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

Article 15

Notified bodies

1 Member States shall notify the Commission and other Member States of the bodies which they have designated for carrying out the tasks pertaining to the procedures referred to in Article 9 and the specific tasks for which the bodies have been designated. The Commission shall assign identification numbers to these bodies, hereinafter referred to as 'notified bodies'.

The Commission shall publish a list of the notified bodies, together with the identification numbers it has allocated to them and the tasks for which they have been notified, in the *Official Journal of the European Communities*. It shall ensure that the list is kept up to date.

Member States shall not be obliged to designate a notified body.

2 Member States shall apply the criteria set out in Annex IX for the designation of bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonised standards shall be presumed to meet the relevant criteria.

3 Member States shall apply continual surveillance of notified bodies to ensure ongoing compliance with the criteria set out in Annex IX. A Member State that has notified a body shall withdraw or restrict that notification if it finds that the body no longer meets the criteria referred to in Annex IX. It shall immediately inform the other Member States and the Commission of any withdrawal of notification or any restriction placed on it.

4 The notified body and the manufacturer, or his authorised representative established in the Community, shall lay down, by common accord, the time limits for completion of the assessment and verification operations referred to in Annexes III to VII.

5 The notified body shall inform the other notified bodies and the competent authority about all certificates suspended or withdrawn and, on request, about certificates issued or refused. It shall also make available, on request, all additional relevant information.

6 Where a notified body finds that pertinent requirements of this Directive have not been met or are no longer met by the manufacturer or where a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the competent authority may become necessary, the notified body shall inform its competent authority thereof. The Member State shall inform the other Member States and the Commission.

7 The notified body shall, on request, supply all relevant information and documents, including budgetary documents, required to enable the Member State to verify compliance with Annex IX requirements.