Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

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ANNEX I

ESSENTIAL REQUIREMENTS

ANNEX II

EC DECLARATION OF CONFORMITY

1. The manufacturer must ensure application of the quality system approved...

2. The EC declaration of conformity is the procedure whereby the...

3. Quality system
   3.1. The manufacturer must lodge an application for assessment of his...
   3.2. Application of the quality system must ensure that the products...
   3.3. The notified body must audit the quality system to determine...
   3.4. The manufacturer must inform the notified body which approved the...

4. Examination of the design of the product
   4.1. In addition to the obligations imposed by Section 3, the...
   4.2. The application must describe the design, manufacture and performances of...
   4.3. The notified body must examine the application and, if the...
   4.4. Changes to the approved design must receive further approval from...

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

6. Administrative provisions

6.1. The manufacturer or his authorised representative must, for a period...
6.2. . . . .
6.3. . . . .

7. Application to devices in Classes IIa and IIb.
7.1. In line with Article 11(2) and (3), this Annex may...
7.2. For devices in Class IIa the notified body shall assess,...
7.3. For devices in Class IIb the notified body shall assess,...
7.4. In choosing representative sample(s) the notified body shall take into...
7.5. Further samples shall be assessed by the notified body as...

8. Application to the devices referred to Article 1(4a)

ANNEX III

EC TYPE-EXAMINATION

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

2. The application includes:

3. The documentation must allow an understanding of the design, the...

4. The notified body must:
4.1. examine and assess the documentation and verify that the type...
4.2. carry out or arrange for the appropriate inspections and the...
4.3. carry out or arrange for the appropriate inspections and the...
4.4. agree with the applicant on the place where the necessary...

5. If the type conforms to the provisions of this Directive,...

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

7. Administrative provisions
7.1. . . . .
7.2. Other notified bodies may obtain a copy of the EC...
7.3. The manufacturer or his authorised representative must keep with the...
7.4. . . . .

ANNEX IV

EC VERIFICATION

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

2. The manufacturer must take all the measures necessary to ensure...

3. The manufacturer must undertake to institute and keep up to...

4. The notified body must carry out the appropriate examinations and...

5. Verification by examination and testing of every product

5.1. Every product is examined individually and the appropriate tests defined...
5.2. The notified body must affix, or have affixed its identification...

6. Statistical verification
6.1. The manufacturer must present the manufactured products in the form...
6.2. A random sample is taken from each batch. The products...
6.3. Statistical control of products will be based on attributes and/or...
6.4. If the batch is accepted, the notified body affixes or...

7. Administrative provisions

8. Application to devices in Class IIa
8.1. in derogation from Sections 1 and 2, by virtue of...
8.2. in derogation from Sections 1, 2, 5 and 6, the...

9. Application to devices referred to in Article 1(4a)

ANNEX V

EC DECLARATION OF CONFORMITY

1. The manufacturer must ensure application of the quality system approved...

2. The EC declaration of conformity is the part of the...

3. Quality system
3.1. The manufacturer must lodge an application for assessment of his...
3.2. Application of the quality system must ensure that the products...
3.3. The notified body must audit the quality system to determine...
3.4. The manufacturer must inform the notified body which approved the...

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

5. Administrative provisions
5.1. The manufacturer or his authorised representative must, for a period...
5.2. . . . .

6. Application to devices in Class IIa
6.1. By way of derogation from Sections 2, 3.1 and 3.2,...
6.2. For devices in Class IIa the notified body shall assess,...
6.3. In choosing representative sample(s) the notified body shall take into...
6.4. Further samples shall be assessed by the notified body as...

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

ANNEX VI

EC DECLARATION OF CONFORMITY

1. The manufacturer must ensure application of the quality system approved...

2. The EC declaration of conformity is the part of the...

3. Quality system
   - 3.1. The manufacturer lodges an application for assessment of his quality...
   - 3.2. Under the quality system, each product or a representative sample...
   - 3.3. The notified body audits the quality system to determine whether...
   - 3.4. The manufacturer must inform the notified body which approved the...

4. Surveillance
   - 4.1. The aim of surveillance is to ensure that the manufacturer...
   - 4.2. The manufacturer must allow the notified body access for inspection...
   - 4.3. The notified body must periodically carry out appropriate inspections and...
   - 4.4. In addition, the notified body may pay unannounced visits to...

5. Administrative provisions
   - 5.1. The manufacturer or his authorised representative must, for a period...
   - 5.2. . . . .

6. Application to devices in Class IIa
   - 6.1. By way of derogation from Sections 2, 3.1 and 3.2,...
   - 6.2. For devices in Class IIa the notified body shall assess,...
   - 6.3. In choosing representative sample(s) the notified body shall take into...
   - 6.4. Further samples shall be assessed by the notified body as...

ANNEX VII

EC DECLARATION OF CONFORMITY

1. The EC declaration of conformity is the procedure whereby the...

2. The manufacturer must prepare the technical documentation described in Section...

3. The technical documentation must allow assessment of the conformity of...

4. The manufacturer shall institute and keep up to date a...

5. With products placed on the market in sterile condition and...

6. Application to devices in Class IIa
   - 6.1. where this Annex is applied in conjunction with the procedure...

ANNEX VIII

STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES

1. For custom-made devices or for devices intended for clinical investigations...

2. The statement must contain the following information:
   2.1. for custom-made devices:
   2.2. for devices intended for the clinical investigations covered by Annex...

3. The manufacturer must also undertake to keep available for the...
   3.1. For custom-made devices, documentation, indicating manufacturing site(s) and allowing an...
   3.2. For devices intended for clinical investigations, the documentation must contain:...

4. The information contained in the declarations concerned by this Annex...

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

ANNEX IX

CLASSIFICATION CRITERIA

I. DEFINITIONS
   1. Definitions for the classification rules
      1.1. Duration
         Transient
         Short term
         Long term
      1.2. Invasive devices
         Invasive device
         Body orifice
         Surgically invasive device
         Implantable device
      1.3. Reusable surgical instrument
      1.4. Active medical device
      1.5. Active therapeutical device
      1.6. Active device for diagnosis
      1.7. Central circulatory system
      1.8. Central nervous system

II. IMPLEMENTING RULES
   2. Implementing rules
      2.1. Application of the classification rules shall be governed by the...
      2.2. If the device is intended to be used in combination...
      2.3. Software, which drives a device or influences the use of...
      2.4. If the device is not intended to be used solely...
      2.5. If several rules apply to the same device, based on...
      2.6. In calculating the duration referred to in Section 1.1 of...

III. CLASSIFICATION
   1. Non-invasive devices
      1.1. Rule 1
      1.2. Rule 2
      1.3. Rule 3
      1.4. Rule 4
   2. Invasive devices

ANNEX X

CLINICAL EVALUATION

ANNEX XI

CRITERIA TO BE MET FOR THE DESIGNATION OF NOTIFIED BODIES

1. The notified body, its Director and the assessment and verification...

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

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

4. The notified body must have:

5. The impartiality of the notified body must be guaranteed. Their...

6. The body must take out civil liability insurance, unless liability...

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

ANNEX XII

CE MARKING OF CONFORMITY

The CE conformity marking shall consist of the initials ‘CE’...
If the marking is reduced or enlarged the proportions given...

(**1**) OJ No C 237, 12.9.1991 and OJ No C 251, 28.9.1992, p. 40.

(**2**) OJ No C 150, 31.5.1993 and OJ No C 176, 28.6.1993.

(**3**) OJ No C 79, 30.3.1992, p. 1.

(**4**) OJ No 22, 9.6.1965, p. 369/65. Directive as last amended by Directive 92/27/EEC (OJ No L 113, 30.4.1992, p. 8).

(**5**) OJ No L 147, 9.6.1975, p. 1. Directive as last amended by Directive 91/507/EEC (OJ No L 270, 26.9.1991, p. 32).

(**6**) OJ No C 136, 4.6.1985, p. 1.

(**7**) OJ No L 189, 20.7.1990, p. 17.

(**8**) OJ No L 139, 23.5.1989, p. 19. Directive as last amended by Directive 92/31/EEC (OJ No L 126, 12.5.1992, p. 11).

(**9**) OJ No L 246, 17.9.1980, p. 1. Directive as last amended by Directive 84/467/Euratom (OJ No L 265, 5.10.1984, p. 4).

(**10**) OJ No L 265, 5.10.1984, p. 1.

(**11**) OJ No L 183, 29.6.1989, p. 1.

(**12**) OJ No L 109, 26.4.1983, p. 8. Directive as last amended by Commission Decision 92/400/EEC (OJ No L 221, 6.8.1992, p. 55).

(**13**) OJ No L 197, 18.7.1987, p. 33.

(**14**) OJ No L 147, 9.6.1975, p. 1. Directive as last amended by Directive 91/507/EEC (OJ No L 270, 26.9.1991, p. 32).

(**15**) OJ No C 185, 22.7.1989, p. 8.

(**16**) OJ No L 262, 27.9.1976, p. 139. Directive as last amended by Directive 84/414/EEC (OJ No L 228, 25.8.1984, p. 25).

(**17**) OJ No L 300, 19.11.1984, p. 179. Directive as amended by the Act of Accession of Spain and Portugal.