ISSN 0378 – 6978

Official Journal
of the European Communities

L 189

Volume 33

20 July 1990

English edition

Legislation

Contents

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other Acts are printed in bold type and preceded by an asterisk.

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 20 June 1990

on the harmonization of the laws of the Member States relating to non-automatic weighing instruments

(90/384/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Member States have the responsibility of protecting the public against incorrect results of weighing operations by means of non-automatic weighing instruments when used for certain categories of applications;

Whereas, in each Member State, mandatory provisions fix in particular the necessary performance requirements of non-automatic weighing instruments by specifying metrological and technical requirements, together with inspection procedures before and after going into service; whereas these mandatory provisions do not necessarily lead to different levels of protection from one Member State to another but do, by their disparity, impede trade within the Community;

Whereas the national provisions ensuring such protection must be harmonized in order to guarantee the free movement of non-automatic weighing instruments while ensuring a justified level of protection in the Community;

Whereas Community legislation as it stands at present provides that, notwithstanding one of the fundamental rules of the Community, namely the free movement of goods, barriers to intra-Community movement resulting from disparities in national laws on the use of products have to be accepted in so far as the provisions of those national laws are recognized as necessary to ensure that the products concerned meet essential requirements; whereas the harmonization of laws in the present case must therefore be confined to those provisions needed to ensure that non-automatic weighing instruments satisfy the essential metrological and performance requirements; whereas, because they are essential, these requirements must replace the corresponding national provisions;

Whereas this Directive therefore contains only mandatory and essential requirements; whereas, to facilitate proof of conformity with the essential requirements, it is necessary to have harmonized standards at European level, in particular as to the metrological, design and construction characteristics, so that instruments complying with those harmonized standards may be assumed to conform to the essential requirements; whereas these standards, harmonized at European level, are drawn up by private bodies and must remain non-mandatory texts; whereas for that purpose 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 for cooperation between the Commission and those two bodies signed on 13 November 1984; whereas, within the meaning of this Directive, a harmonized standard is a technical specification (European standard or harmonized document) adopted by one or both of those bodies upon a remit from the Commission in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in

(1) OJ No C 55, 4. 3. 1989, p. 6, and OJ No C 297, 25. 11. 1989, p. 13.
(2) OJ No C 158, 26. 6. 1989, p. 221, and OJ No C 149, 18. 6. 1990.
(3) OJ No C 194, 31. 7. 1989, p. 1.

the field of technical standards and regulations (1), as amended by Directive 88/182/EEC (2), and the abovementioned general guidelines;

Whereas assessment of conformity with the relevant metrological and technical provisions is necessary to provide effective protection for users and third parties; whereas, the existing conformity assessment procedures differ from one Member State to another; whereas, to avoid multiple assessments of conformity, which are in effect barriers to the free movement of the instruments, arrangements should be made for the mutual recognition of conformity assessment procedures by the Member States; whereas, to facilitate the mutual recognition of conformity assessment procedures, harmonized Community procedures should be set up, together with harmonized criteria for the designation of the bodies responsible for carrying out tasks pertaining to the conformity assessment procedures;

Whereas it is therefore essential to ensure that such designated bodies ensure a high level of quality throughout the Community;

Whereas the presence on a non-automatic weighing instrument of the EC mark of conformity or of the sticker bearing the letter 'M' indicates that there is a presumption that it satisfies the provisions of this Directive and therefore makes it unnecessary to repeat the assessments of conformity already carried out;

Whereas the measures aimed at the gradual establishment of the internal market must be adopted by 31 December 1992; whereas the internal market consists of an area without internal frontiers within which the free movement of goods, persons, services and capital is guaranteed,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope, placing on the market, free movement

Article 1

1. A weighing instrument is defined as a measuring instrument serving to determine the mass of a body by using the action of gravity on that body. A weighing instrument may also serve to determine other mass-related magnitudes, quantities, parameters or characteristics.

A non-automatic weighing instrument is defined as a weighing instrument requiring the intervention of an operator during weighing.

This Directive applies to all non-automatic weighing instruments, hereinafter referred to as 'instruments'.

2. A distinction is made in this Directive between two categories of instrument use:

(a) 1. determination of mass for commercial transactions;

2. determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment;

3. determination of mass for the application of laws or regulations; expert opinion given in court proceedings;

4. determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment;

5. determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories;

6. determination of price on the basis of mass for the purposes of direct sales to the public and the making-up of prepackages;

(b) all applications other than those listed in point 2 (a) of this Article.

Article 2

1. Member States shall take all steps to ensure that instruments may not be placed on the market unless they meet the requirements of this Directive which apply to them.

2. Member States shall take all steps to ensure that instruments may not be put into service for the uses referred to in Article 1 (2) (a) unless they meet the requirements of this Directive which apply to them.

Article 3

Instruments used for the applications listed in Article 1 (2) (a) must satisfy the essential requirements set out in Annex I.

In cases where the instrument includes or is connected to devices which are not used for the applications listed in Article 1 (2) (a), such devices shall not be subject to the essential requirements.

Article 4

1. Member States shall not impede the placing on the market of instruments which meet the requirements of this Directive which apply to them.

(1) OJ No L 109, 26. 4. 1983, p. 8.
(2) OJ No L 81, 26. 3. 1988, p. 75.

2. Member States shall not impede the putting into service for the uses referred to in Article 1 (2) (a) of instruments which meet the requirements of this Directive which apply to them.

Article 5

1. Member States shall presume conformity with the essential requirements referred to in Article 3 in respect of instruments which comply with the relevant national standards implementing the harmonized standards that meet the essential requirements referred to in Article 3.

2. The Commission shall publish the references of the harmonized standards referred to in paragraph 1 in the *Official Journal of the European Communities*.

Member States shall publish the references of the national standards referred to in paragraph 1.

Article 6

Where a Member State or the Commission considers that the harmonized standards referred to in Article 5 (1) do not fully meet the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Directive 83/189/EEC, hereinafter referred to as 'the Committee', giving its reasons for doing so. The Committee shall deliver an opinion without delay.

In the light of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the publications referred to in Article 5 (2).

Article 7

1. Where a Member State considers that instruments bearing the EC mark of conformity referred to in Annex 2, sections 2, 3 and 4, do not meet the requirements of this Directive when properly installed and used for the purposes for which they are intended, it shall take all appropriate measures to withdraw those instruments from the market or to prohibit or restrict their being put into service and/or placed on the market.

The Member State concerned shall immediately inform the Commission of any such measure, indicating the reasons for its decision, and in particular whether non-compliance is due to:

(a) failure to meet the essential requirements referred to in Article 3, where instruments do not meet the standards referred to in Article 5 (1);

(b) incorrect application of the standards referred to in Article 5 (1);

(c) shortcomings in the standards referred to in Article 5 (1) themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible.

After such consultation the Commission shall immediately inform the Member State, which took the action, of the result. Should it find that the measure is justified it shall immediately inform the other Member States.

If the decision is attributed to shortcomings in the standards, the Commission, after consulting the parties concerned, shall bring the matter before the Committee within two months if the Member State which has taken the measures intends to maintain them, and shall subsequently initiate the procedures referred to in Article 6.

3. Where an instrument which does not comply bears the EC mark of conformity, the competent Member State shall take appropriate action against whomsoever has affixed the mark 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.

CHAPTER II

Conformity assessment

Article 8

1. The conformity of instruments to the essential requirements set out in Annex I may be certified by either of the following procedures as selected by the applicant:

(a) EC type examination as referred to in Annex II.1, followed either by the EC declaration of type conformity (guarantee of production quality) as referred to in Annex II.2, or by the EC verification as referred to in Annex II.3.

However, EC type examination shall not be compulsory for instruments which do not use electronic devices and whose load-measuring device does not use a spring to balance the load;

(b) EC unit verification as referred to in Annex II.4.

2. The documents and correspondence relating to the procedures referred to in paragraph 1 shall be drafted in an official language of the Member State where the said procedures are to be carried out, or in a language accepted by the competent body.

3. Where the instruments are subject to other Community Directives concerning other aspects, the EC mark referred to in Article 10 shall indicate in these cases that the instruments also fulfil the requirements of the other Directives.

Article 9

1. Member States shall notify to the other Member States and the Commission the bodies which they have designated for carrying out tasks pertaining to the procedure referred to in Article 8, the specific tasks for which each body has been designated, and the identification codes of the designated bodies.

The Commission shall publish the list of these notified bodies, together with the tasks for which they have been designated, in the *Official Journal of the European Communities* and shall ensure that the list is kept up to date.

2. Member States shall apply the minimum criteria set out in Annex V for the designation of bodies. Bodies which satisfy the criteria fixed by the relevant harmonized standards shall be presumed to satisfy the criteria set out in Annex V.

3. A Member State which has designated a body shall cancel the designation if the body no longer meets the criteria for designation referred to in paragraph 2. It shall immediately inform the other Member States and the Commission thereof and withdraw the notification.

CHAPTER III

EC mark of conformity and inscriptions

Article 10

1. The EC mark of conformity and the required supplementary data as described in Annex IV.1 shall be affixed in a clearly visible, easily legible and indelible form to instruments for which EC conformity has been established.

2. The inscriptions referred to in Annex IV.2 shall be affixed in a clearly visible, easily legible and indelible form to all other instruments.

3. The affixing to instruments of marks which are likely to be confused with the EC mark of conformity shall be prohibited.

Article 11

Where it is established that the EC mark of conformity has been wrongly affixed to instruments:

— not conforming to the standards referred to in Article 5 (1), where the manufacturer has chosen to manufacture instruments that conform to those standards,

— not conforming to an approved type,

— conforming to an approved type which does not meet the essential requirements applicable to it,

— in respect of which the manufacturer has failed to fulfil his obligations under the EC declaration of type conformity (guarantee of production quality),

the competent notified body shall, where necessary, withdraw the EC type-approval and/or the approval of the quality system. Withdrawal of EC type-approval shall have the effect of prohibiting submission for EC verification and the EC declaration of type conformity (guarantee of production quality).

Article 12

Where an instrument which is used for any of the applications referred to in Article 1 (2) (a) includes or is connected to devices that have not been subject to conformity assessment as referred to in Article 8, each of these devices shall bear the symbol restricting its use as defined by Annex IV.3. This symbol shall be affixed to the devices in a clearly visible and indelible form.

CHAPTER IV

Final provisions

Article 13

Member States shall take all steps to ensure that instruments bearing the EC mark attesting conformity with the requirements of this Directive continue to conform to those requirements.

Article 14

Any decision taken pursuant to this Directive and resulting in restrictions on the putting into service of an instrument shall state the exact grounds on which it is based. Such a decision shall be notified without delay to the party concerned, who shall at the same time be informed of the judicial remedies available to him under the laws in force in the Member State in question and of the time limits to which such remedies are subject.

Article 15

1. Member States shall, before 1 July 1992, adopt and publish the laws, regulations and administrative provisions necessary in order to comply with this Directive. They shall forthwith inform the Commission thereof.

2. Member States shall apply such provisions from 1 January 1993.

3. However, by way of derogation from paragraph 2, Member States shall permit during a period of 10 years from the date on which they apply the provisions referred to in

paragraph 1 the placing on the market and/or putting into service of instruments which conform to the rules in force before that date.

4. 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.

5. Directive 73/360/EEC shall be repealed as from 1 January 1993, except as regards the application of paragraph 3.

Article 16

This Directive is addressed to the Member States.

Done at Luxembourg, 20 June 1990.

For the Council

The President

D. J. O'MALLEY

ANNEX I

The essential requirements that must be met by the instruments referred to in Article 1 (2) (a) are set out below. The terminology used is that of the Organisation internationale de Métrologie Légale.

Preliminary observation

Where an instrument includes or is connected to more than one indicating or printing device used for the applications listed in Article 1 (2) (a), those devices which repeat the results of the weighing operation and which cannot influence the correct functioning of the instrument shall not be subject to the essential requirements if the weighing results are printed or recorded correctly and indelibly by a part of the instrument which meets the essential requirements and the results are accessible to both parties concerned by the measurement. However, in the case of instruments used for direct sales to the public, display and printing devices for the vendor and the customer must fulfil the essential requirements.

METROLOGICAL REQUIREMENTS

1. **Units of mass**

The units of mass used shall be the legal units within the meaning of Directive 80/181/EEC (1), as last amended by Directive 85/1/EEC (2).

Subject to compliance with this condition, the following units are permitted:

— SI untis: kilogram, microgram, milligram, gram, tonne,

— Imperial units: pound, ounce (avoirdupois), Troy ounce,

— other non-SI units: metric carat, if weighing precious stones.

For instruments that make use of the Imperial units of mass referred to above, the relevant essential requirements specified below shall be converted to the said Imperial units, using simple interpolation.

2. **Accuracy classes**

2.1. The following accuracy classes have been defined:

I special
II high
III medium
IIII ordinary

The specifications of these classes are given in Table 1.

TABLE 1

Accuracy classes

Class	Verification scale interval (e)	Minimum capacity (Min)	Number of verification scale intervals $n = \frac{Max}{e}$	
		minimum value	minimum value	maximum value
I	0,001 g ⩽ e	100 e	50 000	—
II	0,001 g ⩽ e ⩽ 0,005 g	20 e	100	100 000
	0,1 g ⩽ e	50 e	5 000	100 000
III	0,1 g ⩽ e ⩽ 2 g	20 e	100	10 000
	5 g ⩽ e	20 e	500	10 000
IIII	5 g ⩽ e	10 e	100	1 000

The minimum capacity is reduced to 5e for instruments in classes II and III for determining a conveying tariff.

(1) OJ No L 39, 15. 12. 1980, p. 39.
(2) OJ No L 2, 3. 1. 1985, p. 11.

2.2. *Scale intervals*

2.2.1. The actual scale interval (d) and the verification scale interval (e) shall be in the form:

1×10^k, 2×10^k, or 5×10^k mass units,

k being any integer or zero.

2.2.2. For all instruments other than those with auxiliary indicating devices:

$d = e$

2.2.3. For instruments with auxiliary indicating devices the following conditions apply:

$e = 1 \times 10^k$ g

$d < e \leqslant 10\ d$

except for instruments of class 1 with $d < 10^{-4}$ g, for which $e = 10^{-3}$ g.

3. Classification

3.1. *Instruments with one weighing range*

Instruments equipped with an auxiliary indicating device shall belong to class I or class II. For these instruments the minimum capacity lower limits for these two classes are obtained from Table 1 by replacement in column 3 of the verification scale interval (e) by the actual scale interval (d).

If $d < 10^{-4}$ g, the maximum capacity of class 1 may be less than 50 000 e.

3.2. *Instruments with multiple weighing ranges*

Multiple weighing ranges are permitted, provided they are clearly indicated on the instrument. Each individual weighing range is classified according to 3.1. If the weighing ranges fall into different accuracy classes the instrument shall comply with the severest of the requirements that apply for the accuracy classes in which the weighing ranges fall.

3.3. *Multi-interval instruments*

3.3.1. Instruments with one weighing range may have several partial weighing ranges (multi-interval instruments).

Multi-interval instruments shall not be equipped with an auxiliary indicating device.

3.3.2. Each partial weighing range 1 of multi-interval instruments is defined by:

— its verification scale interval e_i with $e_{(i+1)} > e_i$

— its maximum capacity Max_i with $Max_r = Max$

— its minimum capacity Min_i with $Min_i = Max_{(i-1)}$ and $Min_1 = Min$

where:

$i = 1, 2, \ldots r$,

i = partial weighing range number,

r = the total number of partial weighing ranges.

All capacities are capacities of net load, irrespective of the value of any tare used.

3.3.3. The partial weighing ranges are classified according to Table 2. All partial weighing ranges shall fall into the same accuracy class, this class being the instrument's accuracy class.

TABLE 2

Multi-interval instruments

i = 1, 2, . . . r
i = partial weighing range number
r = total number of partial weighing ranges

Class	Verification scale interval (e)	Minimum capacity (Min)	Number of verification scale intervals	
		Minimum value	Minimum value (1) $n = \frac{Max_i}{e_{(i+1)}}$	Maximum value $n = \frac{Max_i}{e_i}$
I	0,001 g ≤ e_i	100 e_1	50 000	—
II	0,001 g ≤ e_i ≤ 0,05 g	20 e_1	5 000	100 000
	0,1 g ≤ e_i	50 e_1	5 000	100 000
III	0,1 g ≤ e_i	20 e_1	500	10 000
IIII	5 g ≤ e_i	10 e_1	50	1 000

(1) For i = r the corresponding column of Table 1 applies, with e replaced by e_r.

4. **Accuracy**

4.1. On implementation of the procedures laid down in Article 8, the error of indication shall not exceed the maximum permissible error of indication as shown in Table 3. In case of digital indication the error of indication shall be corrected for the rounding error.

The maximum permissible errors apply to the net and tare value for all possible loads, excluded preset tare values.

TABLE 3

Maximum permissible errors

Load				Maximum permissible error
Class I	Class II	Class III	Class IIII	
0 ≤ m ≤ 50 000 e	0 ≤ m ≤ 5 000 e	0 ≤ m ≤ 500 e	0 ≤ m ≤ 50 e	± 0,5 e
50 000 e < m ≤ 200 000 e	5 000 e < m ≤ 20 000 e	500 e < m ≤ 2 000 e	50 e < m ≤ 200 e	± 1,0 e
200 000 e < m	20 000 e < m ≤ 100 000 e	2 000 e < m ≤ 10 000 e	200 e < m ≤ 1 000 e	± 1,5 e

4.2. The maximum permissible errors in service are twice the maximum permissible errors fixed in section 4.1.

5. Weighing results of an instrument shall be repeatable, and shall be reproducible by the other indicating devices used and with other methods of balancing used.

The weighing results shall be sufficiently insensitive to changes in the position of the load on the load receptor.

6. The instrument shall react to small variations in the load.

7. **Influence quantities and time**

7.1. Instruments of classes II, III and IIII, liable to be used in a tilted position, shall be sufficiently insensitive to the degree of tilting that can exist in a normal installed condition.

7.2. The instruments shall meet the metrological requirements within the temperature range specified by the manufacturer. The value of this range shall be at least equal to:

5 °C for an instrument in class I,

15 °C for an instrument in class II,

30 °C for an instrument in class III or IIII.

In the absence of a manufacturer's specification, the temperature range of −10 °C to +40 °C applies.

7.3. Instruments operated from a mains power supply shall meet the metrological requirements under conditions of power supply within the limits of normal fluctuation.

Instruments operated from battery power shall indicate whenever the voltage drops below the minimum required value and shall under those circumstances either continue to function correctly or be automatically put out of service.

7.4. Electronic instruments, except those in class I and in class II if e is less than 1 g, shall meet the metrological requirements under conditions of high relative humidity at the upper limit of their temperature range.

7.5. Loading an instrument in class II, III or IIII for a prolonged period of time shall have a negligible influence on the indication at load or on the zero indication immediately after removal of the load.

7.6. Under other conditions the instruments shall either continue to function correctly or be automatically put out of service (1).

DESIGN AND CONSTRUCTION

8. **General requirements**

8.1. Design and construction of the instruments shall be such that the instruments will preserve their metrological qualities when properly used and installed, and when used in an environment for which they are intended. The value of the mass must be indicated.

8.2. When exposed to disturbances, electronic instruments shall not display the effects of significant faults, or shall automatically detect and indicate them.

Upon automatic detection of a significant fault, electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the fault disappears.

8.3. The requirements of 8.1 and 8.2 shall be met on a lasting basis during a period of time that is normal in view of the intended use of such instruments.

Digital electronic devices shall always exercise adequate control of the correct operation of the measuring process, of the indicating facility, and of all data storage and data transfer.

Upon automatic detection of a significant durability error, electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the error disappears.

8.4. When external equipment is connected to an electronic instrument through an appropriate interface the metrological qualities of the instrument shall not be adversely influenced.

8.5. The instruments shall have no characteristics likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal. Components that may not be dismantled or adjusted by the user shall be secured against such actions.

8.6. Instruments shall be designed to permit ready execution of the statutory controls laid down by this Directive.

9. **Indication of weighing results and other weight values**

The indication of the weighing results and other weight values shall be accurate, unambiguous and non-misleading and the indicating device shall permit easy reading of the indication under normal conditions of use.

The names and symbols of the units referred to in paragraph 1 of this Annex shall comply with the provisions of Directive 80/181/EEC (1) with the addition of the symbol for the metric carat which shall be the symbol 'ct'.

(1) OJ No L 33, 15. 2. 1980, p. 39.

Indication shall be impossible above the maximum capacity (Max), increased by 9e.

An auxiliary indicating device is permitted only to the right of the decimal mark. An extended indicating device may be used only temporarily, and printing shall be inhibited during its functioning.

Secondary indications may be shown, provided that they cannot be mistaken for primary indications.

10. **Printing of weighing results and other weight values**

Printed results shall be correct, suitably identified and unambiguous. The printing shall be clear, legible, non-erasable and durable.

11. **Levelling**

When appropriate, instruments shall be fitted with a levelling device and a level indicator, sufficiently sensitive to allow proper installation.

12. **Zeroing**

Instruments may be equipped with zeroing devices. The operation of these devices shall result in accurate zeroing and shall not cause incorrect measuring results.

13. **Tare devices and preset tare devices**

The instruments may have one or more tare devices and a preset tare device. The operation of the tare devices shall result in accurate zeroing and shall ensure correct net weighing. The operation of the preset tare device shall ensure correct determination of the calculated net value.

14. **Instruments for direct sales to the public with a maximum capacity not greater than 100 kg: additional requirements**

Instruments for direct sale to the public shall show all essential information about the weighing operation and, in the case of price-indicating instruments, shall clearly show the customer the price calculation of the product to be purchased.

The price to pay, if indicated, shall be accurate.

Price-computing instruments shall display the essential indications long enough for the customer to read them properly.

Price-computing instruments may perform functions other than per-article weighing and price computation only if all indications related to all transactions are printed clearly, unambiguously and conveniently arranged on a ticket or label for the customer.

Instruments shall bear no characteristics that can cause, directly or indirectly, indications whose interpretation is not easy or straightforward.

Instruments shall safeguard customers against incorrect sales transactions due to their malfunctioning.

Auxiliary indicating devices and extended indicating devices are not permitted.

Supplementary devices are permitted only if they cannot lead to fraudulent use.

Instruments similar to those normally used for direct sales to the public which do not satisfy the requirements of this section must carry near to the display the indelible marking 'Not to be used for direct sale to the public'.

15. **Price labelling instruments**

Price labelling instruments shall meet the requirements of price indicating instruments for direct sale to the public, as far as applicable to the instrument in question. The printing of a price label shall be impossible below a minimum capacity.

ANNEX II

1. **EC type-examination**

1.1. EC type-examination is the procedure whereby a notified body verifies and certifies that an instrument, representative of the production envisaged, meets the requirements of this Directive that apply to it.

1.2. The application for type-examination shall be lodged by the manufacturer or his authorized representative established within the Community with a single notified body.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition,

— a written declaration that the application has not been lodged with any other notified body,

— the design documentation, as described in Annex III.

The applicant shall place at the disposal of the notified body an instrument, representative of the production envisaged, hereinafter called the 'type'.

1.3. The notified body shall:

1.3.1. examine the design documentation and verify that the type has been manufactured in accordance with that documentation;

1.3.2. agree with the applicant on the location where the examinations and/or tests shall be carried out;

1.3.3. perform or have performed the appropriate examinations and/or tests to check whether the solutions adopted by the manufacturer meet the essential requirements where the standards referred to in Article 5 have not been applied;

1.3.4. perform or have performed the appropriate examinations and/or tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have been applied effectively, thereby assuring conformity with the essential requirements.

1.4. Where the type meets the provisions of this Directive, the notified body shall issue an EC type-approval certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions (if any) for its validity, the necessary data for identification of the approved instrument and, if relevant, a description of its functioning. All the relevant technical elements such as drawings and layouts shall be annexed to the EC type-approval certificate.

The certificate shall have a validity period of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.

In the event of fundamental changes to the design of the instrument, e.g. as a result of the application of new techniques, the validity of the certificate may be limited to two years and extended by three years.

1.5. Each notified body shall periodically make available to all Member States the list of:

— applications received for EC type-examination,

— EC type-approval certificates issued,

— applications for type-certificates refused,

— additions and amendments relating to documents already issued.

Each notified body shall moreover inform all the Member States forthwith of withdrawals of EC type-approval certificates.

Each Member State shall make this information available to the bodies which it has notified

1.6. The other notified bodies may receive a copy of the certificates together with the Annexes to them.

1.7. The applicant shall keep the notified body that has issued the EC type-approval certificate informed of any modification to the approved type.

Modifications to the approved type must receive additional approval from the notified body that issued the EC type-approval certificate where such changes influence conformity with the essential requirements of this Directive or the prescribed conditions for use of the instrument. This additional approval is given in the form of an addition to the original EC type-approval certificate.

2. **EC declaration of type conformity (guarantee of production quality)**

2.1. The EC declaration of type conformity (guarantee of production quality) is the procedure whereby the manufacturer who satisfies the obligations of paragraph 2.2 declares that the instruments concerned are, where applicable, in conformity with the type as described in the EC type-approval certificate and satisfy the requirements of this Directive that apply to them.

The manufacturer shall affix the EC mark to each instrument as well as the inscriptions provided for in Annex IV.

The EC mark shall be accompanied by the identification symbol of the notified body responsible for the EC surveillance referred to in paragraph 2.4.

2.2. The manufacturer shall have adequately implemented a quality system as specified in paragraph 2.3 and shall be subject to EC surveillance as specified in paragraph 2.4.

2.3. *Quality system*

2.3.1. The manufacturer shall lodge an application for approval of this quality system with a notified body.

The application shall include:

— an undertaking to carry out the obligations arising from the approved quality system,

— an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness.

The manufacturer shall make available to the notified body all relevant information, in particular the quality system's documentation and the design documentation of the instrument.

2.3.2. The quality system shall ensure conformity of the instruments with the type as described in the EC type-approval certificate and with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written rules, procedures and instructions. This quality system documentation shall ensure a proper understanding of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

— the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,

— the manufacturing process, the quality control and assurance techniques and the systematic measures that will be used,

— the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out,

— the means to monitor the achievement of the required product quality and the effective operation of the quality system.

2.3.3. The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in paragraph 2.3.2. It shall presume conformity with these requirements in respect of quality systems that implement the corresponding harmonized standard.

It shall notify its decision to the manufacturer and inform the other notified bodies thereof. The notification to the manufacturer shall contain the conclusions of the examination and, in the event of refusal, the justification for the decision.

2.3.4. The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any updating of the quality assurance system in relation to changes brought about by, e.g. new technologies and new quality concepts.

2.3.5. Any notified body that withdraws approval of a quality system shall so inform the other notified bodies.

2.4. *EC surveillance*

2.4.1. The purpose of EC surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

2.4.2. The manufacturer shall grant the notified body access for inspection purposes to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the design documentation,

— the quality records, e.g. the inspection reports and tests and calibration data, reports on the qualifications of the personnel concerned, etc.

The notified body shall periodically carry out audits in order to ensure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report.

In addition, the notified body may carry out unscheduled visits to the manufacturer. During such visits, the notified body may carry out full or partial audits. It shall provide the manufacturer with a report on the visit, and, where appropriate, an audit report.

2.4.3. The notified body shall ensure that the manufacturer maintains and applies the approved quality system.

3. **EC verification**

3.1. The EC verification is the procedure whereby a notified body checks and attest that instruments concerned are, where appropriate, in conformity with the type as described in the EC type-approval certificate and satisfy the requirements of this Directive that apply to them. The notified body shall affix the EC mark to each instrument.

3.2. Each instrument shall be examined and appropriate tests as set out in the relevant standards referred to in Article 5, or equivalent tests, shall be carried out to ensure its conformity with the essential requirements of this Directive.

3.3. The EC mark referred to in 3.1 above shall be accompanied by the identification symbol of the notified body.

3.4. For instruments not subject to EC-type approval, the design documentation referred to in Annex III must be accessible to the notified body to the extent that the latter so requests.

4. **EC unit verification**

4.1. EC unit verification is the procedure whereby a notified body checks and attests that an instrument, generally designed for a specific application, satisfies the requirements of this Directive which apply to it. The notified body shall affix the EC mark to the instrument.

4.2. The instrument shall be examined and appropriate tests as set out in the relevant standards referred to in Article 5, or equivalent tests, shall be carried out to ensure its conformity with the relevant requirements of this Directive.

4.3. The EC mark referred to in 4.1. shall be accompanied by the identification symbol of the notified body.

4.4. The design documentation of the instrument as specified in Annex III shall be made available to the notified body.

5. **Common provisions**

5.1. The EC declaration of type conformity (guarantee of production quality), the EC verification, and the EC unit verification may be carried out at the manufacturer's works or any other location if transport to the place of use does not require dismantling of the instrument, if the taking into service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the gravity value at the place of putting into service is taken into consideration or if the instrument's performance is insensitive to gravity variations. In all other cases, they shall be carried out at the place of use of the instrument.

5.2. If the instrument's performance is sensitive to gravity variations the procedures referred to in 5.1 may be carried out in two stages, where the second stage shall comprise all examinations and tests of which the outcome is gravity-dependent, and the first stage all other examinations and tests. The second stage shall be carried out at the place of use of the instrument. If a Member State has established gravity zones on its territory the expression 'at the place of use of the instrument' may be read as 'in the gravity zone of use of the instrument'.

5.3.1. Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in 5.1, and where these two stages will be carried out by different parties, an instrument which has undergone the first stage of the procedure concerned shall carry the identification symbol of the notified body involved in that stage.

5.3.2. The party which has carried out the first stage of the procedure shall issue for each of the instruments a certificate, containing the necessary data for identification of the instrument and specifying the examinations and tests that have been carried out.

The party which carries out the second stage of the procedure shall carry out those examinations and tests that have not yet been carried out.

5.3.3. The manufacturer who has opted for the EC declaration of type conformity (guarantee of production quality) in stage one may either use this same procedure in stage two or decide to continue in stage two with EC verification.

5.3.4. The EC mark shall be affixed to the instrument after completion of the second stage together with the identification symbol of the notified body involved in stage two.

ANNEX III

DESIGN DOCUMENTATION

The technical documentation must render the design, manufacture and operation of the product intelligible and enable an assessment to be made of its conformity with the requirements of the Directive.

The documentation shall include in so far as relevant for assessment:

— a general description of the type,

— conceptual designs and manufacturing drawings and plans of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of the above, including the operation of the instrument,

— 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 where the standards referred to in Article 5 have not been applied,

— results of design calculations made and of examinations, etc.,

— test reports,

— the EC type-approval certificates and the results of relevant tests on instruments containing parts identical to those in the design.

ANNEX IV

1. **Instruments subject to the EC conformity assessment procedure**

1.1. These instruments must bear:

(a) — the EC mark of conformity comprising the EC symbol as described in Annex VI, followed by the last two digits of the year in which it was affixed,

— the identification symbol(s) of the notified body/bodies that has/have carried out the EC surveillance or the EC verification.

The abovementioned mark and inscriptions shall be affixed to the instrument, distinctly grouped together;

(b) a green sticker at least 12,5 mm × 12,5 mm square bearing a capital letter 'M' printed in black;

(c) the following inscriptions:

— the number of the EC type-approval certificate, where appropriate,

— the manufacturer's mark or name,

— the accuracy class, enclosed in an oval or in two horizontal lines joined by two half circles,

— maximum capacity in the form Max . . .,

— minimum capacity in the form Min . . .,

— verification scale interval in the form e =,

plus, when applicable:

— serial number,

— for instruments consisting of separate but associated units: identification mark on each unit,

— scale interval if it is different from e, in the form d = . . .,

— maximum additive tare effect, in the form T = + . . .,

— maximum subtractive tare effect if it is different from Max, in the form T = - . . .,

— tare interval if it is different from d, in the form d_T = . . .,

— maximum safe load if it is different from Max, in the form Lim . . .,

— the special temperature limits, in the form . . . °C/. . . °C,

— ratio between load recepter and load.

1.2. The instruments shall have adequate facilities for the affixing of the EC mark of conformity and/or inscriptions. These shall be such that it shall be impossible to remove the mark and inscriptions without damaging them, and that the mark and inscriptions shall be visible when the instrument is in its regular operating position.

1.3. Where a data plate is used it shall be possible to seal the plate unless it cannot be removed without being destroyed. If the data plate is sealable it shall be possible to apply a control mark to it.

1.4. The inscriptions Max, Min, *e, d,* shall also be shown near the display of the result if they are not already located there.

1.5. Each load measuring device which is connected or can be connected to one or more load receptors shall bear the relevant inscriptions relating to the said load receptors.

2. **Other instruments**

The other instruments must bear:

— the manufacturer's mark or name,

— maximum capacity in the form Max . . .

These instruments may not bear the stickers provided for in 1.1 (b).

3. **Restrictive use symbol specified in Article 12**

This symbol shall be constituted by a capital letter 'M' printed in black on a red background at least 25 mm × 25 mm square with two intersecting diagonals forming a cross.

ANNEX V

Set out below are the minimum criteria to be applied by Member States when designating bodies for the carrying-out of tasks pertaining to the procedures referred to in Article 8.

1. The bodies shall dispose of the necessary personnel, means and equipment.
2. The personnel shall have technical competence and professional integrity.
3. The bodies shall work independently of all circles, groups or persons having direct or indirect interest in non-automatic weighing instruments regarding the carrying-out of the tests, the preparation of the reports, the issuing of the certificates and the surveillance requested by this Directive.
4. The personnel shall respect the professional secret.
5. The bodies shall have taken out a civil liability insurance if their civil liability is not covered by the State under national law.

The fulfilment of the conditions under points 1 and 2 shall be periodically verified by the Member States.

ANNEX VI

COUNCIL DIRECTIVE

of 20 June 1990

on the approximation of the laws of the Member States relating to active implantable medical devices

(90/385/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas in each Member State active implantable medical devices must give patients, users and other persons a high level of protection and achieve the intended level of performance when implanted in human beings;

Whereas several Member States have sought to ensure that level of safety by mandatory specifications relating both to the technical safety features and the inspection procedures for such devices; whereas those specifications differ from one Member State to another;

Whereas national provisions ensuring that safety level should be harmonized in order to guarantee the free movement of active implantable medical devices without lowering existing and justified levels of safety in the Member States;

Whereas harmonized measures must be distinguished from measures taken by Member States to manage the financing of public health and sickness insurance schemes directly or indirectly concerning such devices; whereas, therefore, such provisions do not affect the right of Member States to implement the abovementioned measures in compliance with Community law;

Whereas maintaining or improving the level of protection achieved in Member States constitutes one of this Directive's essential objectives as defined by the essential requirements;

Whereas rules governing active implantable medical devices can be confined to those provisions needed to satisfy the essential requirements; whereas, because they are essential, these requirements must replace corresponding national provisions;

Whereas, in order to facilitate proof of conformity with these essential requirements and to permit monitoring of that conformity, it is desirable to have Europe-wide harmonized standards in respect of the prevention of risks in connection with the design, manufacture and packaging of active implantable medical devices; whereas such standards harmonized at European level are drawn up by private-law bodies and must retain their status as non-mandatory texts; whereas, to that end, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as being the competent bodies to adopt harmonized standards in accordance with the general guidelines for cooperation between the Commission and these two bodies, signed on 13 November 1984; whereas, for the purposes of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted by either or both of these bodies, as instructed by the Commission pursuant to the provisions of 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 (4), as last amended by Directive 88/182/EEC (5), and under the abovementioned general guidelines;

Whereas evaluation procedures have to be established and accepted by common accord between the Member States in accordance with Community criteria;

Whereas the specific nature of the medical sector makes it advisable to make provision for the notified body and the manufacturer or his agent established in the Community to fix, by common accord, the time limits for completion of the evaluation and verification operations for the conformity of devices,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to active implantable medical devices.

(1) OJ No C 14, 18. 1. 1989, p. 4.
(2) OJ No C 120, 16. 5. 1989, p. 75, and OJ No C 149, 18. 6. 1990.
(3) OJ No C 159, 26. 6. 1989, p. 47.
(4) OJ No L 109, 26. 4. 1983, p. 8.
(5) OJ No L 81, 26. 3. 1988, p. 75.

2. For the purposes 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, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the:

— diagnosis, prevention, monitoring, treatment or alleviation of disease or injury,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

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

(b) 'active medical device' means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;

(c) 'active implantable medical device' means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

(d) 'custom-made device' means any active implantable medical device specifically made in accordance with a medical specialist's written prescription which gives, under his responsibility, specific design characteristics and is intended to be used only for an individual named patient;

(e) 'device intended for clinical investigation' means any active implantable medical device intended for use by a specialist doctor when conducting investigations in an adequate human clinical environment;

(f) 'intended purpose' means the use for which the medical device is intended and for which it is suited according to the data supplied by the manufacturer in the instructions;

(g) 'putting into service' means making available to the medical profession for implantation.

3. Where an active implantable medical device is intended to administer a substance defined as a medicinal product within the meaning of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products [1], as last amended by Directive 87/21/EEC [2], that substance shall be subject to the system of marketing authorization provided for in that Directive.

4. Where an active implantable medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 65/65/EEC, that device must be evaluated and authorized in accordance with the provisions of this Directive.

5. This Directive constitutes a specific Directive within the meaning of Article 2 (2) of Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility [3].

Article 2

Member States shall take all necessary steps to ensure that the devices referred to in Article 1 (2) (c) and (d) may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly implanted, maintained and used in accordance with their intended purposes.

Article 3

The active implantable medical devices referred to in Article 1 (2) (c), (d) and (e), hereinafter referred to as 'devices', must satisfy the essential requirements set out in Annex 1, which shall apply to them account being taken of the intended purpose of the devices concerned.

Article 4

1. Member States shall not impede the placing on the market or the putting into service within their territory of devices bearing the CE mark.

2. Member States shall not create any obstacles to:

— devices intended for clinical investigations being made available to specialist doctors for that purpose if they satisfy the conditions laid down in Article 10 and in Annex 6,

— custom-made devices being placed on the market and put into service if they satisfy the conditions laid down in Annex 6 and are accompanied by the statement referred to in that Annex.

These devices shall not bear the CE mark.

3. At trade fairs, exhibitions, demonstrations, etc., Member States shall not prevent the showing of devices which do not conform to this Directive, provided that a visible sign clearly indicates that such devices do not conform

(1) OJ No 22, 9. 2. 1965, p. 369/65.
(2) OJ No L 15, 17. 1. 1987, p. 36.
(3) OJ No L 139, 23. 5. 1989, p. 19.

and cannot be put into service until they have been made to comply by the manufacturer or his authorized representative established within the Community.

4. When a device is put into service, Member States may require the information described in sections 13, 14 and 15 of Annex 1 to be in their national language(s).

Article 5

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 adopted pursuant to the harmonized standards the references of which have been published in the *Official Journal of the European Communities;* Member States shall publish the references of such national standards.

Article 6

1. Where a Member State or the Commission considers that the harmonized standards referred to in Article 5 do not entirely meet the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Directive 83/189/EEC, giving the reasons therefor. The Committee shall deliver an opinion without delay.

In the light of the opinion of the Committee, the Commission shall inform Member States of the measures to be taken with regard to the standards and the publication referred to in Article 5.

2. A Standing Committee, hereinafter referred to as the 'Committee', shall be set up, composed of the representatives of the Member States and chaired by the representative of the Commission.

The Committee shall draw up its rules of procedure.

Any matter relating to the implementation and practical application of this Directive may be brought before the Committee, in accordance with the procedure set out below.

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion 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

1. Where a Member State finds that the devices referred to in Article 1 (2) (c) and (d), correctly put into service and used in accordance with their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or their being put into service.

The Member State shall immediately inform the Commission of any such measure, 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, where the device does not meet in full or in part the standards referred to in Article 5;

(b) incorrect application of those standards;

(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 (1),

— 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 device which does not comply bears the CE mark, the competent Member State shall take appropriate action against whomsoever has affixed the mark 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 8

1. Member States shall take the necessary steps to ensure that information brought to their knowledge regarding the incidents mentioned below involving a device is recorded and evaluated in a centralized manner:

(a) any deterioration in the characteristics and performances of a device, as well as any inaccuracies in the instruction leaflet which might lead to or might have led to the death of a patient or to a deterioration in his state of health;

(b) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

2. Member States shall, without prejudice to Article 7, forthwith inform the Commission and the other Member States of the incidents referred to in paragraph 1 and of the relevant measures taken or contemplated.

Article 9

1. In the case of devices other than those which are custom-made or intended for clinical investigations, the manufacturer must, in order to affix the CE mark, at his own choice:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex 2; or

(b) follow the procedure relating to EC type-examination set out in Annex 3, coupled with:

(i) the procedure relating to EC verification set out in Annex 4, or

(ii) the procedure relating to the EC declaration of conformity to type set out in Annex 5.

2. In the case of custom-made devices, the manufacturer must draw up the declaration provided for in Annex 6 before placing each device on the market.

3. Where appropriate, the procedures provided for in Annexes 3, 4 and 6 may be discharged by the manufacturer's authorized representative established in the Community.

4. The records and correspondence relating to the procedures referred to in paragraphs 1, 2 and 3 shall be in an official language of the Member State in which the said procedures will be carried out and/or in a language acceptable to the notified body defined in Article 11.

Article 10

1. In the case of devices intended for clinical investigations, the manufacturer or his authorized representative established in the Community shall, at least 60 days before the commencement of the investigations, submit the statement referred to in Annex 6 to the competent authorities of the Member State in which the investigations are to be conducted.

2. The manufacturer may commence the relevant clinical investigations at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary, based on considerations of public health or public order.

3. The Member States shall, if necessary, take the appropriate steps to ensure public health and order.

Article 11

1. Each Member State shall notify the other Member States and the Commission of the bodies which they have designated for carrying out the tasks pertaining to the procedures referred to in Articles 9 and 13, the specific tasks for which each body has been designated and the identifying logo of these bodies, hereinafter referred to as 'notified bodies'.

The Commission shall publish a list of these notified bodies, together with the tasks for which they have been notified, in the *Official Journal of the European Communities* and shall ensure that the list is kept up to date.

2. Member States shall apply the minimum criteria, set out in Annex 8, for the designation of bodies. Bodies that satisfy the criteria fixed by the relevant harmonized standards shall be presumed to satisfy the relevant minimum 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 thereof.

4. The notified body and the manufacturer or his agent established in the Community shall fix, by common accord, the time limits for completion of the evaluation and verification operations referred to in Annexes 2 to 5.

Article 12

1. Devices other than those which are custom made or intended for clinical investigations considered to meet the essential requirements referred to in Article 3 must bear the EC mark of conformity.

2. The EC mark of conformity, as shown in Annex 9, must appear in a visible, legible and indelible form on the sterile pack and, where appropriate, on the sales packaging, if any, and on the instruction leaflet.

It must be accompanied by the logo of the notified body responsible for implementation of the procedures set out in Annexes 2, 4 and 5.

3. The affixing of marks likely to be confused with the EC mark of conformity shall be prohibited.

Article 13

Where it is established that the EC mark has been wrongly affixed, in particular, in respect of devices:

— that do not conform to the relevant standards referred to in Article 5, should the manufacturer have opted for conformity therewith,

— that do not conform to an approved type,

— that conform to an approved type which does not meet the relevant essential requirements,

— regarding which the manufacturer has failed to fulfil his obligations under the relevant EC declaration of conformity,

the notified body shall take appropriate measures and forthwith inform the competent Member State thereof.

Article 14

Any decision taken pursuant to this Directive and resulting in the refusal of or restrictions on the placing on the market and/or putting into service of a device shall state the exact grounds on which it is based. Such decision 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 laws in force in the Member State in question and of the time limits to which such remedies are subject.

Article 15

Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to all 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.

Article 16

1. Before 1 July 1992, Member States shall adopt and publish the laws, regulations and administrative provisions necessary in order to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply such provisions from 1 January 1993.

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, for the period up to 31 December 1994, permit the placing on the market and putting into service of devices complying with national rules in force in their territory on 31 December 1992.

Article 17

This Directive is addressed to the Member States.

Done at Luxembourg, 20 June 1990.

For the Council

The President

D. J. O'MALLEY

ANNEX 1

ESSENTIAL REQUIREMENTS

I. GENERAL REQUIREMENTS

1. The devices must be designed and manufactured in such a way that, when implanted under the conditions and for the purposes laid down, their use does not compromise the clinical condition or the safety of patients. They must not present any risk to the persons implanting them or, where applicable, to other persons.

2. The devices must achieve the performances intended by the manufacturer, viz. be designed and manufactured in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a) as specified by him.

3. The characteristics and performances referred to in sections 1 and 2 must not be adversely affected to such a degree that the clinical condition and safety of the patients or, as appropriate, of other persons are compromised during the lifetime of the device anticipated by the manufacturer, where the device is subjected to stresses which may occur during normal conditions of use.

4. The devices must be designed, manufactured and packed in such a way that their characteristics and performances are not adversely affected in the storage and transport conditions laid down by the manufacturer (temperature, humidity, etc.).

5. Any side effects or undesirable conditions must constitute acceptable risks when weighed against the performances intended.

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

6. The solutions adopted by the manufacturer for the design and construction of the devices must comply with safety principles taking account of the generally acknowledged state of the art.

7. Implantable devices must be designed, manufactured and packed in a non-reusable pack according to appropriate procedures to ensure they are sterile when placed on the market and, in the storage and transport conditions stipulated by the manufacturer, remain so until the packaging is removed and they are implanted.

8. Devices must be designed and manufactured in such a way as to remove or minimize as far as possible:

   — the risk of physical injury in connection with their physical, including dimensional, features,

   — risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,

   — risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration,

   — risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment,

   — risks connected with ionizing radiation from radioactive substances included in the device, in compliance with the protection requirements laid down in Directive 80/836/Euratom [1], as amended by Directives 84/467/Euratom [2] and 84/466/Euratom [3],

   — risks which may arise where maintenance and calibration are impossible, including:

      — excessive increase of leakage currents,

      — ageing of the materials used,

      — excess heat generated by the device,

      — decreased accuracy of any measuring or control mechanism.

[1] OJ No L 246, 17. 9. 1980, p. 1.
[2] OJ No L 265, 5. 10. 1984, p. 4.
[3] OJ No L 265, 5. 10. 1984, p. 1.

9. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in I. 'General requirements', with particular attention being paid to:

— the choice of materials used, particularly as regards toxicity aspects,

— mutual compatibility between the materials used and biological tissues, cells and body fluids, account being taken of the anticipated use of the device,

— compatibility of the devices with the substances they are intended to administer,

— the quality of the connections, particularly in respect of safety,

— the reliability of the source of energy,

— if appropriate, that they are leakproof,

— proper functioning of the programming and control systems, including software.

10. Where a device incorporates, as an integral part, a substance which, when used separately, is likely to be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC, and whose action in combination with the device may result in its bioavailability, the safety, quality and usefulness of the substance, account being taken of the purpose of the device, must be verified by analogy with the appropriate methods specified in Directive 75/318/EEC (1), as last amended by Directive 89/341/EEC (2).

11. The devices and, if appropriate, their component parts must be identified to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices and their component parts.

12. Devices must bear a code by which they and their manufacturer can be unequivocably identified (particularly with regard to the type of device and year of manufacture); it must be possible to read this code, if necessary, without the need for a surgical operation.

13. When a device or its accessories bear instructions required for the operation of the device or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

14. Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:

14.1. On the sterile pack:

— the method of sterilization,

— an indication permitting this packaging to be recognized as such,

— the name and address of the manufacturer,

— a description of the device,

— if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations',

— if the device is custom-made, the words 'custom-made device',

— a declaration that the implantable device is in a sterile condition,

— the month and year of manufacture,

— an indication of the time limit for implanting a device safely.

14.2. On the sales packaging:

— the name and address of the manufacturer,

— a description of the device,

— the purpose of the device,

— the relevant characteristics for its use,

— if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations',

(1) OJ No L 147, 9. 6. 1975, p. 1.
(2) OJ No L 142, 25. 5. 1989, p. 11.

— if the device is custom-made, the words: 'custom-made device',

— a declaration that the implantable device is in a sterile condition,

— the month and year of manufacture,

— an indication of the time limit for implanting a device safely,

— the conditions for transporting and storing the device.

15. When placed on the market, each device must be accompanied by instructions for use giving the following particulars:

— the year of authorization to affix the CE mark,

— the details referred to in 14.1 and 14.2, with the exception of those referred to in the eighth and ninth indents,

— the performances referred to in section 2 and any undesirable side effects,

— information allowing the physician to select a suitable device and the corresponding software and accessories,

— information constituting the instructions for use allowing the physician and, where appropriate, the patient to use the device, its accessories and software correctly, as well as information on the nature, scope and times for operating controls and trials and, where appropriate, maintenance measures,

— information allowing, if appropriate, certain risks in connection with implantation of the device to be avoided,

— information regarding the risks of reciprocal interference (*) in connection with the presence of the device during specific investigations or treatment,

— the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of resterilization,

— an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential requirements.

The instruction leaflet must also include details allowing the physician to brief the patient on the contra-indications and the precautions to be taken. These details should cover in particular:

— information allowing the lifetime of the energy source to be established,

— precautions to be taken should changes occur in the device's performance,

— precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, etc.,

— adequate information regarding the medicinal products which the device in question is designed to administer.

16. Confirmation that the device satisfies the requirements in respect of characteristics and performances, as referred to in I. 'General requirements', in normal conditions of use, and the evaluation of the side effects or undesirable effects must be based on clinical data established in accordance with Annex 7.

(*) 'Risks of reciprocal interference' means adverse effects on the device caused by instruments present at the time of investigations or treatment, and vice versa.

ANNEX 2

EC DECLARATION OF CONFORMITY

(Complete quality assurance system)

1. The manufacturer shall apply the quality system approved for the design, manufacture and final inspection of the products concerned as specified in sections 3 and 4 and shall be subject to EC surveillance as specified in section 5.

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

The manufacturer shall apply the CE mark in accordance with Article 12 and draw up a written declaration of conformity. This declaration shall cover one or more identified specimens of the product and shall be kept by the manufacturer. The CE mark shall be accompanied by the identifying logo of the notified body responsible.

3. **Quality system**

3.1. The manufacturer shall make an application for evaluation of his quality system to a notified body.

The application shall include:

— all the appropriate items of information for the category of products manufacture of which is envisaged,

— the quality-system documentation,

— an undertaking to fulfil the obligations arising from the quality system as approved,

— an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,

— an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system. The undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

(i) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in his state of health;

(ii) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

3.2. The 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 controls.

All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality-system documentation must make possible a uniform interpretation of the quality 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 the design and of the products, including control of products which do not conform;

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

— the design specifications, including the standards which will be applied and a description of the solutions adopted to fulfil the essential requirements which apply to the products when the standards referred to in Article 5 are not applied in full,

— the techniques of control and verification of the design, the processes and systematic actions which will be used when the products are being designed;

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

— the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

— 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 effected before, during and after production, the frequency with which they will take place, and the test equipment used.

3.3. Without prejudice to Article 13 of this Directive, the notified body shall effect an audit of the quality system to determine whether it meets the requirements referred to in 3.2. It shall presume conformity with these requirements for the quality systems which use the corresponding harmonized standards.

The team entrusted with the evaluation shall include at least one member who has already had experience of evaluations of the technology concerned. The evaluation procedure shall include an inspection on the manufacturer's premises.

The decision shall be notified to the manufacturer after the final inspection. It shall contain the conclusions of the control and a reasoned evaluation.

3.4. The manufacturer shall inform the notified body which has approved the quality system of any plan to alter the quality system.

The notified body shall evaluate the proposed modifications and shall verify whether the quality system so modified would meet the requirements referred to in 3.2; it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the control and a reasoned evaluation.

4. **Examination of the design of the product**

4.1. In addition to the obligations incumbent on him under section 3, the manufacturer shall make an application for examination of the design dossier relating to the product which he plans to manufacture and which falls into the category referred to in 3.1.

4.2. The application shall describe the design, manufacture, and performances of the product in question and shall include the necessary particulars which make it possible to evaluate whether it complies with the requirements of this Directive.

It shall include *inter alia:*

— the design specifications, including the standards which have been applied,

— the necessary proof of their appropriations, in particular where the standards referred to in Article 5 have not been applied in full. This proof must include the results of the appropriate tests carried out by the manufacturer or carried out under his responsibility,

— a statement as to whether or not the device incorporates, as an integral part, a substance as referred to in section 10 of Annex 1, whose action in combination with the device may result in its bioavailability, together with data on the relevant trials conducted,

— the clinical data referred to in Annex 7,

— the draft instruction leaflet.

4.3. The notified body shall examine the application and, where the product complies with 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 supplemented by further tests or proof so that compliance with the requirements of the Directive may be evaluated. The certificate shall contain the conclusions of the examination, the conditions of its validity, the data needed for identification of the approved design and, where appropriate, a description of the intended use of the product.

4.4. The applicant shall inform the notified body which issued the EC design examination certificate of any modification made to the approved design. Modifications made to the approved design must obtain supplementary approval from the notified body which issued the EC design examination certificate where such modifications may affect conformity with the essential requirements of this Directive or the conditions prescribed for the use of the product. This supplementary approval shall be given in the form of an addendum to the EC design examination certificate.

5. **Surveillance**

5.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations arising from the approved quality system.

5.2. The manufacturer shall authorize the notified body to carry out all necessary inspections and shall supply it with all appropriate information, in particular:

— the quality-system documentation,

— the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, etc.,

— the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardizations/calibrations and the qualifications of the staff concerned, etc.

5.3. The notified body shall periodically carry out appropriate inspections and evaluations in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an evaluation report.

5.4. In addition, the notified body may make unannounced visits to the manufacturer, and shall supply him with an inspection report.

6. The notified body shall communicate to the other notified bodies all relevant information concerning approvals of quality systems issued, refused and withdrawn.

ANNEX 3

EC TYPE-EXAMINATION

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

2. The application for EC type-examination shall be made by the manufacturer, or by his authorized representative established in the Community, to 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 made by the latter,

— a written declaration specifying that an application has not been made to any other notified body,

— the documentation described in section 3 needed to allow an evaluation to be made of the conformity of a representative sample of the production in question, hereinafter referred to as '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.

3. The documentation must make it possible to understand 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,

— design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of parts, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary for the understanding of the abovementioned drawings and diagrams and of the operation of the product,

— a list of the standards referred to in Article 5, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements where the standards referred to in Article 5 have not been applied,

— the results of design calculations, investigations and technical tests carried out, etc.,

— a statement as to whether or not the device incorporates, as an integral part, a substance as referred to in section 10 of Annex 1, whose action in combination with the device may result in its bioavailability, together with data on the relevant trials conducted,

— the clinical data referred to in Annex 7,

— the draft instruction leaflet.

4. The notified body shall:

4.1. examine and evaluate the documentation, verify that the type has been manufactured in accordance with that documentation; it shall also record the items which have been designed in accordance with the applicable provisions of the standards referred to in Article 5, as well as the items for which the design is not based on the relevant provisions of the said standards;

4.2. carry out or have carried out the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the essential requirements of this Directive where the standards referred to in Article 5 have not been applied;

4.3. carry out or have carried out the appropriate inspections and the tests necessary to verify whether, where 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 inspections and tests will be carried out.

5. Where the type meets the provisions of this Directive, the notified body shall issue an EC type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, the conclusions of the control, the conditions under which the certificate is valid and the information necessary for identification of the type approved.

   The significant parts of the documentation shall be attached 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 modification made to the approved product.

   Modifications to the approved product must receive further approval from the notified body which issued the EC type-examination certificate where such modifications may affect conformity with the essential requirements or with the conditions of use specified for the product. This new approval shall be issued, where appropriate, in the form of a supplement to the initial EC type-examination certificate.

7. Each notified body shall communicate to the other notified bodies all relevant information on EC-type examination certificates and supplements issued, refused or withdrawn.

8. Other notified bodies may obtain a copy of the EC type-examination certificates and/or the supplements to them. The annexes to the certificates shall be made available to the other notified bodies when a reasoned application is made and after first informing the manufacturer.

ANNEX 4

EC VERIFICATION

1. EC verification is the act by which a notified body verifies and certifies that products conform to the type described in the EC type-examination certificate and satisfy the relevant requirements of this Directive.

2. The manufacturer shall, before the start of manufacture, prepare documents defining the manufacturing process, in particular as regards sterilization, together with all the routine, pre-established provisions to be implemented to ensure homogeneity of production and conformity of the products with the type described in the EC type-examination certificate as well as with the relevant requirements of the Directive.

3. The manufacturer shall undertake to institute and keep up-dated a post-marketing surveillance system. The undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following events immediately on learning of them:

   (i) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in his state of health;

   (ii) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

4. The notified body shall carry out EC verification by controls and tests on the products on a statistical basis as specified in 5. The manufacturer must authorize the notified body to evaluate the efficiency of the measures taken pursuant to section 2, by audit where appropriate.

5. **Statistical verification**

5.1. The manufacturer shall present the manufactured products in the form of homogeneous batches.

5.2. A random sample shall be taken from each batch. The products which make up the sample shall be examined individually and appropriate tests, defined in the relevant standard(s) referred to in Article 5, or equivalent tests, shall be carried out to verify the conformity of the products with the type described in the EC type-examination certificate, in order to determine whether the batch is to be accepted or rejected.

5.3. Statistical control of products will be based on attributes, entailing a sampling system with the following characteristics:

   — a level of quality corresponding to a probibility of acceptance of 95 %, with a non-conformity percentage of between 0,29 and 1 %,

   — a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity percentage of between 3 and 7 %.

5.4. If a batch is accepted, the notified body shall draw up a written certificate of conformity. All the products in the batch may be placed on the market, with the exception of those products in the sample which were found not to conform.

   If a batch is rejected, the notified body which is responsible shall take the appropriate measures to prevent the batch from being placed on the market.

   If justified on practical grounds, the manufacturer may affix the CE mark during manufacture, under the responsability of the notified body, in accordance with Article 12, accompanied by the identifying logo of the notified body responsible for statistical verification.

ANNEX 5

EC DECLARATION OF CONFORMITY TO TYPE

(Assurance of production quality)

1. The manufacturer shall apply the quality system approved for the manufacture and shall conduct the final inspection of the products concerned as specified in 3; he shall be subject to the surveillance referred to in section 4.

2. This declaration of conformity is the procedural element whereby the manufacturer who satisfies the obligations of section 1 guarantees and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of the Directive which apply to them.

The manufacturer shall affix the CE mark in accordance with Article 12 and draw up a written declaration of conformity. This declaration shall cover one or more identified specimens of the product and shall be kept by the manufacturer. The CE mark shall be accompanied by the identifying logo of the notified body responsible.

3. **Quality system**

3.1. The manufacturer shall make an application for evaluation of his quality system to a notified body.

The application shall include:

— all appropriate information concerning the products which it is intended to manufacture,

— the quality-system documentation,

— an undertaking to fulfil the obligations arising from the quality system as approved,

— an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,

— where appropriate, the technical documentation relating to the approved type and a copy of the EC type-examination certificate,

— an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system. The undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

(i) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in his state of health;

(ii) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

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 shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality-system documentation must make possible a uniform interpretation of the quality 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 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 the design and of the products, including control of products which do not conform;

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

— the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

— 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 which will be effected before, during and after production, the frequency with which they will take place, and the test equipment used.

3.3. Without prejudice to Article 13, the notified body shall effect an audit of the quality system to determine whether it meets the requirements referred to in 3.2. It shall presume conformity with these requirements for the quality systems which use the corresponding harmonized standards.

The team entrusted with the evaluation shall include at least one member who has already had experience of evaluations of the technology concerned. The evaluation procedure shall include an inspection on the manufacturer's premises.

The decision shall be notified to the manufacturer after the final inspection. It shall contain the conclusions of the control and a reasoned evaluation.

3.4. The manufacturer shall inform the notified body which has approved the quality system of any plan to alter that system.

The notified body shall evaluate the proposed modifications and shall verify whether the quality system so modified would meet the requirements referred to in 3.2; it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the control and a reasoned evaluation.

4. **Surveillance**

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations which arise from the approved quality system.

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

— the quality-system documentation,

— the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardizations/calibrations and the qualifications of the staff concerned, etc.

4.3. The notified body shall periodically carry out appropriate inspections and evaluations in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an evaluation report.

4.4. In addition, the notified body may make unannounced visits to the manufacturer, and shall supply him with an inspection report.

5. The notified body shall communicate to the other notified bodies all relevant information concerning approvals of quality systems issued, refused or withdrawn.

ANNEX 6

STATEMENT CONCERNING DEVICES INTENDED FOR SPECIAL PURPOSES

1. The manufacturer or his authorized representative established within the Community shall draw up for custom-made devices or for devices intended for clinical investigations the statement comprising the elements stipulated in section 2.

2. The statement shall comprise the following information:

2.1. For custom-made devices:

— data allowing the device in question to be identified,

— a statement affirming that the device is intended for exclusive use by a particular patient, together with his name,

— the name of the doctor who drew up the prescription and, if applicable, the name of the clinic concerned,

— the particular features of the device as described by the medical prescription concerned,

— a statement affirming that the device complies with the essential requirements given in Annex 1 and, where applicable, indicating which essential requirements have not been wholly met, together with the grounds.

2.2. For devices intended for clinical investigations covered in Annex 7:

— data allowing the devices in question to be identified,

— an investigation plan giving in particular the purpose, scope and number of the devices concerned,

— the name of the doctor and of the institution responsible for the investigations,

— the place, date of commencement and duration scheduled for the investigations,

— a statement affirming that the device in question complies with the essential requirements apart from the aspects constituting the object of the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient.

3. The manufacturer shall undertake to keep available for the competent national authorities:

3.1. For custom-made devices, documentation enabling the design, manufacture and performances of the product, including the expected performances, to be understood, so as to allow conformity with the requirement of this Directive to be assessed.

The manufacturer shall take all necessary measures to see that the manufacturing process ensures that the products manufactured conform to the documentation referred to in the first paragraph.

3.2. For devices intended for clinical investigations, the documentation shall also contain:

— a general description of the product,

— design drawings, manufacturing methods, in particular as regards sterilization, and diagrams of parts, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary for the understanding of the said drawings and diagrams and of the operation of the product,

— a list of the standards laid down in Article 5, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements of the Directive where the standards in Article 5 have not been applied,

— the results of the design calculations, checks and technical tests carried out, etc.

The manufacturer shall take all necessary measures to see that the manufacturing process ensures that the products manufactured conform to the documentation referred to in 3.1 and in in the first paragraph of this section.

The manufacturer may authorize the evaluation, by audit where necessary, of the effectiveness of these measures.

ANNEX 7

CLINICAL EVALUATION

1. **General provisions**

1.1. Adequacy of the clinical data presented, as referred to in section 4.2 of Annex 2, and in section 3 of Annex 3, shall be based, account being taken as appropriate of the relevant harmonized standards, on either:

1.1.1. a collation of currently available relevant scientific literature covering the intended use of the device and the techniques therefor, as well as, if appropriate, a written report making a critical assessment of this collation; or

1.1.2. the results of all clinical investigations made, including those carried out in accordance with section 2.

1.2. All data must remain confidential unless it is deemed essential that they be divulged.

2. **Clinical investigation**

2.1. *Purpose*

The purpose of clinical investigation is to:

— verify that, under normal conditions of use, the performances of the device comply with those indicated in section 2 of Annex 1,

— determine any undesirable side effects, under normal conditions of use, and assess whether they are acceptable risks having regard to the intended performance of the device.

2.2. *Ethical consideration*

Clinical investigations shall be made in accordance with the Declaration of Helsinki approved by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and amended by the 29th World Medical Assembly in Tokyo, Japan, in 1975 and the 35th World Medical Assembly in Venice, Italy, in 1983. It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Declaration of Helsinki. This includes every step in the clinical investigation from first consideration of need and justification of the study to publication of results.

2.3. *Methods*

2.3.1. Clinical investigations shall be performed according to an appropriate state of the art plan of investigation defined in such a way as to confirm or refute the manufacturer's claims for the device; the investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions.

2.3.2. The procedures utilized to perform the investigations shall be appropriate to the device under examination.

2.3.3. Clinical investigations shall be performed in circumstances equivalent to those which would be found in normal conditions of use of the device.

2.3.4. All appropriate features, including those involving the safety and performances of the device, and its effects on the patients, shall be examined.

2.3.5. All adverse events shall be fully recorded.

2.3.6. The investigations shall be performed under the responsibility of an appropriately qualified medical specialist, in an appropriate environment.

The medical specialist shall have access to the technical data regarding the device.

2.3.7. The written report, signed by the responsible medical specialist, shall comprise a critical evaluation of all the data collected during the clinical investigation.

ANNEX 8

MINIMUM CRITERIA TO BE MET WHEN DESIGNATING INSPECTION BODIES TO BE NOTIFIED

1. The body, its director and the staff responsible for carrying out the evaluation and verification operations shall not be the designer, manufacturer, supplier or installer of devices which they control, nor the authorized representative of any of those parties. They may not become directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

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

3. The body must be able to carry out all the tasks in one of Annexes 2 to 5 assigned to such a body and for which it has been notified, whether those tasks are carried out by the body itself or under its responsibility. In particular, it must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with evaluation and verification; it must also have access to the equipment necessary for the verifications required.

4. The staff responsible for control operations must have:

   — sound vocational training covering all the evaluation and verification operations for which the body has been designated,

   — satisfactory knowledge of the requirements of the controls they carry out and adequate experience of such operations,

   — the ability required to draw up the certificates, records and reports to demonstrate that the controls have been carried out.

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

6. The body must take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for controls.

7. The staff of the body are bound to observe professional secrecy with regard to all information gained in carrying out their tasks (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 giving effect to it.

ANNEX 9

CE MARK OF CONFORMITY