevent the national legislation implementing the abovementioned Directives from deepening the differences;
- to create a favourable environment with uniform conditions of competition to enable the industry to benefit from the scale of the European Economic Area and to help make European industry more competitive.

2. THE IMPACT ON BUSINESS

(a) Nature of the businesses concerned

The in vitro diagnostic device industry is highly developed in the Community and the EFTA countries. Estimates put world production in 1992 at ECU 12.2 billion, of which 39% was from the USA, 38% from Western Europe and 12% from Japan.

Most of the 350 to 400 European undertakings in this sector are small or medium-sized businesses. Research activities are intense and account for an estimated 15 to 20% of the jobs in this industry.

(b) Geographical distribution of the industry and market

In Europe the leading manufacturers of in vitro diagnostic medical devices are Germany, Switzerland, France, Sweden, the Netherlands, the United Kingdom, Italy and Belgium. In 1992 the total market of ECU 4.6 billion broke down as follows: Germany 25%; Italy 23%; France 18%; Spain 12%; United Kingdom 4%; Belgium 3.5%; Switzerland 3%; Austria 3%; Netherlands 2%; Sweden 2%; Finland 1%; Denmark 1%; Norway 1%; Ireland 0.5% (source: European Diagnostic Manufacturers Association, EDMA).

(c) Are these businesses in regions eligible for regional aid in the Member States and under the ERDF?

No particular concentration in these regions is known.

3. WHAT WILL BUSINESS HAVE TO DO TO COMPLY WITH THE PROPOSAL?

The proposal lays down the essential requirements which devices placed on the market must meet in order to protect the health and safety of patients, users and third parties. These requirements will be given firmer shape by harmonized standards which will be drafted by the European standardization organizations CEN/CENELEC and will remain voluntary.

Before placing their devices on the market, manufacturers must ensure that they comply with the regulations. The conformity assessments for an extremely large proportion of the devices will be conducted solely on the manufacturers' responsibility, without the intervention of any third party.

The Directive will require manufacturers to apply the appropriate quality assurance principles for the devices manufactured.

However, in the case of devices particularly sensitive for health protection purposes, particularly AIDS and hepatitis tests, third party certification of the design and manufacture of the devices is required.

For monitoring purposes, manufacturers must notify one of the competent authorities in the Community of their marketing activities and of any undesirable incidents.

4. WHAT ECONOMIC EFFECTS IS THE PROPOSAL LIKELY TO HAVE?

(a) On employment

The proposal will have no particular impact on employment. However, the requisite adaptation to the new rules will help to safeguard existing jobs and, in certain cases, to create new ones.

(b) On investment and the creation of new businesses

The proposal will have no direct impact on business start-ups or investment. Conditions on the single market to be created could have consequences for distribution of the devices. It will be possible to organize distribution according to the needs of the European market without having to maintain separate distribution systems in each Member State.

(c) On the competitive position of businesses

Initially, adaptation to the new requirements and implementation of the quality principles, where still necessary, will give rise to extra costs. The three-year transition period following adoption of the Directive will make it possible to spread these costs over this entire period.

Once the adjustments have been completed, businesses will be able to benefit from the greater rationalization. Harmonization of the diverging regulatory systems will cut the costs caused by the current divergency. The European dimension of the market in turn will allow economies of scale.

Businesses will face tougher competition from both inside and outside the Community. The abovementioned effects of the proposal will make European businesses more competitive at international level.

Once the Community legislation is adopted the Community will be able to use it in its international negotiations to improve access for the European industry to markets in third countries.

(d) On public health

By ensuring that the devices placed on the market are reliable, the Directive will provide greater protection for public health. In particular, the performance and reliability of in vitro diagnostic devices will make it easier to take medical decisions at an early stage of treatment and yield savings in health care costs.

5. DOES THE PROPOSAL CONTAIN MEASURES TO TAKE ACCOUNT OF THE SPECIFIC SITUATION OF SMALL AND MEDIUM-SIZED FIRMS?

The proposal contains no specific measures applicable solely to small firms.

The Directive is limited to the essential protection requirements, which will be laid down in voluntary harmonized standards, and will therefore provide a legal framework which can be applied flexibly. The introduction of harmonized standards will make it easier to comply with the Directive, particularly for small firms. The manufacturer's declaration proposed for a very large proportion of the devices will limit the costs generated by the regulations and thus take particular account of the interests of small businesses.

The Commission will continue to ensure close involvement by the European federations representing the vast majority of small firms in this industry when implementing the proposed Directive.

6. CONSULTATION AND OPINION OF THE TWO SIDES OF INDUSTRY

Since 1991 the Commission has consulted the industrial and trade federations concerned with the aid of various working papers. Four meetings were held to examine a working paper at various stages. In addition, in 1992 and 1993 the EDMA, assisted by the Commission, organized two workshops specially on the proposal. Many bilateral meetings have been held with the parties concerned and talks on the subject have been given at numerous conferences.

The following federations and organizations have been consulted:

(a) **Manufacturers**

EDMA (European Diagnostic Manufacturers Association)

EUROM (European Federation of Precision, Mechanical and Optical Industries)

ELPA (European Laboratory Plastics Association)

(b) Users

IFCC (International Federation of Clinical Chemistry)

ECCLS (European Council for Clinical and Laboratory Standards)

ICSH (International Council for Standardization in Haematology)

ESCMID (European Society for Clinical Microbiology and Infectious Diseases)

WASP (World Association of Societies of Pathology - European section).

The parties concerned have recognized the need for harmonization with the aid of a Directive and support the principles established in this proposal.

The EDMA, which represents more than 300 small firms, and the other industrial federations mentioned above have stressed the need to uphold the principle that the conformity assessment for a large proportion of the devices can be conducted on the manufacturers' responsibility. Under these circumstances, the introduction of the vigilance procedures combined with notification of new devices are recognized as adequate monitoring arrangements. Consequently, in the industry's view, any moves to extend third party certification could upset the balance of the monitoring measures proposed.

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