Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

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ANNEX I

ESSENTIAL REQUIREMENTS

ANNEX II

LIST OF DEVICES REFERRED TO IN ARTICLE 9(2) AND (3)

List A
Reagents and reagent products, including related calibrators and control materials,...
List B
Reagents and reagent products, including related calibrators and control materials,...

ANNEX III

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 take necessary measures to ensure that the...

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

6. For devices for self-testing the manufacturer shall lodge an application...
   - 6.1. The application shall enable the design of the device to...
   - 6.2. The notified body shall examine the application and, if the...
   - 6.3. The applicant shall inform the notified body which issued the...

ANNEX IV

EC DECLARATION OF CONFORMITY

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

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

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 devices...
   - 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. For devices covered by Annex II, List A, in addition...
   - 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...
   - 4.5. The manufacturer shall inform the notified body without delay if...

5. Surveillance

5.1. The aim of surveillance is to ensure that the manufacturer...
5.2. The manufacturer must authorise 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. Verification of manufactured products covered by Annex II, List A...
6.1. In the case of devices covered by Annex II, List...
6.2. The manufacturer may place the devices on the market, unless...

ANNEX V

EC TYPE-EXAMINATION

1. EC type-examination is the part of the procedure whereby a...

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

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

4. The notified body shall:
4.1. examine and assess the documentation and verify that the type...
4.2. perform or have performed appropriate examinations and the tests necessary...
4.3. carry out or ask for the appropriate examinations 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 manufacturer shall inform the notified body without delay if...
6.1. Changes to the approved device must receive further approval from...

7. Administrative provisions

ANNEX VI

EC VERIFICATION

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

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

2.2. To the extent that for certain aspects the final testing...

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. One or more random samples, as necessary, are taken from...
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...

ANNEX VII

EC DECLARATION OF CONFORMITY

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

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

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 devices...
   3.3. The notified body must audit the quality system to determine...
   3.4. The manufacturer shall inform the notified body which approved the...

4. Surveillance

5. Verification of manufactured products covered by Annex II, List A...
   5.1. In the case of devices covered by Annex II, List...
   5.2. The manufacturer may place the devices on the market, unless...

ANNEX VIII

STATEMENT AND PROCEDURES CONCERNING DEVICES FOR PERFORMANCE EVALUATION

1. For devices for performance evaluation the manufacturer or his authorised...

2. The statement shall contain the following information:

3. The manufacturer shall also undertake to keep available for the...

4. The provisions of Article 10(1), (3) and (5) shall apply...

ANNEX IX

CRITERIA 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 inspection staff must have:

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

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

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

ANNEX X

CE MARKING OF CONFORMITY

If the marking is reduced or enlarged the proportions given...

(**1**) OJ C 172, 7.7.1995, p. 21 and OJ C 87, 18.3.1997, p. 9.

(**2**) OJ C 18, 22.1.1996, p. 12.

(**3**) Opinion of the European Parliament of 12 March 1996 (OJ C 96, 1.4.1996, p. 31), Council common position of 23 March 1998 (OJ C 178, 10.6.1998, p. 7) and Decision of the European Parliament of 18 June 1998 (OJ C 210, 6.7.1998). Council Decision of 5 October 1998.

(**4**) OJ C 136, 4.6.1985, p. 1.

(**5**) OJ L 189, 20.7.1990, p. 17. Directive as last amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

(**6**) OJ L 169, 12.7.1993, p. 1.

(**7**) OJ L 207, 23.7.1998, p. 1.

(**8**) OJ L 159, 29.6.1996, p. 1.

(**9**) OJ L 139, 23.5.1989, p. 19. Directive as last amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

(**10**) OJ L 204, 21.7.1998, p. 37. Directive as last amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

(**11**) OJ L 220, 30.8.1993, p. 23.

(**12**) OJ L 197, 18.7.1987, p. 33.

(**13**) OJ C 102, 4.4.1996, p. 1.