# Procedure file

## Basic information

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| COD - Ordinary legislative procedure (ex-codecision procedure)<br>Directive | 1995/0013(COD) |
| In vitro diagnostic medical devices: security requirements<br>Repealed by 2012/0267(COD)<br><br>Subject<br>2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance<br>4.20.02 Medical research<br>4.20.04 Pharmaceutical products and industry<br>4.60.02 Consumer information, advertising, labelling | Procedure completed |

## Key players

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| European Parliament | Committee responsible | Rapporteur | Appointed |
| | ECON Economic and Monetary Affairs, Industrial Policy | RDE POMPIDOU Alain | 24/05/1995 |
| | Former committee responsible | | |
| | ECON Economic and Monetary Affairs, Industrial Policy | RDE POMPIDOU Alain | 24/05/1995 |
| | Former committee for opinion | | |
| | BUDG Budgets | | |
| | ENER Research, Technological Development and Energy | The committee decided not to give an opinion. | |
| | RELA External Economic Relations | The committee decided not to give an opinion. | |
| | ENVI Environment, Public Health and Consumer Protection | PPE TRAKATELLIS Antonios | 19/04/1995 |
| | CONT Budgetary Control | The committee decided not to give an opinion. | |
| Council of the European Union | Council configuration | Meeting | Date |
| | General Affairs | 2120 | 05/10/1998 |
| | Environment | 2076 | 23/03/1998 |
| | Competitiveness (Internal Market, Industry, Research and Space) | 2051 | 27/11/1997 |
| | Competitiveness (Internal Market, Industry, Research and Space) | 2007 | 21/05/1997 |

## Key events

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| 24/10/1994 | Additional information | | Summary |
| 15/05/1995 | Committee referral announced in Parliament, 1st reading | | |
| 06/02/1996 | Vote in committee, 1st reading | | Summary |
| | Committee report tabled for plenary, 1st | | |

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| 06/02/1996 | reading | A4-0031/1996 | |
| 12/03/1996 | Debate in Parliament | | Summary |
| 12/03/1996 | Decision by Parliament, 1st reading | T4-0115/1996 | Summary |
| 21/05/1997 | Debate in Council | 2007 | |
| 02/04/1998 | Committee referral announced in Parliament, 2nd reading | | |
| 03/06/1998 | Vote in committee, 2nd reading | | Summary |
| 17/06/1998 | Debate in Parliament | | Summary |
| 18/06/1998 | Decision by Parliament, 2nd reading | T4-0362/1998 | Summary |
| 05/10/1998 | Act approved by Council, 2nd reading | | |
| 27/10/1998 | Final act signed | | |
| 27/10/1998 | End of procedure in Parliament | | |
| 07/12/1998 | Final act published in Official Journal | | |

## Technical information

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| Procedure reference | 1995/0013(COD) |
| Procedure type | COD - Ordinary legislative procedure (ex-codecision procedure) |
| Procedure subtype | Legislation |
| Legislative instrument | Directive |
| | Repealed by 2012/0267(COD) |
| Legal basis | EC before Amsterdam E 100A |
| Stage reached in procedure | Procedure completed |
| Committee dossier | ECON/4/09931 |

## Documentation gateway

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|---|---|---|---|---|---|
| Legislative proposal | | COM(1995)0130<br>OJ C 172 07.07.1995, p. 0021 | 19/04/1995 | EC | Summary |
| Economic and Social Committee: opinion, report | | CES1153/1995<br>OJ C 018 22.01.1996, p. 0012 | 25/10/1995 | ESC | Summary |
| Committee draft report | | PE215.154 | 20/11/1995 | EP | |
| Committee report tabled for plenary, 1st reading/single reading | | A4-0031/1996<br>OJ C 078 18.03.1996, p. 0002 | 06/02/1996 | EP | |
| Amendments tabled in committee | | PE215.154/AM | 27/02/1996 | EP | |
| Committee opinion | BUDG | PE213.562/DEF | 27/02/1996 | EP | |
| Committee opinion | ENVI | PE215.227/DEF | 27/02/1996 | EP | |
| Text adopted by Parliament, 1st reading/single reading | | T4-0115/1996<br>OJ C 096 01.04.1996, p. 0017-0031 | 12/03/1996 | EP | Summary |
| Modified legislative proposal | | COM(1996)0643 | 20/12/1996 | EC | Summary |

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| | | OJ C 087 18.03.1997, p. 0009 | | | |
| Council position | | 05255/1/1998<br>OJ C 178 10.06.1998, p. 0007 | 23/03/1998 | CSL | Summary |
| Commission communication on Council's position | | SEC(1998)0555 | 26/03/1998 | EC | Summary |
| Amendments tabled in committee | | PE226.975/AM | 27/05/1998 | EP | |
| Committee draft report | | PE226.975 | 27/05/1998 | EP | |
| Committee recommendation tabled for plenary, 2nd reading | | A4-0225/1998<br>OJ C 210 06.07.1998, p. 0009 | 03/06/1998 | EP | |
| Text adopted by Parliament, 2nd reading | | T4-0362/1998<br>OJ C 210 06.07.1998, p. 0170-0194 | 18/06/1998 | EP | Summary |
| Commission opinion on Parliament's position at 2nd reading | | COM(1998)0548 | 02/10/1998 | EC | Summary |
| Implementing legislative act | | 32002D0364<br>OJ L 131 16.05.2002, p. 0017-0030 | 07/05/2002 | EU | |

## Additional information

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| European Commission | EUR-Lex |

## Final act

Directive 1998/79
OJ L 331 07.12.1998, p. 0001 Summary

## In vitro diagnostic medical devices: security requirements

CATEGORY OF REFERRAL: Proposal for Directive 2. Expected date of referral: December 1994 3. Previous Community legislation: Directive 93/42 of 14 June 1993 on medical devices excluding devices used for in-vitro diagnosis and active implantable devices. Related legislation 73/23, 87/404, 88/378, 89/106, 89/336, 89/392, 89/684, 90/384, 90/385 amended by 93/68, 90/396, 91/263, and 92/42. PREVIOUS POSITION OF EP: Amendments and legislative Resolution A3-0178/92 on medical devices (OJ C150 of 15/06/1992) and EP decision on medical devices (OJ C150 of 31/05/1993). The EP found the general tenor of the proposal satisfactory but adopted a number of amendments, especially in regard to restricting administrative formalities, increasing consultation opportunities for manufacturers, and making some of the definitions more precise. SITUATION IN THE MEMBER STATES: no national legislation available.

## In vitro diagnostic medical devices: security requirements

1) OBJECTIVE To ensure the free movement of in vitro diagnostic devices by harmonizing the national laws on the reliability of these products and on the protection of the health and safety of patients, users and third parties. 2) CONTENTS 1. This proposal applies to in vitro diagnostic medical devices. 2. These devices are products used for the in vitro analysis of tissues or substances from the human body. The types of analysis covered are as follows: * state of health; * congenital diseases or anomalies; * checking the progress of courses of treatment; * determining compatibility in the case of organ or blood donations. 3. The proposal lays down the objectives or "essential requirements" of safety, health, design and manufacture which must be met by in vitro diagnostic medical devices when they are manufactured and placed on the market. 4. Harmonized European standards on the prevention of risks relating to the design, manufacture and packaging of products are drawn up by the European standards bodies on the basis of the essential requirements. These standards, which are not mandatory, are published in the Official Journal of the European Communities in the form of national standards with identical contents. 5. Any product manufactured in accordance with harmonized standards is presumed to conform to the essential requirements. 7. The product conformity assessment procedures and the essential requirements are based on the modular approach set out in Council Decision 93/465/EEC. Conformity assessment is the responsibility of: * manufacturers or their authorized representatives themselves; or * more rarely, bodies which may be designated by the Member States in accordance with joint evaluation criteria and notified to the Commission and the other Member States. 8. Before they can be placed on the market, devices must bear the CE marking of conformity which: * confirms that they conform to the provisions of this proposal; * consists of a single graduated drawing the "CE" mark, accompanied by the identification number of the notified body responsible for following the procedures; * is affixed by the manufacturer or his authorized representative established in the Community. 9. If a device is subject to other Directives which require "CE" marking, the affixing of the mark also indicates that the device conforms to the requirements of those Directives. 10. Any other mark may also be affixed to the devices provided there is no risk of it being confused with the conformity mark. 11. Penalties must be imposed by the Member States if they find that the mark has been unduly affixed. 12. There is a safety

clause which allows any Member State, in an emergency, to withdraw the devices, when correctly installed, maintained and used for their intended purpose, from the market if they may compromise the safety of property and the health and/or safety of users or third parties. 13. Administrative cooperation and the exchange of information between the Member States are necessary to guarantee conformity with this proposal. 14. There is a transitional period of four years during which the Member States will authorize the placing on the market and/or putting into service of devices confirming to the rules in force in their territory from the date of adoption of this proposal. Source : European Commission - Info92 - 02/96?

## In vitro diagnostic medical devices: security requirements

The ESC endorsed the proposal and was pleased that the implementation of the in vitro diagnostic medical devices directive would remain in the hands of the Member States. This was a further indication that the concept of subsidiarity had been correctly understood by the Commission. The ESC noted that control materials for external quality assurance were expressly excluded from the scope of the draft Directive. This should be reviewed, at least in respect of stable control materials, which were frequently in no way different from those used for internal monitoring. In the ESC?s view, the directive should embrace all control materials, irrespective of the way in which they were used in medical laboratories. Exceptions could be made in the case of preparations using fresh blood, which could only be conserved for limited periods. The European standards bodies CEN/Cenelec should establish a standard in order to take account more effectively of the traceability requirement. It was important for users to continue to participate in the work of the working parties concerned on any future further development of the directive on in vitro diagnostic medical devices. The ESC considered that, particularly for self-testing devices, the ?instructions for use? should be in the language of the target country so that they could be understood by the users.

## In vitro diagnostic medical devices: security requirements

The committee made substantial changes to the report by Mr Alain POMPIDOU (UPE, F) concerning the directive on in vitro diagnostic medical devices. The directive hoped to establish harmonised standards with a view to completing the internal market for these products. Nevertheless, since in vitro diagnostic reagents were derived from the human body, it was important to draw up provisions to provide the maximum guarantees for users. The Committee on Economic and Monetary Affairs did not adopt the amendments tabled by Mr POMPIDOU aimed at defining three types of reagents to enable specific standards to be drawn up in accordance with the risk of error these products might entail. However, the members retained the idea of establishing a European database bringing together all the information provided by manufacturers and agreed on the need for Member States to apply continual surveillance of the quality and safety of these devices after being placed on the market. The other amendments were aimed at: - improving safety, particularly with regard to packaging; - reducing the risk of infection and eliminating the risks for users and patients; - ensuring that when the products were placed on the market, the information accompanying them was in the national language(s) and, if symbols or codes were used, that they were easily understood by non-professional users (self-testing devices); - ensuring extensive information, including the requirement for manufacturers to notify the relevant authorities in each Member State involved when their product was placed on the market. ?

## In vitro diagnostic medical devices: security requirements

In adopting the report by Mr Alain POMPIDOU (RDE, F), the European Parliament amended the directive on in vitro diagnostic medical devices. It calls for the establishment of a European Union databank containing data provided by the manufacturers and stresses the need for continuous assessment, by the Member States, of the quality and safety of such devices after they have been placed on the market. Other amendments seek to enhance the safety of products, particularly as regards packaging, and to reduce to the minimum the risks to users and patients. The EP calls for information on such products to be drawn up in the national language of the final user and, in the case of devices for self-testing, to be comprehensible to non-professional users. The EP also completes Annex II, which lists those reagents requiring a stringent monitoring of quality, by adding self-testing reagents and those of biological origin for the diagnosis of genetic diseases. ?

## In vitro diagnostic medical devices: security requirements

The rapporteur, Mr Pompidou (UPE, F), referred to the problems associated with this proposal, which had to reconcile two essential requirements, namely to ensure the free movement of products while at the same time protecting the health and safety of EU citizens. He thought that the ?new approach? was not appropriate for dealing with the problems posed by the stability of biological reactants, which in 35% of cases could lead to serious errors in diagnosis. For this reason he called for a quality control system to be introduced before and after the product was placed on the market, as this was the only way in which public health and safety could be guaranteed. Finally, the rapporteur stressed that a centralised database was needed in order to ensure consistency in the information being supplied to this sector. Commissioner Bangemann said that everyone was in favour of providing better protection for patients and declared that the Commission could accept 47 of the 78 amendments tabled. These were Amendments Nos 1 to 6, 8, 10 to 16, 19 and 21 in part, 22 to 29, 32 to 34, 36 to 39, 41, 42, 44 and 45 to 47 in part, 48 to 52, 56 in part, 58 to 60, 68 in part and 74. However, the Commission could not accept the compulsory use of labels in the national language of the country in which the product was marketed. The Commissioner went on to explain that most of the products were used by professionals who had a knowledge of foreign languages and that the cost of such a measure would be excessive, especially for smaller countries. However, he did not rule out the possibility of Member States introducing this requirement on a national basis. Finally, Mr Bangemann expressed his support for a regulatory committee.

## In vitro diagnostic medical devices: security requirements

The modified Commission proposal on in vitro diagnostic medical devices incorporates a number of amendments adopted by Parliament, and in particular those concerning: - clearer demarkation of the scope in comparison with Directive 89/392/EEC relating to machinery; - the

clarification that the aspects concerning medical prescriptions for devices are not affected by the harmonizations; - the tightening-up of the protection requirements with a view, in particular, to minimizing the risks, including the risks relating to the packaging; - the clarification of the powers of the Member States' authorities and the strengthening of their market surveillance powers; - the establishment of a European Union database on the products placed on the market; - extension of the group of in vitro diagnostic devices which must be submitted to third-party certification before they are placed on the market; - the inclusion in the scope of Directive 93/42/EEC of certain medical devices manufactured using products derived from human tissues or cells; - the amendments to Directive 93/42/EEC to bring it closer into line with this Directive. The Commission has not approved the amendments concerning: the obligation that the information accompanying the products placed on the market must be available in the national language(s); the type of committee; application of the transitional system for notification of devices placed on the market to all Member States. ?

## In vitro diagnostic medical devices: security requirements

The Council common position is based on the amended Commission proposal and incorporates in full or in part most of the amendments put forward by Parliament and accepted by the Commission. The one significant exception is the amendments concerning the inclusion of certain medical devices manufactured using substances derived from human tissue or cells in the scope of Directive 93/42/EEC. In fact the common position covers only the section on in vitro diagnostic medical devices, including in vitro diagnostic devices manufactured using substances of human origin. It does not incorporate the section of the proposal aiming to modify Directive 93/42/EEC to include medical devices other than those for in vitro diagnosis which have been manufactured from human tissues. This section of the proposal is still at the first reading stage in the Council and is to be the subject of separate legislation. The main changes to the Commission proposal to increase the safety of in vitro diagnostic medical devices are: (a) field of application: the directive does not affect national laws requiring devices to be issued only on a medical prescription; it also covers devices designed to monitor therapeutic treatment; (b) essential requirements: these are also concerned with the packaging of devices in so far as such packaging is related to the safety and performance aspects of the device; (c) devices subject to certification by a third party: Annex II of the common position lists, in addition to the extension already provided by the amended proposal, a number of devices for which certification by a third party will be required; this annex makes a distinction between products used in particular for blood transfusions (list A tests for blood groups, HIV and Hepatitis B, C and D) and products regarded as sensitive which require the intervention of a third party before they are placed on the market (list B); the list at Annex II has been extended to take account in particular of the medical conditions under which they are used, the consequences of false negative or positive results and the experience of the Member States; (d) market monitoring measures: the common position provides for a European databank to be set up containing data relating to registration of manufacturers and devices, certificates and data obtained in accordance with the vigilance procedure; it states that Member States have an obligation to monitor the safety and quality of devices placed on the market. The Council has also introduced new provisions with regard to the following aspects: (a) technical specifications: the common position provides that for devices listed at Annex II list A and if necessary for those on list B, 'common technical specifications' should be drawn up; these specifications would establish appropriate performance evaluation and re-evaluation criteria and replace national documents on these subjects. (b) strengthening evaluation and conformity procedures: in order to ensure an optimal level of safety for devices normally used for blood transfusions, Annex IV (full quality assurance system) requires for devices on list A of Annex II a particular assessment of the products' design; in addition, each batch of manufactured products is subject to additional checks on samples of the manufactured products; (c) rules applicable to the notified bodies: the common position states that the notified bodies have an obligation to suspend or withdraw certificates in given circumstances; the designation criteria for these bodies are also set out in greater detail; (d) particular health monitoring measures: a new provision makes it possible to take transitional national measures or Community measures to prohibit or restrict the availability of certain products or groups of products or to subject them to particular requirements. ?

## In vitro diagnostic medical devices: security requirements

The Commission accepts the common position. It calls on Parliament and the Council to conclude the legislative procedure as quickly as possible in order to bring about the necessary improvement in health protection in the in vitro diagnostic devices sector. The Commission stresses that legislation on medical devices manufactured using substances of human origin should be produced as soon as possible and will contribute to this accordingly. ?

## In vitro diagnostic medical devices: security requirements

Reporting for the Committee Mr Alain POMPIDOU (UFE, F) recommends that Parliament makes a few changes to the Council Common Position on a Directive on safety requirements for in vitro medical devices. Unlike medicines which are administered to the human body, in vitro diagnostics is carried out outside the human body on samples taken form patients. This include methods for the diagnosis of illnesses and screening of blood. The rapporteur notes that Council has accepted most of those amendments adopted by Parliament at first reading which were supported by the Commission. He therefore proposes only a small number of amendments seeking to strengthen the Common Position. In particular, while it is up to each Member State to decide whether instructions for use must be translated into its language or not, the rapporteur considers that this must be mandatory for self-testing devices such as pregnancy tests.?

## In vitro diagnostic medical devices: security requirements

Commissioner Bangemann accepted all the rapporteur?s amendments, which contained welcome clarifications and additions. He was also in favour of setting up a European database in this area.

## In vitro diagnostic medical devices: security requirements

In adopting the recommendation for second reading by Mr Alain POMPIDOU (UPEF) European Parliament stressed the need. - to draw up as quickly as possible legislation concerning medical devices manufactured from substance of human origin; - avoid distortion of competition concerning self testing devices; - translate into the language of the final user the instructions for use and the labelling of self test devices; - include screening methods by serum tests of chromosome 21; - development market DNA microchips with a view to screening for genetic diseases or the predisposition to certain genetic diseases (concerning which manufacture should inform the relevant authorities of the introduction of new products onto the market with regard to both the technology used and the substances to be analysed or other parameters; - preserve the confidentiality of information concerning persons undergoing diagnosis or tests and protect individuals against any discrimination based on inherited genetic characteristic of men and women.?

## In vitro diagnostic medical devices: security requirements

The Commission can accept the six amendments adopted by Parliament at second reading. ?

## In vitro diagnostic medical devices: security requirements

OBJECTIVES: to harmonise and improve the safety standards of in vitro diagnostic medical devices with a view to completing the internal market in this sector; to safeguard the health and safety of patients, users of the products in question and third parties.

COMMUNITY MEASURE: European Parliament and Council Directive 98/79/EC on in vitro diagnostic medical devices.

CONTENT: in vitro diagnostic medical devices are a sub-category of the medical devices defined in Directive 93/42/EEC. These devices are used in medicine for in vitro analysis of samples taken from the human body. The medical applications include analyses to evaluate the state of health (e.g. cholesterol, pregnancy), diagnose congenital diseases or anomalies, check the progress of a course of treatment (e.g. dosage and effect of drugs) or determine safety and compatibility in the case of organ or blood donations (e.g. to check for HIV or hepatitis).

The directive lays down the conditions under which in vitro diagnostic medical devices may be placed on the market. It sets out the main requirements in terms of reliability of the devices, taking account of their purpose, and in terms of the protection of users and third parties. In addition, it harmonises the procedures for evaluating compliance to be applied by manufacturers before placing devices on the market.

The directive requires Member States to implement a vigilance procedure so that any information which comes to their attention in relation to incidents involving devices carrying the CE mark is registered and evaluated centrally.

In order to monitor the market, the directive makes provision for the implementation of a European database containing data relating to registration of manufacturers and devices, certificates and data obtained in accordance with the vigilance procedure. It states that Member States have an obligation to monitor the safety and quality of devices placed on the market.

Finally, the directive makes it possible to take transitional national measures or Community measures to prohibit or restrict the placing on the market of certain products or groups of products on grounds of public health.

ENTRY INTO FORCE: 7 December 1998.

DEADLINE FOR TRANSPOSITION: 7 December 1999. Provision applicable from 7 June 2000.