

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

Preliminary remark

This version of the Active Implantable Medical Devices (AIMD) Directive includes all amendments which will enter into force on 1 January 1995, and were included in the following Directives:

- CE marking Directive 93/68/EEC of 22 July 1993 (OJEC No L 220 of 30 August 1993)
- Medical Devices (MD) Directive 93/42/EEC of 14 June 1993 (OJEC No L 169 of 12 July 1993)

The original text of the amended parts of the AIMD Directive can be found at the end of this chapter. All parts amended by the CE marking Directive are marked with one asterix (*), parts amended by the MD Directive are marked with two asterisks (**).

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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

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

31 other persons a high level of protection and
32 achieve the intended level of performance when
33 implanted in human beings;

34
35 Whereas several Member States have sought to
36 ensure that level of safety by mandatory
37 specifications relating both to the
38 technical safety features and the inspection
39 procedures for such devices; whereas those
40 specifications differ from one Member State to
41 another;

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

49
50 Whereas harmonized measures must be
51 distinguished from measures taken by Member
52 States to manage the financing of public health
53 and sickness insurance schemes directly or
54 indirectly concerning such devices; whereas,
55 therefore, such provisions do not affect the
56 right of Member States to implement the
57 abovementioned measures in compliance with
58 Community law;

59
60 Whereas maintaining or improving the level of
61 protection achieved in Member States
62 constitutes one of this Directive's essential
63 objectives as defined by the essential
64 requirements;

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

72
73 Whereas, in order to facilitate proof of
74 conformity with these essential requirements
75 and to permit monitoring of that conformity, it
76 is desirable to have Europe-wide harmonized
77 standards in respect of the prevention of risks
78 in connection with the design, manufacture and
79 packaging of active implantable medical
80 devices; whereas such standards harmonized at
81 European level are drawn up by private-law
82 bodies and must retain their status as non-
83 mandatory texts; whereas, to that end, the

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

84 European Committee for Standardization (CEN) and
85 the European Committee for Electrotechnical
86 Standardization (Cenelec) are recognized as
87 being the competent bodies to adopt harmonized
88 standards in accordance with the general
89 guidelines for cooperation between the
90 Commission and these two bodies, signed on 13
91 November 1984; whereas, for the purpose of this
92 Directive, a harmonized standard is a
93 technical specification (European standard or
94 harmonization document) adopted by either or
95 both of these bodies, as instructed by the
96 Commission pursuant to the provisions of
97 Council Directive 83/189/EEC of 28 March
98 1983 laying down a procedure for the
99 provision of information in the field of
100 technical standards and regulations (4), as
101 last amended by Directive 88/182/EEC (5), and
102 under the abovementioned general guidelines;

103
104 Whereas evaluation procedures have to be
105 established and accepted by common accord
106 between the Member States in accordance with
107 Community criteria;

108
109 Whereas the specific nature of the medical
110 sector makes it advisable to make provision for
111 the notified body and the manufacturer or his
112 agent established in the Community to fix, by
113 common accord, the time limits for completion
114 of the evaluation and verification operations
115 for the conformity of devices,

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ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

119 HAS ADOPTED THIS DIRECTIVE:
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122
123 Article 1
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125
126 1. This Directive shall apply to active
127 implantable medical devices.
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130 2. For the purpose of this Directive, the
131 following definitions shall apply:
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133 (a) "medical device" means any instrument,
134 apparatus, appliance, material or other
135 article, whether used alone or in
136 combination, together with any accessories
137 or software for its proper functioning,
138 intended by the manufacturer to be used for
139 human beings in the:

140
141 - diagnosis, prevention, monitoring,
142 treatment or alleviation of disease or
143 injury,
144

145 - investigation, replacement or modification
146 of the anatomy or of a physiological
147 process,
148

149 - control of conception,
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151 and which does not achieve its principal
152 intended action by pharmacological,
153 chemical, immunological or metabolic
154 means, but which may be assisted in its
155 function by such means;
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157 (b) "active medical device" means any medical
158 device relying for its functioning on a
159 source of electrical energy or any source of
160 power other than that directly generated by
161 the human body or gravity;
162

163 (c) "active implantable medical device" means
164 any active medical device which is intended

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

165 to be totally or partially introduced,
166 surgically or medically, into the human body
167 or by medical intervention into a natural
168 orifice, and which is intended to remain
169 after the procedure;
170

171 (d) "custom-made device" means any active
172 implantable medical device specifically made
173 in accordance with a medical specialist's
174 written prescription which gives, under
175 his responsibility, specific design
176 characteristics and is intended to be used
177 only for an individual named patient;
178

179 (e) "device intended for clinical
180 investigation" means any active implantable
181 medical device intended for use by a
182 specialist doctor when conducting
183 investigations in an adequate human clinical
184 environment;
185

186 (f) "intended purpose" means the use for which
187 the medical device is intended and for which
188 it is suited according to the data
189 supplied by the manufacturer in the
190 instructions;
191

192 (g) "putting into service" means making
193 available to the medical profession for
194 implantation.
195

196 (**) (h) "placing on the market" means the
197 first making available in return for
198 payment or free of charge of a device
199 other than a device intended for
200 clinical investigation, with a view to
201 distribution and/or use on the Community
202 market, regardless of whether it is new
203 or fully refurbished;
204

205 (i) "manufacturer" means the natural or
206 legal person with responsibility for the
207 design, manufacture, packaging and
208 labelling of a device before it is
209 placed on the market under his own name,

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

210 regardless of whether these operations
211 are carried out by that person himself
212 or on his behalf by a third party.
213

214 The obligations of this Directive to be
215 met by manufacturers also apply to the
216 natural or legal person who assembles,
217 packages, processes, fully refurbishes
218 and/or labels one or more ready-made
219 products and/or assigns to them their
220 intended purpose as a device with a view
221 to their being placed on the market
222 under his own name. This subparagraph
223 does not apply to the persons who, while
224 not a manufacturer within the meaning of
225 the first subparagraph, assembles or
226 adapts devices already on the market to
227 their intended purpose for an individual
228 patient;
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231 3. Where an active implantable medical device
232 is intended to administer a substance defined
233 as a medicinal product within the meaning of
234 Council Directive 65/65/EEC of 26 January 1965
235 on the approximation of provisions laid down
236 by law, regulation or administrative action
237 relating to proprietary medicinal products (1),
238 as last amended by Directive 87/21/EEC (2),
239 that substance shall be subject to the
240 system of marketing authorization provided for
241 in that Directive.
242
243

244 4. Where an active implantable medical device
245 incorporates, as an integral part, a substance
246 which, if used separately, may be considered to
247 be a medicinal product within the meaning of
248 Article 1 of Directive 65/65/EEC, that
249 device must be evaluated and authorized in
250 accordance with the provisions of this
251 Directive.
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254 5. This Directive constitutes a specific
255 Directive within the meaning of Article 2
256 (2) of Council Directive 89/336/EEC of 3
257 May 1989 on the approximation of the laws
258 of the Member States relating to
259 electromagnetic compatibility (3).

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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 prevent the placing on the market or the putting into service within their territory of devices complying with the provisions of this Directive and bearing the CE marking provided for in Article 12 which indicate that they have been the subject of an evaluation of their conformity in accordance with Article 9.
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 Article 6,

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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

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320 These devices shall not bear the CE marking.

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323 3. At trade fairs, exhibitions,
324 demonstrations, etc., Member States shall
325 not prevent the showing of devices which do
326 not conform to this Directive, provided that a
327 visible sign clearly indicates that such
328 devices do not conform and cannot be put into
329 service until they have been made to comply by
330 the manufacturer or his authorized
331 representative established within the
332 Community.

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

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341 (*) 5. (a) Where the devices are subject to
342 other Directives concerning other
343 aspects and which also provide
344 for the affixing of the CE
345 marking, the latter shall
346 indicate that the devices are
347 also presumed to conform to the
348 provisions of the other
349 Directives.

350

351 (b) However, where one or more of
352 these Directives allow the
353 manufacturer, during a
354 transitional period, to choose
355 which arrangements to apply, the
356 CE marking shall indicate
357 conformity to the provisions only
358 of those Directives applied by
359 the manufacturer. In this case,
360 particulars of the Directives

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

361 applied, as published in the
362 *Official Journal of the European*
363 *Communities*, must be given in the
364 documents, notices or
365 instructions required by the
366 Directives and accompanying such
367 devices; these documents, notices
368 or instructions shall be
369 accessible without it being
370 necessary to destroy the
371 packaging which keeps the device
372 sterile.

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Article 5

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378 Member States shall presume compliance with the
379 essential requirements referred to in Article 3
380 in respect of devices which are in conformity
381 with the relevant national standards adopted
382 pursuant to the harmonized standards the
383 references of which have been published in the
384 *Official Journal of the European Communities*;
385 Member States shall publish the references of
386 such national standards.

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Article 6

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393 1. Where a Member State or the Commission
394 considers that the harmonized standards
395 referred to in Article 5 do not entirely
396 meet the essential requirements referred to in
397 Article 3, the Commission or the Member State
398 concerned shall bring the matter before the
399 Standing Committee set up under Directive
400 83/189/EEC, giving the reasons therefor. The
401 Committee shall deliver an opinion without
402 delay.

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

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ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

411 2. A Standing Committee, hereinafter referred
412 to as the "Committee", shall be set up,
413 composed of the representatives of the Member
414 States and chaired by the representative of
415 the Commission.

416
417 The Committee shall draw up its rules of
418 procedure.

419
420 Any matter relating to the implementation and
421 practical application of this Directive may be
422 brought before the Committee, in accordance
423 with the procedure set out below.

424
425 The representative of the Commission shall
426 submit to the Committee a draft of the
427 measures to be taken. The Committee shall
428 deliver its opinion according to the urgency
429 of the matter, if necessary by taking a vote.

430
431 The opinion shall be recorded in the minutes;
432 in addition, each Member State shall have the
433 right to ask to have its position recorded in
434 the minutes.

435
436 The Commission shall take the utmost account
437 of the opinion delivered by the Committee.
438 It shall inform the Committee of the manner in
439 which its opinion has been taken into account.

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Article 7

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

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458 The Member State shall immediately inform the
459 Commission of any such measure, indicating the
460 reasons for its decision and, in particular,
461 whether non-compliance with this Directive is
462 due to:

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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464 (a) failure to meet the essential requirements
465 referred to in Article 3, where the device
466 does not meet in full or in part the
467 standards referred to in Article 5;

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469 (b) incorrect application of those standards;

470

471 (c) shortcomings in the standards themselves.

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474 2. The Commission shall enter into
475 consultation with the parties concerned as
476 soon as possible. Where, after such
477 consultation, the Commission finds that:

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479 - the measures are justified, it shall
480 immediately so inform the Member State which
481 took the initiative and the other
482 Member States; where the decision referred
483 to in paragraph 1 is attributed to
484 shortcomings in the standards, the
485 Commission shall, after consulting the
486 parties concerned, bring the matter before
487 the Committee referred to in Article 6 (1)
488 within two months if the Member State which
489 has taken the decision intends to maintain
490 it and shall initiate the procedures
491 referred to in article 6 (1),

492

493 - the measures are unjustified, it shall
494 immediately so inform the Member State
495 which took the initiative and the
496 manufacturer or his authorized
497 representative established within the
498 Community.

499

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501 3. Where a device which does not comply bears
502 the CE marking, the competent Member State
503 shall take appropriate action against
504 whomsoever has affixed the mark and shall
505 inform the Commission and the other Member
506 States thereof.

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509 4. The Commission shall ensure that the
510 Member States are kept informed of the
511 progress and outcome of this procedure.
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Article 8

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518 1. Member States shall take the necessary
519 steps to ensure that information brought to
520 their knowledge regarding the incidents
521 mentioned below involving a device is recorded
522 and evaluated in a centralized manner:
523

524 (a) any deterioration in the characteristics
525 and performances of a device, as well as
526 any inaccuracies in the instruction
527 leaflet which might lead to or might have
528 led to the death of a patient or to a
529 deterioration in his state of health;
530

531 (b) any technical or medical reason resulting
532 in withdrawal of a device from the market
533 by the manufacturer.
534

535

536 2. Member States shall, without prejudice to
537 Article 7, forthwith inform the Commission and
538 the other Member States of the incidents
539 referred to in paragraph 1 and of the relevant
540 measures taken or contemplated.
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Article 9

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547 1. In the case of devices other than those
548 which are custom-made or intended for clinical
549 investigations, the manufacturer must, in
550 order to affix the CE marking, at his own
551 choice:
552

553 (a) follow the procedure relating to the EC
554 declaration of conformity set out in Annex
555 2; or
556

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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

560

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

563

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

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

573

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

579

580

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

587

588

589 (**) **Article 9a**

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591

592 1. Where a Member State considers that
593 the conformity of a device or family of
594 devices should be established, by way of
595 derogation from the provisions of
596 Article 9, by applying solely one of the
597 given procedures chosen from among those
598 referred to in Article 9, it shall submit a
599 duly substantiated request to the
600 Commission and ask it to take the necessary
601 measures. These measures shall be adopted
602 in accordance with the procedure referred
603 to in Article 7 (2) of Directive
604 93/42/EEC.

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2. The Commission shall inform the Member States of the measures taken and, where appropriate, publish the relevant parts of these measures in the *Official Journal of the European Communities*.

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.

(**) Member States may however authorize manufacturers to start the clinical investigations in question before the expiry of the 60-day period, provided that the Ethical Committee concerned has delivered a favourable opinion with respect to the investigation programme in question.

(**) 2a. The authorization referred to in the second subparagraph of paragraph 2 may be subject to approval by the competent authority.

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

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Article 11

(*) 1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the procedures referred to in Article 9 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this 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

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

705 1. Devices other than those which are custom
706 made or intended for clinical investigations
707 considered to meet the essential requirements
708 referred to in article 3 must bear the CE
709 marking of conformity.

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712 2. The CE marking of conformity, as shown in
713 Annex 9, must appear in a visible, legible
714 and idelible form on the sterile pack and,
715 where appropriate, on the sales packaging, if
716 any, and on the instruction leaflet.

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718 (*) It must be followed by the identification
719 number of the notified body responsible
720 for implementation of the procedures set
721 out in annexes 2, 4 and 5.

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724 (*) 3. The affixing of markings on the
725 devices which are likely to decieve
726 third parties as to the meaning and form
727 of the CE marking shall be prohibited.
728 Any other marking may be affixed to the
729 packaging or to the instruction leaflet
730 accompanying the device provided that the
731 visibility and legibility of the CE
732 marking is not hereby reduced.

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Article 13

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737

738 (*) Without prejudice to Article 7:

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740 (a) where a Member State establishes
741 that the CE marking has been
742 affixed unduly, the manufacturer or
743 his authorized representative
744 established in the Community shall
745 be obliged to end the
746 infringement under conditions
747 imposed by the Member State;

748

749 (b) where non-compliance continues, the
750 Member State must take all
751 appropriate measures to restrict or
752 prohibit the placing on the market
753 of the device in question or to
754 ensure that it is withdrawn from the

755 market in accordance with the
756 procedures laid down in article 7.

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Article 14

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762 Any decision taken pursuant to this Directive
763 and resulting in the refusal of or
764 restrictions on the placing on the market
765 and/or putting into service of a device shall
766 state the exact grounds on which it is based.
767 Such decision shall be notified without delay
768 to the party concerned, who shall at the same
769 time be informed of the remedies available to
770 him under the laws in force in the Member
771 State in question and of the time limits to
772 which such remedies are subject.

773

774 (**) In the event of a decision as referred
775 to in the previous paragraph the
776 manufacturer, or his authorized
777 representative established in the
778 Community, shall have an opportunity to
779 put forward his viewpoint in advance,
780 unless such consultation is not
781 possible because of the urgency of the
782 measures to be taken.

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Article 15

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788 Member States shall ensure that all the
789 parties involved in the application of this
790 Directive are bound to observe confidentiality
791 with regard to all information obtained in
792 carrying out their tasks. This does not affect
793 the obligations of Member States and notified
794 bodies with regard to mutual information and
795 the dissemination of warnings.

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Article 16

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801 1. Before 1 July 1992, Member States shall
802 adopt and publish the laws, regulations and
803 administrative provisions necessary in order

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

804 to comply with this Directive. They shall
805 forthwith inform the Commission thereof.

806
807 They shall adopt such provisions from 1
808 January 1993.

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810
811 2. Member States shall communicate to the
812 Commission the texts of the provisions of
813 national law which they adopt in the field
814 covered by this Directive.

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816
817 3. Member States shall, for the period up to
818 31 December 1994, permit the placing on the
819 market and putting into service of devices
820 complying with national rules in force in
821 their territory on 31 December 1992.

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Article 17

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826

827 This Directive is addressed to the Member
828 States.

829

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831

832 Done at Luxembourg, 20 June 1990.

833

834

For the Council

835

836

The President

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838

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,

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

- 894 - risks connected with the use of energy sources with particular reference, where electricity is used, to
895 insulation, leakage currents and overheating of the devices,
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- 897 - risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external
898 electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration,
899
- 900 - risks connected with medical treatment, in particular those resulting from the use of defibrillators or
901 high-frequency surgical equipment,
902
- 903 - risks connected with ionizing radiation from radioactive substances included in the device, in
904 compliance with the protection requirement laid down in Directive 80/836/Euratom (1), as amended
905 by Directives 84/467/Euratom (2) and 84/466/Euratom (3),
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- 907 - risks which may arise where maintenance and calibration are impossible, including:
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- 909 - excessive increase of leakage currents,
 - 910
 - 911 - ageing of the materials used,
 - 912
 - 913 - excess heat generated by the devices,
 - 914
 - 915 - decreased accuracy of any measuring or control mechanism.
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- 918 9. The devices must be designed and manufactured in such a way as to guarantee the characteristics and
919 performances referred to in I. "General requirements", with particular attention being paid to:
920
- 921 - the choice of materials used, particularly as regards toxicity aspects,
922
 - 923 - mutual compatibility between the materials used and biological tissues, cells and body fluids, account
924 being taken of the anticipated use of the device,
925
 - 926 - compatibility of the devices with the substances they are intended to administer,
927
 - 928 - the quality of the connections, particularly in respect of safety,
929
 - 930 - the reliability of the source of energy,
931
 - 932 - if appropriate, that they are leakproof,
933
 - 934 - proper functioning of the programming and control systems, including software.
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- 937 10. Where a device incorporates, as an integral part, a substance which, when used separately, is likely to be
938 considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC, and whose action in
939 combination with the device may result in its bioavailability, the safety, quality and usefulness of the
940 substance, account being taken of the purpose of the device, must be verified by analogy with the
941 appropriate methods specified in Directive 75/318/EEC (1), as last amended by Directive
942 89/341/EEC (2).
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- 945 11. The devices and, if appropriate, their component parts must be identified to allow any necessary measure to
946 be taken following the discovery of a potential risk in connection with the devices and their component
947 parts.
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ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

- 950 12. Devices must bear a code by which they and their manufacturer can be unequivocally identified
951 (particularly with regard to the type of device and year of manufacture); it must be possible to read this
952 code, if necessary, without the need for surgical operation.
953
954
- 955 13. When a device or its accessories bear instructions required for the operation of the device or indicate
956 operating or adjustment parameters, by means of a visual system, such information must be
957 understandable to the user and, as appropriate, the patient.
958
959
- 960 14. Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of
961 generally recognized symbols:
962
- 963 14.1. On the sales packaging:
964
- 965 - the method of sterilization,
 - 966 - an indication permitting this packaging to be recognized as such,
 - 967 - the name and address of the manufacturer,
 - 968 - a description of the device,
 - 969 - if the device is intended for clinical investigations, the words: "exclusively for clinical
970 investigations",
 - 971 - if the device is custom-made, the words "custom-made device",
 - 972 - a declaration that the implantable device is in a sterile condition,
 - 973 - the month and year of manufacture,
 - 974 - an indication of the time limit for implanting a device safely.
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- 984 14.2. On the sales packaging:
985
- 986 - the name and address of the manufacturer,
 - 987 - a description of the device,
 - 988 - the purpose of the device,
 - 989 - the relevant characteristics for its use,
 - 990 - if the device is intended for clinical investigations, the words: "exclusively for clinical
991 investigations",
 - 992 - if the device is custom-made, the words: "custom-made device",
 - 993 - a declaration that the implantable device is in sterile condition,
 - 994 - the month and year of manufacture,
 - 995 - an indication of the time limit for implanting a device safely,
 - 996 - the conditions for transporting and storing the device.
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ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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1008 15. When placed on the market, each device must be accompanied by instructions for use giving the following
1009 particulars:

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1011 - the year of authorization to affix the CE mark,

1012

1013 - the details referred to in 14.1 and 14.2, with the exception of those referred to in the eighth and ninth
1014 indents,

1015

1016 - the performances referred to in section 2 and any undesirable side effects,

1017

1018 - information allowing the physician to select a suitable device and the corresponding software and
1019 accessories,

1020

1021 - information constituting the instructions for use allowing the physician and, where appropriate, the
1022 patient to use the device, its accessories and software correctly, as well as information on the nature,
1023 scope and times for operating controls and trials and, where appropriate, maintenance measures,

1024

1025 - information allowing, if appropriate, certain risks in connection with implantation of the device to be
1026 avoided,

1027

1028 - information regarding the risks of reciprocal interference (*) in connection with the presence of the
1029 device during specific investigations or treatment,

1030

1031 - the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details
1032 of appropriate methods of re-sterilization,

1033

1034 - an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility
1035 of the manufacturer to comply with the essential requirements.

1036

1037 The instruction leaflet must also include details allowing the physician to brief the patient on the
1038 contra-indications and the precautions to be taken. These details should cover in particular:

1039

1040 - information allowing the lifetime of the energy source to be established,

1041

1042 - precautions to be taken should changes occur in the device's performance,

1043

1044 - precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to
1045 magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure,
1046 acceleration, etc.,

1047

1048 - adequate information regarding the medicinal products which the device in question is designed to
1049 administer.

1050

1051

1052 16. Confirmation that the device satisfies the requirements in respect of characteristics and performances, as
1053 referred to in I. "General requirements", in normal conditions of use, and the evaluation of the side effects or
1054 undesirable effects must be based on clinical data established in accordance with Annex 7.

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1058 (*) "Risks of reciprocal interference" means adverse effects on the device caused by instruments present at the time of investigations
1059 or treatment, and vice versa.

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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.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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1079 (*) The manufacturer or his authorized
1080 representative established within the
1081 Community shall affix the CE marking in
1082 accordance with Article 12 and shall draw up a
1083 written declaration of conformity.
1084
1085 This declaration shall cover one or more
1086 identified examples of the product and shall be
1087 kept by the manufacturer or his authorized
1088 representative established within the
1089 Community.
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1091 The CE marking shall be accompanied by the
1092 identification number of the notified body
1093 responsible;

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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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:

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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- 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.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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- 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 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.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

- 1249 (*) 6. **Administrative provisions**
1250
1251 6.1. For at least five years from last date of
1252 manufacture of the product, the
1253 manufacturer shall keep available for the
1254 national authorities:
1255
1256 - the declaration of conformity,
1257
1258 - the documentation referred to in the
1259 second indent of section 3.1,
1260
1261 - the amendments referred to in
1262 section 3.4,
1263
1264 - the documentation referred to in
1265 section 4.2,
1266
1267 - the decisions and reports of the
1268 notified body referred to in
1269 sections 3.4, 4.3 and 5.4.
1270
1271 6.2. On request, the notified body shall make
1272 available to the other notified bodies and
1273 the competent authority all relevant
1274 information on approvals of quality
1275 systems issued, refused or withdrawn.
1276
1277 6.3. Where neither the manufacturer nor his
1278 authorized representative are established
1279 in the Community, the task of keeping
1280 available for the authorities the technical
1281 documentation referred to in Article 4 (2)
1282 shall fall to the person responsible for
1283 placing the appliance on the Community
1284 market;
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ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

ANNEX 3

EC type-examination

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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, 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 statements as to whether or not the device incorporates, as an integral part, a substance as referred to in sections 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.

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

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

- 1346 applicable provisions of the standards referred to in Article 5, as well as the items for which the design is not
1347 based on the relevant provisions of the said standards;
1348
- 1349 4.2. carry out or have carried out the appropriate inspections and the tests necessary to verify whether the
1350 solutions adopted by the manufacturer satisfy the essential requirements of this Directive where the
1351 standards referred to in Article 5 have not been applied;
1352
- 1353 4.3. carry out or have carried out the appropriate inspections and the tests necessary to verify whether, where
1354 the manufacturer has chosen to apply the relevant standards, these have actually been applied;
1355
- 1356 4.4. agree with the applicant on the place where the necessary inspections and tests will be carried out.
1357
- 1358
- 1359 5. Where the type meets the provisions of this Directive, the notified body shall issue an EC type-examination
1360 certificate to the applicant. The certificate shall contain the name and address of the manufacturer, the
1361 conclusions of the control, the conditions under which the certificate is valid and the information necessary
1362 for identification of the type approved.
1363
- 1364 The significant parts of the documentation shall be attached to the certificate and a copy shall be kept by the
1365 notified body.
1366
- 1367
- 1368 6. The applicant shall inform the notified body which issued the EC type-examination certificate of any
1369 modification made to the approved product.
1370
- 1371 Modifications to the approved product must receive further approval from the notified body which issued
1372 the EC type-examination certificate where such modifications may affect conformity with the essential
1373 requirements or with the conditions of use specified for the product. This new approval shall be issued,
1374 where appropriate, in the form of a supplement to the initial EC type-examination certificate.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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7. **Administrative provisions**
- 7.1. On request, each notified body shall make available to the other notified bodies and the competent authority, all relevant information on EC type-examination certificates and addenda issued, refused or withdrawn.
- 7.2. Other notified bodies may obtain a copy of the EC type examination certificates and/or the addenda to them. The annexes to the certificates shall be made available to the other notified bodies when a reasoned application is made and after the manufacturer has been informed.
- 7.3. The manufacturer or his authorized 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 manufacture of the last appliance.
- 7.4. Where neither the manufacturer nor his authorized representative are established in the Community, the task of keeping the technical documentation available for the authorities shall fall to the person responsible for placing the appliance concerned on the Community market;

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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1409 8. Other notified bodies may obtain a copy of the EC type-examination certificate and/or the supplements to
1410 them. The annexes to the certificates shall be made available to the other notified bodies when a reasoned
1411 application is made and after first informing the manufacturer.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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ANNEX 4

EC verification

- (*) 1. EC verification is the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the products subject to the provisions of section 3 are in conformity with the type as described in the EC type-examination certification and satisfy the requirements of this Directive that apply to them.
2. The manufacturer or his authorized representative established within the Community 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 certification and to the requirements of this Directive that apply to them. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each product and draw up a written declaration of conformity.
3. The manufacturer shall, before the start of manufacture, prepare documents defining the manufacturing processes, in particular as regards sterilization, together with all the routine, pre-established provisions to be implemented to ensure uniformity of production and conformity of the products with the type as described in the EC type-examination certificate as well as with the relevant requirements of this Directive.
4. The manufacturer shall undertake to institute and keep updated a post-marketing surveillance system. This undertaking shall include the obligation on the part of the manufacturer to notify the competent authorities of the following events immediately on learning of them:
- (i) any change 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 deterioration of his state of health;
 - (ii) any technical or medical reason resulting in the withdrawal of a device from the market by a manufacturer.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

1472 5. The notified body shall carry out the
1473 appropriate examinations and tests in order to
1474 check the conformity of the product to the
1475 requirements of this Directive by examination
1476 and testing of products on a statistical basis, as
1477 specified in section 6. The manufacturer must
1478 authorize the notified body to evaluate the
1479 efficiency of the measures taken pursuant to
1480 section 3, by audit where appropriate.

1481 1482 6. **Statistical verification**

1483
1484 6.1. Manufacturers shall present the products
1485 manufactured in the form of uniform batches
1486 and shall take all necessary measures in order
1487 that the manufacturing process ensures the
1488 uniformity of each batch produced.

1489
1490 6.2. A random sample shall be taken from each
1491 batch. Products in a sample shall be
1492 individually examined and appropriate tests, as
1493 set out in the standard(s) referred to in
1494 Article 5, or equivalent tests shall be carried
1495 out to verify their conformity to the type as
1496 described in the EC type-examination
1497 certificate and thereby determine whether a
1498 batch is to be accepted or rejected.

1499
1500 6.3. Statistical control of products shall be based
1501 on attributes, entailing a sampling system with
1502 the following characteristics:

1503
1504 - a level of quality corresponding to a
1505 probability of acceptance of 95%, with a
1506 non-conformity percentage of between 0,29
1507 and 1%,

1508
1509 - a limit quality corresponding to a probability
1510 of acceptance of 5%, with a percentage of
1511 non-conformity of between 3 and 7%.

1512
1513 6.4. Where batches are accepted, the notified body
1514 shall affix, or cause to be affixed, its
1515 identification number to each product and
1516 draw up a written certificate of conformity
1517 related to the tests carried out. All products in
1518 the batch may be placed on the market except
1519 for those products from the sample which were
1520 found not to be in conformity.

1521
1522 Where a batch is rejected, the notified body
1523 shall take appropriate measures to prevent the
1524 placing on the market of that batch. In the
1525 event of frequent rejection of batches the
1526 notified body may suspend the statistical
1527 verification.

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1529 The manufacturer may, under the
1530 responsibility of the notified body, affix the
1531 latter's identification number during the
1532 manufacturing process.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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- 6.5. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

ANNEX 5

EC declaration of conformity to type

(Assurance of production quality)

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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.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

1558 (*) The manufacturer or his authorized representative
1559 established within the Community shall affix the CE
1560 marking in accordance with Article 12 and draw up
1561 a written declaration of conformity. This declaration
1562 shall cover one or more identified specimens of the
1563 product and shall be kept by the manufacturer. The
1564 CE marking shall be accompanied by the
1565 identification number of the notified body
1566 responsible.
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ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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1569 **3. Quality system**
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1571 3.1. The manufacturer shall make an application for evaluation of his quality system to a notified body.

1572
1573 The application shall include:

- 1574 - all appropriate information concerning the products which it is intended to manufacture,
- 1575 - the quality-system documentation,
- 1576 - an undertaking to fulfil the obligations arising from the quality system as approved,
- 1577 - an undertaking to maintain the approved quality system in such a way that it remains adequate and
- 1578 efficacious,
- 1579 - where appropriate, the technical documentation relating to the approved type and a copy of the EC
- 1580 type-examination certificate,
- 1581 - an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance
- 1582 system. The undertaking shall include an obligation for the manufacturer to notify the competent
- 1583 authorities of the following incidents immediately after learning of them:
- 1584 (i) any deterioration in the characteristics or performances, and any inaccuracies in the instruction
- 1585 leaflet for a device which might lead to or have led to the death of a patient or a deterioration in his
- 1586 state of health;
- 1587 (ii) any technical or medical reason resulting in withdrawal of a device from the market by the
- 1588 manufacturer.

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1599 3.2. Application of the quality system must ensure that the products conform to the type described in the EC
1600 type-examination certificate.

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1602 All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be
1603 documented in a systematic and orderly manner in the form of written policies and procedures. This
1604 quality-system documentation must make possible a uniform interpretation of the quality policies and
1605 procedures such as quality programmes, quality plans, quality manuals and quality records.

1606
1607 It shall include in particular an adequate description of:

- 1608 (a) the manufacturer's quality objectives;
- 1609 (b) the organization of the business and in particular:
 - 1610 - the organizational structures, the responsibilities of the managerial staff and their organizational
 - 1611 authority where manufacture of the products is concerned,
 - 1612 - the methods of monitoring the efficient operation of the quality system and in particular its ability
 - 1613 to achieve the desired quality of the design and of the products, including control of products
 - 1614 which do not conform;
- 1615 (d) the techniques of control and of quality assurance at the manufacturing stage and in particular:
 - 1616 - the processes and procedures which will be used, particularly as regards sterilization, purchasing
 - 1617 and the relevant documents,
 - 1618 - product identification procedures drawn up and kept up-to-date from drawings, specifications or
 - 1619 other relevant documents at every stage of manufacture;

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

- 1628 (e) the appropriate tests and trials which will be effected before, during and after production, the
1629 frequency with which they will take place, and the test equipment used.
1630
- 1631 3.3. Without prejudice to Article 13, the notified body shall effect an audit of the quality system to determine
1632 whether it meets the requirements referred to in 3.2. It shall presume conformity with these requirements
1633 for the quality systems which use the corresponding harmonized standards.
1634
- 1635 The team entrusted with the evaluation shall include at least one member who has already had experience
1636 of evaluations of the technology concerned. The evaluation procedure shall include an inspection on the
1637 manufacturer's premises.
1638
- 1639 The decision shall be notified to the manufacturer after the final inspection. It shall contain the conclusions
1640 of the control and a reasoned evaluation.
1641
- 1642 3.4. The manufacturer shall inform the notified body which has approved the quality system of any plan to alter
1643 that system.
1644
- 1645 The notified body shall evaluate the proposed modifications and shall verify whether the quality system so
1646 modified would meet the requirements referred to in 3.2; it shall notify the manufacturer of its decision.
1647 This decision shall contain the conclusions of the control and a reasoned evaluation.
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- 1650 4. **Surveillance**
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- 1652 4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations which arise from the
1653 approved quality system.
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- 1655 4.2. The manufacturer shall authorize the notified body to carry out all necessary inspections and shall supply it
1656 with all appropriate information, in particular:
1657
- 1658 - the quality-system documentation,
 - 1659
 - 1660 - the data stipulated in the part of the quality system relating to manufacture, such as reports concerning
1661 inspections, tests, standardizations/calibrations and the qualifications of the staff concerned, etc.
1662
- 1663 4.3. The notified body shall periodically carry out appropriate inspections and evaluations in order to ascertain
1664 that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an
1665 evaluation report.
1666
- 1667 4.4. In addition, the notified body may make unannounced visits to the manufacturer, and shall supply him
1668 with an inspection report.
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- 1671 5. The notified body shall communicate to the other notified bodies all relevant information concerning
1672 approvals of quality systems issued, refused or withdrawn.

ANNEX 6

Statement concerning devices intended for special purposes

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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 investigation,
 - 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,

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

- 1732 - design drawings, manufacturing methods, in particular as regards sterilization, and diagrams of parts,
1733 sub-assemblies, circuits, etc.,
1734
- 1735 - the descriptions and explanations necessary for the understanding of the said drawings and diagrams
1736 and of the operation of the product,
1737
- 1738 - a list of the standards laid down in Article 5, applied in full or in part, and a description of the solutions
1739 adopted to satisfy the essential requirements of the Directive where the standards in Article 5 have not
1740 been applied,
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- 1742 - the results of the design calculations, checks and technical tests carried out, etc.
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- 1744 The manufacturer shall take all necessary measures to see that the manufacturing process ensures that the
1745 products manufactured conform to the documentation referred to in 3.1 and in the first paragraph of this
1746 section.
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- 1748 The manufacturer may authorize the evaluation, by audit where necessary, of the effectiveness of these
1749 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.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

- 1810 2.3.5. All adverse events shall be fully recorded.
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- 1812 2.3.6. The investigations shall be performed under the responsibility of an appropriately qualified medical
1813 specialist, in an appropriate environment.
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1815 The medical specialist shall have access to the technical data regarding the device.
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- 1817 2.3.7. The written report, signed by the responsible medical specialist, shall comprise a critical evaluation of all
1818 the data collected during the clinical investigation.

ANNEX 8

Minimum criteria to be met when designating inspection bodies to be notified

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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 the 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.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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ANNEX 9

CE CONFORMITY MARKING

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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- The CE conformity marking shall consist of the initials "CE" taking the following form:

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- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

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- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

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This minimum dimension may be waived for small-scale devices.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

Original text of the amended parts

The original text of the AIMD Directive, which has been amended by the CE marking Directive (93/68/EEC), can be found below. The amendments of the MD Directive (93/42/EEC) are all additions to the original version of the AIMD Directive.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

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 marking.

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.

Article 12

2. (Second subparagraph)

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 CE marking of conformity shall be prohibited.

Article 13

Where it is established that the CE marking 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,

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

- 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.

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

Annex 2

Section 2, second paragraph:

The manufacturer shall apply the CE marking 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 marking shall be accompanied by the identifying logo of the notified body responsible.

Section 6:

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

Section 7:

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.

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**

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE

- 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 probability 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 marking during manufacture, under the responsibility of the notified body, in accordance with Article 12, accompanied by the identifying logo of the notified body responsible for statistical verification.

ANNEX 5

Section 2, second subparagraph:

The manufacturer shall affix the CE marking 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 marking shall be accompanied by the identifying logo of the notified body responsible.

ANNEX 9

CE marking of conformity

ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE