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)

ANNEX 1

ESSENTIAL REQUIREMENTS

8. Devices must be designed and manufactured in such a way...
9. The devices must be designed and manufactured in such a...
10. Where a device incorporates, as an integral part, a substance...
11. The devices and, if appropriate, their component parts must be...
12. Devices must bear a code by which they and their...
13. When a device or its accessories bear instructions required for...
14. Every device must bear, legibly and indelibly, the following particulars,...
    - 14.1. On the sterile pack:
    - 14.2. On the sales packaging:
15. When placed on the market, each device must be accompanied...
16. Confirmation that the device satisfies the requirements in respect of...

ANNEX 2

EC DECLARATION OF CONFORMITY

1. The manufacturer shall apply the quality system approved for the...

2. The declaration of conformity is the procedure by means of...

3. Quality system
    - 3.1. The manufacturer shall make an application for evaluation of his...
    - 3.2. The application of the quality system must ensure that the...
    - 3.3. Without prejudice to Article 13 of this Directive, the notified...
    - 3.4. The manufacturer shall inform the notified body which has approved...

4. Examination of the design of the product
    - 4.1. In addition to the obligations incumbent on him under section...
    - 4.2. The application shall describe the design, manufacture and performances of...
    - 4.3. The notified body shall examine the application and, where the...
    - 4.4. The applicant shall inform the notified body which issued the...

5. Surveillance
    - 5.1. The aim of surveillance is to ensure that the manufacturer...
    - 5.2. The manufacturer shall authorize the notified body to carry out...
    - 5.3. The notified body shall periodically carry out appropriate inspections and...
    - 5.4. In addition, the notified body may make unannounced visits to...

6. Administrative provisions
    - 6.1. For at least 15 years from the last date of...
    - 6.2. On request, the notified body shall make available to the...
    - 6.3. . . . .

7. Application to the devices referred to in Article 1(4a):

ANNEX 3

EC TYPE-EXAMINATION

1. EC type-examination is the procedure whereby a notified body observes...

2. The application for EC type-examination shall be made by the...

3. The documentation must make it possible to understand the design,...

4. The notified body shall:
   - 4.1. examine and evaluate the documentation, verify that the type has...
   - 4.2. carry out or have carried out the appropriate inspections and...
   - 4.3. carry out or have carried out the appropriate inspections and...
   - 4.4. agree with the applicant on the place where the necessary...

5. Where the type meets the provisions of this Directive, the...

6. The applicant shall inform the notified body which issued the...

7. Administrative provisions
   - 7.1. On request, each notified body shall make available to the...
   - 7.2. Other notified bodies may obtain a copy of the EC...
   - 7.3. The manufacturer or his authorized representative shall keep with the...
   - 7.4. . . . .

ANNEX 4

EC VERIFICATION

1. EC verification is the procedure whereby the manufacturer or his...

2. The manufacturer or his authorized representative established within the Community...

3. The manufacturer shall, before the start of manufacture, prepare documents...

4. The manufacturer shall undertake to institute and keep updated a...

5. The notified body shall carry out the appropriate examinations and...

6. Statistical verification
   - 6.1. Manufacturers shall present the products manufactured in the form of...
   - 6.2. A random sample shall be taken from each batch. Products...
   - 6.3. Statistical control of products will be based on attributes and/or...
   - 6.4. Where batches are accepted, the notified body shall affix, or...
   - 6.5. The manufacturer or his authorized representative shall ensure that he...

7. Application to the devices referred to in Article 1(4a):

ANNEX 5

EC DECLARATION OF CONFORMITY TO TYPE

1. The manufacturer shall apply the quality system approved for the...

2. This declaration of conformity is the procedural element whereby the...

3. Quality system
   - 3.1. The manufacturer shall make an application for evaluation of his...
   - 3.2. Application of the quality system must ensure that the products...

3.3. Without prejudice to Article 13, the notified body shall effect...
3.4. The manufacturer shall inform the notified body which has approved...

4. Surveillance
4.1. The aim of surveillance is to ensure that the manufacturer...
4.2. The manufacturer shall authorize the notified body to carry out...
4.3. The notified body shall periodically carry out appropriate inspections and...
4.4. In addition, the notified body may make unannounced visits to...

5. The notified body shall communicate to the other notified bodies...

6. Application to the devices referred to in Article 1(4a):

ANNEX 6

STATEMENT CONCERNING DEVICES INTENDED FOR SPECIAL PURPOSES

1. The manufacturer or his authorized representative established within the Community...

2. The statement shall comprise the following information:
2.1. For custom-made devices:
2.2. For devices intended for clinical investigations covered in Annex 7:...

3. The manufacturer shall undertake to keep available for the competent...
3.1. For custom-made devices, documentation, indicating manufacturing site(s) and enabling the...
3.2. For devices intended for clinical investigations, the documentation shall also...

4. The information included in the declarations covered by this Annex...

5. For custom-made devices, the manufacturer must undertake to review and...

ANNEX 7

CLINICAL EVALUATION

1. General provisions
1.1. As a general rule, confirmation of conformity with the requirements...
1.1.1. Either a critical evaluation of the relevant scientific literature currently...
1.1.2. Or a critical evaluation of the results of all the...
1.1.3. Or a critical evaluation of the combined clinical data provided...
1.2. Clinical investigations shall be performed unless it is duly justified...
1.3. The clinical evaluation and its outcome shall be documented. This...
1.4. The clinical evaluation and its documentation must be actively updated...
1.5. Where demonstration of conformity with essential requirements based on clinical...
1.6. All data must remain confidential unless it is deemed essential...

2. Clinical investigation
2.1. Purpose
2.2. Ethical consideration

2.3. Methods
- 2.3.1. Clinical investigations shall be performed according to an appropriate state...
- 2.3.2. The procedures utilized to perform the investigations shall be appropriate...
- 2.3.3. Clinical investigations shall be performed in circumstances equivalent to those...
- 2.3.4. All appropriate features, including those involving the safety and performances...
- 2.3.5. All serious adverse events must be fully recorded and immediately...
- 2.3.6. The investigations shall be performed under the responsibility of an...
- 2.3.7. The written report, signed by the responsible medical specialist, shall...

ANNEX 8

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

1. The body, its director and the staff responsible for carrying...

2. The body and its staff must carry out the evaluation...

3. The body must be able to carry out all the...

4. The staff responsible for control operations must have:

5. The impartiality of inspection staff must be guaranteed. Their remuneration...

6. The body must take out liability insurance unless liability is...

7. The staff of the body are bound to observe professional...

ANNEX 9

CE CONFORMITY MARKING

The CE conformity marking shall consist of the initials ‘...

(**1**) OJ No C 14, 18.1.1989, p. 4.

(**2**) OJ No C 120, 16.5.1989, p. 75, and
OJ No C 149, 18.6.1990.

(**3**) OJ No C 159, 26.6.1989, p. 47.

(**4**) OJ No L 109, 26.4.1983, p. 8.

(**5**) OJ No L 81, 26.3.1988, p. 75.