Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

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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 laid down in Article 189b of the Treaty[(3)],

(1) Whereas measures should be adopted for the smooth operation 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;

(2) 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 authorisation procedures for *in vitro* diagnostic medical devices are different; whereas the existence of such disparities creates barriers to trade, and whereas the need to establish harmonised rules has been confirmed by a comparative survey of national legislations carried out on behalf of the Commission;

(3) Whereas the harmonisation of national legislation is the only means of removing such barriers to free trade and of preventing new barriers from arising; whereas this objective cannot be achieved in a satisfactory manner by other means by the individual Member States; whereas this Directive lays down only such requirements as are necessary and sufficient to ensure, under the best safety conditions, free movement of the *in vitro* diagnostic medical devices to which it applies;

(4) Whereas the harmonised provisions must be distinguished from 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 harmonised provisions do not affect the ability of the Member States to implement such measures provided that they comply with Community law;

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

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(6) Whereas, in accordance with the principles set out in the Council resolution of 7 May 1985 on a new approach to technical harmonisation and standards[(4)], rules regarding the design, manufacture and packaging 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 minimise and reduce risks, should be applied with discretion, taking into account the technology and practice at the time of design and technical and economic considerations compatible with a high level of protection of health and safety;

(7) Whereas the major part of medical devices are covered by Council Directive 90/385/EEC of 20 June 1990 on the approximation of laws relating to active implantable medical devices[(5)] and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[(6)] with the exclusion of *in vitro* diagnostic medical devices; whereas this Directive seeks to extend the harmonisation to *in vitro* diagnostic medical devices and whereas, in the interest of uniform Community rules, this Directive is based largely on the provisions of the said two Directives;

(8) Whereas instruments, apparatus, appliances, materials or other articles, including software, which are intended to be used for research purposes, without any medical objective, are not regarded as devices for performance evaluation;

(9) Whereas, although internationally certified 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;

(10) Whereas, having regard to the principle of subsidiarity, reagents which are produced within health-institution laboratories for use in that environment and are not subject to commercialtransactions are not covered by this Directive;

(11) Whereas, however, devices that are manufactured and intended to be used in a professional and commercial context for purposes of medical analysis without being marketed are subject to this Directive;

(12) Whereas mechanical laboratory equipment especially designed for *in vitro* diagnostic examinations falls within the scope of this Directive and whereas, therefore, in order to harmonise the relevant directives, Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery[(7)], should be appropriately amended to bring it into line with this Directive;

(13) Whereas this Directive should include requirements regarding the design and manufacture of devices emitting ionizing radiation; whereas this Directive does not affect the application of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation[(8)];

(14) Whereas, since electromagnetic compatibility aspects form an integral part of the essential requirements of this Directive, Council Directive 89/336/EEC of 2 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility[(9)] does not apply;

(15) 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 harmonised standards in respect of the prevention of risks associated with the design, manufacture and packaging of medical devices; whereas such harmonised 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 Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) are recognised as the competent bodies for the adoption ofharmonised standards in accordance with the general guidelines on cooperation between the Commission and those two bodies signed on 13 November 1984;

(16) Whereas, for the purpose of this Directive, a harmonised standard is a technical specification (European standard of harmonisation document) adopted, on a mandate from the Commission, by CEN or Cenelec or by both of those bodies in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations[(10)], and pursuant to the abovementioned general guidelines;

(17) Whereas, by way of exception to the general principles, the drawing up of common technical specifications takes account of a current practice in some Member States whereby for selected devices mainly used for the evaluation of the safety of blood supply and of organ donation, such specifications are adopted by the public authorities; whereas it is appropriate that these particular specifications should be replaced by common technical specifications; whereas these common technical specifications can be used for performance evaluation and reevaluation;

(18) Whereas scientific experts from various interested parties could be involved in the drafting of common technical specifications and in the examination of other specific or general questions;

(19) Whereas manufacturing, as covered by this Directive, also includes the packaging of the medical device, insofar as such packaging is related to the safety and performance aspects of this device;

(20) Whereas certain devices have a limited life owing to the decline in their performance over time, which is related, for example, to the deterioriation in their physical or chemical properties, including the sterility or integrity of the packaging; whereas the manufacturer should determine and indicate the period during which the device will perform as intended; whereas the labelling should indicate the date until which the device or one of its components can be used with complete safety;

(21) Whereas, in Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical

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harmonisation directives[(11)], the Council laid down harmonised 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 Directives 90/385/EEC and 93/42/EEC;

(22) Whereas it is necessary, essentially for the purpose of the conformity assessment procedures, to group *in vitro* diagnostic medical devices into two main 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 laid down in Directive 98/34/EC, 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;

(23) Whereas, among the *in vitro* diagnostic medical devices for which intervention of a notified body is required, the groups of products used in blood transfusion and the prevention of AIDS and certain types of hepatitis require a conformity assessment guaranteeing, with a view to their design and manufacture, an optimum level of safety and reliability;

(24) 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 developments in the field of health protection; whereas such updating measures must be taken in line with procedure III(a) as laid down in Council Decision 87/373/EEC of 13 July 1987 laying down the procedures for the exercise of implementing powers conferred on the Commission[(12)];

(25) Whereas an agreement on a modus vivendi between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the Treaty was reached on 20 December 1994[(13)];

(26) Whereas medical devices should, as a general rule, bear the CE marking indicating 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;

(27) Whereas manufacturers will be able, when the intervention of a notified body is required, to choose from a list of bodies published by the Commission; whereas, although Member States do not have an obligation to designate such notified bodies, they must ensure that bodies designated as notified bodies comply with the assessment criteria laid down in this Directive;

(28) Whereas the director and staff of the notified bodies should not, themselves or through an intermediary, have any interest in the establishments subject to assessment and verification which is likely to compromise their independence;

(29) Whereas the competent authorities in charge of market surveillance should be able, particularly in emergencies, to contact the manufacturer or his authorised representative

established in the Community, in order to take any protection measures that should prove necessary; whereas cooperation and exchange of information between Member States are necessary with a view to uniform application of this Directive, in particular for the purpose of market surveillance; whereas to that end it is necessary to establish and manage a database containing data on manufacturers and their authorised representatives, on devices placed on the market, on certificates issued, suspended or withdrawn, and on the vigilance procedure; whereas a system of adverse incident reporting (vigilance procedure) constitutes a useful tool for surveillance of the market, including the performance of new devices; whereas information obtained from the vigilance procedure as well as from external quality assessment schemes is useful for decision-making on classification of devices;

(30) Whereas it is essential that manufacturers notify the competent authorities of the placing on the market of 'new products' with regard both to the technology used and the substances to be analysed or other parameters; whereas this is true in particular of high-density DNA probe devices (known as micro-chips) used in genetic screening;

(31) Whereas, when a Member State considers that, as regards a given product or group of products, it is necessary, in order to protect health and safety and/or ensure compliance with the imperatives of public health, in accordance with Article 36 of the Treaty, to prohibit or restrict their availability or to subject it to special conditions, it may take any transitional measures that are necessary and justified; whereas, in such cases, the Commission consults the interested parties and the Member States and, if the national measures are justified, adopts the necessary Community measures, in accordance with procedure III(a) as laid down in Decision 87/373/EEC;

(32) Whereas this Directive covers *in vitro* diagnostic medical devices manufactured from tissues, cells or substances of human origin; whereas it does not refer to the other medical devices manufactured using substances of human origin; whereas, therefore, work will have to continue in this connection in order to produce Community legislation as soon as possible;

(33) Whereas, in view of the need to protect the integrity of the human person during the sampling, collection and use of substances derived from the human body, it is appropriate to apply the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine; whereas, furthermore, national regulations relating to ethics continue to apply;

(34) Whereas, in the interests of overall consistency between directives on medical devices, some of the provisions of this Directive should be incorporated into Directive 93/42/EEC, which needs to be amended accordingly;

(35) Whereas it is necessary to draw up as quickly as possible the legislation which is lacking on medical devices manufactured using substances of human origin,

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