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

Article 9

Conformity assessment procedures

1 For all devices other than those covered by Annex II and devices for performance evaluation, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex III and draw up the EC declaration of conformity required before placing the devices on the market.

For all devices for self-testing other than those covered by Annex II and devices for performance evaluation, the manufacturer shall, prior to the drawing up of the aforementioned declaration of conformity, fulfil the supplementary requirements set out in Annex III, point 6. Instead of applying this procedure, the manufacturer may follow the procedure referred to in paragraphs 2 or 3.

2 For all devices referred to in List A in Annex II other than those intended for performance evaluation, the manufacturer shall, in order to affix the CE marking either:

- a follow the procedure relating to the EC declaration of conformity set out in Annex IV (full quality assurance), or
- b follow the procedure relating to EC type-examination set out in Annex V coupled with the procedure relating to the EC declaration of conformity set out in Annex VII (production quality assurance).

3 For all devices referred to in List B in Annex II other than those intended for performance evaluation, the manufacturer shall for the purposes of affixing the CE marking, follow either:

- a the procedure relating to the EC declaration of conformity set out in Annex IV (full quality assurance) or
- b the procedure relating to EC type-examination set out in Annex V couplet with:
  - (i) the procedure relating to EC verification set out in Annex VI, or
  - (ii) the procedure relating to the EC declaration of conformity set out in Annex VII (production quality assurance).

4 In the case of devices for performance evaluation, the manufacturer shall follow the procedure referred to in Annex VIII and draw up the statement set out in that Annex before such devices are made available.

This provision does not affect national regulations relating to the ethical aspects of carrying out performance evaluation studies using tissues or substances of human origin.

5 During the conformity assessment procedure for a device, the manufacturer and, if involved, the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate state of manufacture.

6 The manufacturer may instruct his authorised representative to initiate the procedures provided for in Annexes III, V, VI and VIII.

7 The manufacturer must keep the declaration of conformity, the technical documentation referred to in Annexes III to VIII, as well as the decisions, reports and certificates, established by notified bodies, and make it available to the national authorities for inspection purposes for a period ending five years after the last product has been manufactured. Where the manufacturer is not established in the Community, the obligation to make the aforementioned documentation available on request applies to his authorised representative.

8 Where the conformity assessment procedure involves intervention of a notified body, the manufacturer, or authorised representative, may apply to a body of his choice within the framework of tasks for which the body has been notified.

9 The notified body may require, where duly justified, any information or data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

10 Decisions taken by the notified bodies in accordance with Annexes III, IV, and V shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of up to five years.

11 The records and correspondence relating to the procedures referred to in paragraphs 1 to 4 shall be in an official language of the Member State in which the procedures are carried out and/or in another Community language acceptable to the notified body.

12 By way of derogation from paragraphs 1 to 4, the competent authorities may authorise, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 to 4 have not been carried out and the use of which is in the interest of protection of health.

13 The provisions of this Article shall apply accordingly to any natural or legal person who manufacturers devices covered by this Directive and, without placing them on the market, puts them into service and uses them in the context of his professional activity.