
STATUTORY INSTRUMENTS

1995 No. 1671

CONSUMER PROTECTION

The Active Implantable Medical Devices (Amendment and Transitional Provisions) Regulations 1995

<i>Made</i>	- - - -	<i>30th June 1995</i>
<i>Laid before Parliament</i>		<i>10th July 1995</i>
<i>Coming into force</i>	- -	<i>8th August 1995</i>

The Secretary of State, in exercise of the powers conferred by section 11 of the Consumer Protection Act 1987(1), after consultation in accordance with section 11(5) of that Act with organisations appearing to her to be representative of interests substantially affected by these Regulations, with such other persons as appear to her to be appropriate and with the Health and Safety Commission, and the Secretary of State as respects Great Britain and the Department of Health and Social Services for Northern Ireland as respects Northern Ireland, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(2) and in each case in exercise of all other powers so enabling them, hereby make the following Regulations:—

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Active Implantable Medical Devices (Amendment and Transitional Provisions) Regulations 1995 and shall come into force on 8th August 1995.

(2) In these Regulations “the principal Regulations” means the Active Implantable Medical Devices Regulations 1992(3).

Amendment of regulation 2(1) of the principal Regulations

2.—(1) Regulation 2(1) of the principal Regulations (interpretation) shall be amended in accordance with the following provisions of this regulation.

(2) In the definition of “authorised representative” the words “European Economic” shall be omitted.

(3) The definition of “EC mark” shall be omitted and after the definition of “authorised representative” there shall be inserted the following definitions—

(1) 1987 c. 43.

(2) See S.I. 1991/2289, Article 2, which designates the Secretary of State and the Department of Health and Social Services for Northern Ireland for the purposes of section 2(2) in relation to active implantable medical devices.

(3) S.I. 1992/3146.

““CE marking” means the marking which indicates that one or more of the procedures referred to in regulation 5 has, or as the case may be, have been followed and which complies with the provisions of Schedule 1;

“the Community” means the European Economic Area established under the EEA Agreement;”.

(4) After the definition of “the Directive” there shall be inserted the following definition—

““the EEA Agreement” means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992 as adjusted by the Protocol signed at Brussels on 17th March 1993;”.

(5) In the definition of “harmonised Standard” for the words “Commission of the European Economic Community” there shall be substituted the words “European Commission”.

(6) After the definition of “intended purpose” there shall be inserted the following definition—

““manufacturer” means the person who is responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party;”.

(7) For the definition of “member State” there shall be substituted the following definition—

““member State” means a State which is a Contracting Party to the EEA Agreement;”.

(8) For the definition of “placed on the market” there shall be substituted the following definition—

““placing on the market” means, in relation to a device, the first making available in return for payment or free of charge of a new or fully refurbished device other than a device intended for clinical investigation, with a view to distribution, use, or both, on the Community market;”.

(9) In paragraph (c) of the definition of “relevant national Standard” the words “of the European Economic Community” shall be omitted.

(10) In the definition of “relevant notified body logo” for the word “logo”, wherever that word appears, there shall be substituted the words “identification number”.

Amendment of references to the term EC mark

3. For the term “EC mark” wherever it occurs in the principal Regulations there shall be substituted the term “CE marking”.

Amendment of regulation 3(4) of the principal Regulations

4. For paragraph (4) of regulation 3 of the principal Regulations (essential requirements for devices) there shall be substituted the following paragraphs—

“(4) In the case of a device which has been put into service—

- (a) the essential requirements specified in paragraph 14 of Schedule 2 are complied with only if the particulars there specified are in English (whether or not they are also in another language and whether or not the device is for professional use); and
- (b) the essential requirements specified in paragraph 13, so far as they relate to instructions required for the operation of a device and in paragraph 15 of Schedule 2, are complied with only if the instructions are in English or another Community language.

(4A) Where the instructions for use referred to in paragraph (4)(b) are not in English, any packaging, label or promotional literature must carry a clear statement in English stating the language in which the instructions are given.”.

Amendment of regulation 4 of the principal Regulations

5.—(1) Regulation 4 of the principal Regulations (EC mark) shall be amended in accordance with the following provisions of this regulation.

(2) In paragraph (1) for the words “accompanied by the relevant notified body logo” there shall be substituted the words “followed by the relevant notified body identification number”.

(3) In sub-paragraph (b) of paragraph (1) there shall be inserted at the beginning the words “where appropriate,”.

(4) In paragraph (3) for the words “a mark which is likely to be confused with the EC mark” there shall be substituted the words “a marking which is likely to deceive third parties as to the meaning and form of the CE marking”.

(5) After paragraph (3) there shall be added the following paragraphs—

“(4) Any other marking may be affixed to a device’s packaging or to the instruction leaflet accompanying the device, provided that the visibility and legibility of the CE marking are not thereby reduced.

(5) Where a device comes within the scope of a directive other than the Directive and that other directive provides for the affixing of the CE marking, the CE marking shall not be affixed unless the relevant requirements of that other directive are also satisfied.

(6) Where a directive other than the Directive permits a manufacturer to choose which arrangements to apply during a transitional period, the CE marking shall indicate that the device fulfils only the provisions of those directives applied by the manufacturer.

(7) In a case falling within paragraph (6), particulars of the directives applied by the manufacturer, as published in the Official Journal of the European Communities, shall be given in the documents, notices or instructions required by the directives and accompanying the device, and these documents, notices or instructions shall be accessible without it being necessary to destroy the packaging which keeps the device sterile.”.

Amendment of regulation 5 of the principal Regulations

6.—(1) Regulation 5 of the principal Regulations (procedure for affixing EC mark) shall be amended in accordance with the following provisions of this regulation.

(2) In paragraph (2) after the word “manufacturer” there shall be inserted the words “or his authorised representative”.

(3) In sub-paragraph (c) of paragraph (2) for the word “specimens” there shall be substituted the word “examples”.

(4) In paragraph (4) for the words “a notified body verifies and certifies” there shall be substituted the words “the manufacturer ensures and declares”.

(5) In paragraph (5) after the word “manufacturer” there shall be inserted the words “or his authorised representative” and in sub-paragraph (d) for the word “specimens” there shall be substituted the word “examples”.

(6) After paragraph (6) there shall be inserted the following paragraphs—

“(6A) Any manufacturer of a device or any notified body following a conformity assessment procedure for affixing the CE marking to a device shall take account of the results of any assessment or verification operation which has been carried out in accordance with the Directive or these Regulations at any intermediate stage of manufacture of the device.

(6B) Where a conformity assessment procedure involves the intervention of a notified body, the manufacturer of a device or his authorised representative may apply to any notified

body which has been designated in accordance with Article 11 of the Directive to carry out tasks in respect of that type of device for the purposes of that conformity assessment procedure.

(6C) Where a manufacturer has supplied information or data to a notified body in the course of a conformity assessment procedure, the notified body may require the manufacturer to provide any additional information or data which the notified body considers necessary for the purposes of that procedure.

(6D) A decision made by a notified body in accordance with Schedule 5 or Schedule 6 shall—

- (a) specify the period of validity of the decision; and
- (b) be valid for an initial period of not more than 5 years.

(6E) Where an agreement under which a notified body agrees to carry out a conformity assessment procedure for a manufacturer allows the manufacturer to apply to the notified body at a specified time for an extension of the period of validity of a decision mentioned in paragraph (6D), the notified body may extend the validity of the decision for further periods of 5 years, each such period commencing on the expiry of the preceding period.

(6F) Where the procedures referred to in this regulation have not been carried out in relation to an individual device, the Secretary of State may authorise the placing on the market and putting into service of that device if she is satisfied that this would be in the interest of the protection of health.”.

Amendment of regulation 7 of the principal Regulations

7.—(1) Regulation 7 of the principal Regulations (clinical investigations) shall be amended in accordance with the following provisions of this regulation.

(2) In paragraph (2) for the words “relating to the health or safety of patients, users or others” there shall be substituted the words “of public health or public policy”.

(3) After paragraph (2) there shall be inserted the following paragraph—

“(2A) Where the relevant ethics committee has issued a favourable opinion on a programme of clinical investigation, the Secretary of State may give written notice to the manufacturer or his authorised representative within 60 days of the giving of notice under paragraph (1) that devices may be made available for the purposes of those investigations at any time after the giving of notice under that paragraph.”.

Insertion of regulation 7A into the principal Regulations

8. After regulation 7 of the principal Regulations (clinical investigations) there shall be inserted the following regulation—

“Obligations of persons other than manufacturers

7A.—(1) Subject to paragraph (2), any obligation of a manufacturer under these Regulations shall extend to a person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name.

(2) Paragraph (1) shall not apply to a person who assembles or adapts devices already on the market to their intended purpose for an individual patient.”.

Amendment of regulation 8 of the principal Regulations

9. After paragraph (5) of regulation 8 of the principal Regulations (notified bodies) there shall be added the following paragraphs—

“(6) The Secretary of State may refuse to designate a body as a notified body, or may withdraw designation of a body as a notified body, if it fails to pay any fee or other charge in accordance with regulations made under section 56 of the Finance Act 1973(4) in connection with services provided by the Secretary of State in carrying out her functions for the purposes of the Directive.

(7) For the purpose of deciding whether or not a body is one in respect of which the conditions specified in Schedule 9 are fulfilled as respects the tasks which it carries out or is to carry out, the Secretary of State may arrange for the inspection of—

- (a) any premises occupied, or plant or equipment used, in connection with the carrying out of any such task; or
- (b) any premises occupied, or plant or equipment used, by a manufacturer where the body is a notified body undertaking any task in relation to that manufacturer,

and may take into account for the purposes of her decision any refusal of reasonable facilities for such inspection and the results of any such inspection.”.

Amendment of regulation 9 of the principal Regulations

10.—(1) Regulation 9 of the principal Regulations (prohibition on supply etc.) shall be amended in accordance with the following provisions of this regulation.

(2) In paragraph (1) for the words “has been placed on the market or put into service and” there shall be substituted the words “constitutes placing on the market or putting into service a device”.

(3) In sub-paragraph (2)(b) for the words “a mark” there shall be substituted the words “a marking”.

(4) In paragraph (4) the words “or his authorised representative” shall be omitted.

Insertion of regulations 10A and 10B into the principal Regulations

11. After regulation 10 of the principal Regulations (enforcement etc.) there shall be inserted the following regulations—

“Unduly affixed CE marking

10A.—(1) Except in the case of a device which the Secretary of State considers to be unsafe, where she has reasonable grounds for suspecting that the CE marking has been affixed to any device in relation to which any provision of these Regulations has not been complied with, she may serve upon the manufacturer or his authorised representative a notice—

- (a) specifying the description of the device to which the notice relates;
- (b) stating that she suspects that the CE marking has been affixed to the device in circumstances where a provision of these Regulations has not been complied with and the reasons for that suspicion;
- (c) specifying the provision referred to in sub-paragraph (b);
- (d) requiring the person on whom the notice is served—

- (i) to secure that any device to which the notice relates conforms as regards the provision concerning the CE marking within such period as may be specified in the notice; or
 - (ii) to provide evidence within that period to the satisfaction of the Secretary of State that all the provisions of these Regulations have been complied with so far as they relate to that device; and
- (e) warning the person on whom the notice is served that unless the requirement of sub-paragraph (d) is met, further action may be taken under these Regulations in respect of that device or any device of the same type supplied by that person.

(2) Where the Secretary of State serves a notice referred to in paragraph (1), sections 14, 16 or 17 of the 1987 Act shall not be applied as respects any device to which the notice relates until the period referred to in paragraph (1)(d) has expired and unless at the expiry of that period the person on whom the notice was served has failed to comply with its requirements.

(3) The notice referred to in paragraph (1) may include directions as to the measures to be taken by the person on whom the notice is served to secure conformity of the device with the provisions of these Regulations including different ways of securing conformity; and any such directions as are included are requirements of the notice for the purposes of paragraph (2).

Centralised system of records etc.

10B. The Secretary of State shall perform, as respects the United Kingdom, the functions of the member State under Article 8 of the Directive.”.

Amendment of regulation 12 of the principal Regulations

12.—(1) Regulation 12 of the principal Regulations (notification of decisions etc.) shall be amended in accordance with the following provisions of this regulation.

(2) After paragraph (1) there shall be inserted the following paragraph—

“(1A) Except in cases of emergency, before the Secretary of State or a notified body makes a decision referred to in paragraph (1), the manufacturer or his authorised representative shall have an opportunity to submit his comments to the Secretary of State who, or the notified body which, is considering making such decision.”.

(3) In paragraph (2) for “paragraph (1)” there shall be substituted the words “paragraphs (1) and (1A)”.

Substitution for Schedule 1 to the principal Regulations

13. For Schedule 1 to the principal Regulations (EC mark) there shall be substituted the Schedule to these Regulations.

Amendment of Schedule 3 to the principal Regulations

14.—(1) Sub-paragraph (1) of paragraph 1 of Schedule 3 to the principal Regulations (evaluation etc. of clinical data) shall be amended in accordance with the following provisions of this regulation.

(2) For the words “Adequacy of the” there shall be substituted the word “The”.

(3) For the words “paragraphs 1(c) and 2” there shall be substituted the words “paragraphs 1(2) (c) and 2”.

Amendment of Schedule 5 to the principal Regulations

15.—(1) Schedule 5 to the principal Regulations (EC declaration of conformity procedure) shall be amended in accordance with the following provisions of this regulation.

(2) In sub-paragraph (1) of paragraph 2 after the words “The application” there shall be inserted the words “shall be signed by or on behalf of the manufacturer and”.

(3) In sub-paragraph (4)(b)(ii) of paragraph 3 for the words “harmonised Standards” there shall be substituted the words “the manufacturer’s standards of quality”.

(4) For sub-paragraph (4) of paragraph 10 there shall be substituted the following paragraph—

“(4) The notified body shall make available to the other notified bodies or to the Secretary of State, on their or her request, the information necessary to establish in respect of which quality systems it has issued, refused or withdrawn approval.”.

(5) After sub-paragraph (4) there shall be added the following paragraphs—

“(5) For at least five years from the last date of manufacture of the device, the manufacturer shall keep available for the Secretary of State—

- (a) the declaration of conformity;
- (b) the documentation referred to in paragraph 2(1)(c);
- (c) any modification plans referred to in paragraph 5(1);
- (d) the documentation referred to in paragraph 6(2); and
- (e) the decisions and reports of the notified body referred to in paragraphs 5(3), 7(1), 10(2) and 10(3).

(6) Where neither the manufacturer nor his authorised representative is established in the Community, the obligation to keep available the technical documentation referred to in paragraph 6(2) shall fall upon the person responsible for placing the device on the market.”.

Amendment of Schedule 6 to the principal Regulations

16.—(1) Schedule 6 to the principal Regulations (EC type-examination procedure) shall be amended in accordance with the following provisions of this regulation.

(2) For paragraph 7 there shall be substituted the following paragraph—

“7. Each notified body shall make available to the other notified bodies or to the Secretary of State, on their or her request, the information necessary to establish in respect of which devices it has issued, refused or withdrawn EC type-examination certificates and addenda.”.

(3) In sub-paragraph (2) of paragraph 8 for the words “copies of those parts of the documentation which are attached to a certificate under paragraph 4(3)” there shall be substituted the words “a copy of any annex to a certificate”.

(4) After paragraph 8 there shall be added the following paragraphs—

“9. The manufacturer or his authorised representative shall keep with the technical documentation a copy of the EC type-examination certificates and the supplements to them for a period of at least five years from the date of manufacture of the last appliance.

10. Where neither the manufacturer nor his authorised representative is established in the Community, the obligation to keep available the technical documentation for the Secretary of State shall fall upon the person responsible for placing the device on the market.”.

Amendment of Schedule 7 to the principal Regulations

17.—(1) Schedule 7 to the principal Regulations (EC verification procedure) shall be amended in accordance with the following provisions of this regulation.

(2) In paragraph 1 for the word “homogeneity” there shall be substituted the word “uniformity”.

(3) After paragraph 1 there shall be inserted the following paragraph—

“1A. The manufacturer or his authorised representative—

- (a) shall take all measures necessary in order that the manufacturing process ensures conformity of the products to the type as described in the EC type-examination certificate and to the requirements of the Directive that apply to them; and
- (b) shall affix the CE marking to each product and draw up a written declaration of conformity.”.

(4) In sub-paragraph (2)(a) of paragraph 2 for the words “any deterioration” there shall be substituted the words “any change”.

(5) For sub-paragraph (1) of paragraph 3 there shall be substituted the following sub-paragraph—

“(1) The notified body shall carry out the appropriate examination and tests in order to check the conformity of the product to the requirements of the Directive by examination and testing of products on a statistical basis in accordance with paragraph 4.”.

(6) For sub-paragraph (1) of paragraph 4 there shall be substituted the following sub-paragraph—

“(1) The manufacturer shall present the manufactured products to the notified body in the form of uniform batches, and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.”.

(7) In sub-paragraph (4)(b) of paragraph 4 for the words “non-conformity percentage of” there shall be substituted the words “percentage of non-conformity”.

(8) In sub-paragraph (5) of paragraph 4 after the words “the notified body” there shall be inserted the words “shall affix, or cause to be affixed, its identification number to each device and”.

(9) After sub-paragraph (6) of paragraph 4 there shall be inserted the following sub-paragraph—

“(6A) In the event of frequent rejection of batches, the notified body may suspend the statistical verification.”.

(10) In sub-paragraph (7) of paragraph 4 for the word “logo” there shall be substituted the word “number”.

(11) After sub-paragraph (7) of paragraph 4 there shall be added the following sub-paragraph—

“(8) The manufacturer or his authorised representative shall ensure that he is able to supply the notified body’s certificates of conformity on request.”.

Transitional provision

18. Nothing in regulation 9(2) of the principal Regulations shall prohibit the supply, offer to supply, agreement to supply, exposure for supply or possession for supply before 1st January 1997 of a device if the supply, offer to supply, agreement to supply, exposure for supply or possession for supply of the device is in accordance with the marking arrangements in force in that part of the United Kingdom on 31st December 1994.

28th June 1995

Virginia Bottomley
One of Her Majesty's Principal Secretaries of
State

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland
this

L.S.

30th day of June 1995.

F.A. Elliott
Permanent Secretary

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

SCHEDULE

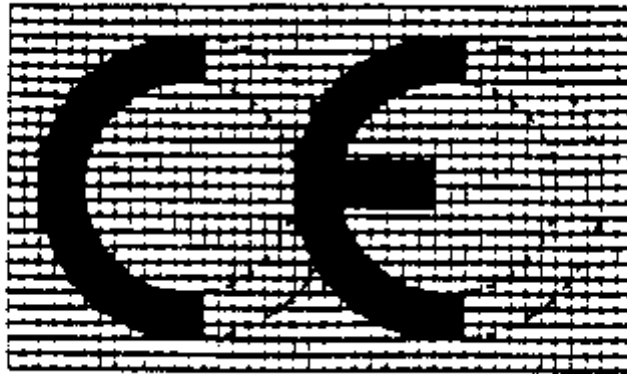
Regulation 13.

“SCHEDULE 1

Regulation 2(1)

CE CONFORMITY MARKING (CORRESPONDING TO ANNEX IX OF THE DIRECTIVE)

1. The CE conformity marking shall consist of a symbol comprising the letters “CE” taking the form shown below.



2. If the CE marking is reduced or enlarged the proportions shown in the illustration in paragraph 1 shall be maintained.

3. The letters comprising the CE marking must have substantially the same vertical dimension, which shall be at least 5mm except in the case of small-scale devices.”

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations (“the Regulations”) amend the Active Implantable Medical Devices Regulations 1992 (“the principal Regulations”) which implement Council Directive [90/385/EEC](#) (OJNo. L 189, 20.7.90, p. 17) (“the active implantable medical devices Directive”). The Regulations implement those provisions in Council Directive [93/42/EEC](#) (OJ No. L 169, 12.7.93, p. 1) (“the medical devices Directive”) which amend the active implantable medical devices Directive. The Regulations also implement in part Council Directive [93/68/EEC](#) (OJ No. L 220, 30.8.93, p. 1) (“the CE marking Directive”) which amends a series of directives on technical harmonisation and standards which includes the active implantable medical devices Directive. The Regulations also make certain other minor amendments to the principal Regulations.

Regulation 2 amends certain definitions in the principal Regulations and introduces new definitions.

Regulation 3 substitutes for the term “EC mark” wherever it occurs in the principal Regulations the term “CE marking”.

Regulation 4 amends regulation 3(4) of the principal Regulations which specifies the language which must be used on the packaging etc. of a device.

Regulation 5 introduces amendments to regulation 4 which concern the CE marking and which are required under the CE marking Directive.

Regulation 6 introduces amendments to regulation 5 required under both the medical devices Directive and the CE marking Directive. The amendments concern the conformity assessment procedures to be carried out in order that the CE marking may be affixed to devices.

Regulation 7 amends the provisions on clinical investigations in regulation 7 of the principal Regulations. The amendments introduce a new provision whereby the Secretary of State may authorise a clinical investigation to take place before the 60 day period referred to in regulation 7(1) of the principal Regulations has elapsed.

Regulation 8 introduces new regulation 7A which sets out the obligations of persons other than manufacturers.

Regulation 9 amends regulation 8 of the principal Regulations on notified bodies. New provisions are introduced under which the Secretary of State may refuse to designate or may withdraw designation from bodies when certain fees are not paid. The amendments also provide that the Secretary of State may inspect certain premises etc. for the purposes of carrying out her functions in relation to notified bodies.

Regulation 10 amends the provisions in regulation 9 of the principal Regulations on prohibition on supply etc..

Regulation 11 introduces new regulations 10A and 10B. Regulation 10A deals with enforcement. It provides for a two stage procedure to be used in cases in which the Secretary of State has reasonable grounds for believing that the CE marking has been wrongly affixed to a device which she does not consider to be unsafe.

Regulation 12 amends the provisions in regulation 12 of the principal Regulations on notification of decisions etc..

Regulation 13 substitutes a new Schedule 1 to the principal Regulations. This Schedule illustrates the CE marking and contains requirements as to its dimensions etc..

Regulation 14 introduces amendments to Schedule 3 to the principal Regulations which deals with the evaluation of clinical data.

Regulations 15, 16 and 17 amend Schedules 5, 6 and 7 respectively to the principal Regulations. These Schedules set out the conformity assessment procedures to be followed by manufacturers.

Regulation 18 contains a transitional provision required under the CE marking Directive.

A compliance cost assessment is available, copies of which have been placed in the libraries of both Houses of Parliament. Copies of the assessment are also available from the Medical Devices Agency, 11th Floor South, Hannibal House, Elephant and Castle, London, SE1 6TQ.