Basic information

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In vitro diagnostic medical devices: security requirements Repealed by 2012/0267(COD) **Subject** 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 4.20.02 Medical research 4.20.04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

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ECON Economic and Monetary Affairs, Industrial Policy	POMPIDOU Alain (RDE)	24/05/1995

Former committee responsible	Former rapporteur	Appointed
ECON Economic and Monetary Affairs, Industrial Policy	POMPIDOU Alain (RDE)	24/05/1995

Former committee for opinion	Former rapporteur for opinion	Appointed
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	TRAKATELLIS Antonios (PPE)	19/04/1995
CONT Budgetary Control	The committee decided not to give an opinion.	

Council of the

Council configuration	Meetings	Date

European Union	General Affairs	2120	1998-10-05
	Competitiveness (Internal Market, Industry, Research and Space)	2051	1997-11-27
	Competitiveness (Internal Market, Industry, Research and Space)	2007	1997-05-21
	Environment	2076	1998-03-23

Key events

Date	Event	Reference	Summary
24/10/1994	Additional information		Summary
19/04/1995	Legislative proposal published	COM(1995)0130	
15/05/1995	Committee referral announced in Parliament, 1st reading		
06/02/1996	Vote in committee, 1st reading		
06/02/1996	Committee report tabled for plenary, 1st reading	A4-0031/1996	
12/03/1996	Debate in Parliament		Summary
20/12/1996	Modified legislative proposal published	COM(1996)0643	Summary
21/05/1997	Debate in Council		
23/03/1998	Council position published	05255/1/1998	Summary
02/04/1998	Committee referral announced in Parliament, 2nd reading		
03/06/1998	Vote in committee, 2nd reading		Summary
03/06/1998	Committee recommendation tabled for plenary, 2nd reading	A4-0225/1998	
17/06/1998	Debate in Parliament		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

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Amendments and repeals	Repealed by 2012/0267(COD)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

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A4-0031/1996 OJ C 078 18.03.1996, p. 0002	06/02/1996	
Text adopted by Parliament, 1st reading/single reading		T4-0115/1996 OJ C 096 01.04.1996, p. 0017-0031	12/03/1996	Summary
Committee recommendation tabled for plenary, 2nd reading		A4-0225/1998 OJ C 210 06.07.1998, p. 0009	03/06/1998	
Text adopted by Parliament, 2nd reading		T4-0362/1998 OJ C 210 06.07.1998, p. 0170-0194	18/06/1998	Summary

Council of the EU

Document type	Reference	Date	Summary
Council position	05255/1/1998 OJ C 178 10.06.1998, p. 0007	23/03/1998	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(1995)0130 OJ C 172 07.07.1995, p. 0021	19/04/1995	Summary
Modified legislative proposal	COM(1996)0643  OJ C 087 18.03.1997, p. 0009	20/12/1996	Summary
Commission communication on Council's position	SEC(1998)0555 	26/03/1998	Summary
Commission opinion on Parliament's position at 2nd reading	COM(1998)0548 	02/10/1998	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1153/1995 OJ C 018 22.01.1996, p. 0012	25/10/1995	Summary
EU	Implementing legislative act	32002D0364 OJ L 131 16.05.2002, p. 0017-0030	07/05/2002	

Additional information

Source	Document	Date

European Commission	EUR-Lex	

Final act	
Directive 1998/0079 OJ L 331 07.12.1998, p. 0001	Summary

In vitro diagnostic medical devices: security requirements

1995/0013(COD) - 02/10/1998 - Commission opinion on Parliament's position at 2nd reading

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

In vitro diagnostic medical devices: security requirements

1995/0013(COD) - 26/03/1998 - Commission communication on Council's position

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

1995/0013(COD) - 20/12/1996 - Modified legislative proposal

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

1995/0013(COD) - 25/10/1995

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

1995/0013(COD) - 12/03/1996

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

1995/0013(COD) - 23/03/1998 - Council position

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

1995/0013(COD) - 27/10/1998 - Final act

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.

In vitro diagnostic medical devices: security requirements

1995/0013(COD) - 18/06/1998 - Text adopted by Parliament, 2nd reading

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

1995/0013(COD) - 19/04/1995

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