ANNEX I

Interpretation of the criteria set out in Annex 8 to Directive 90/385/EEC and in Annex XI to Directive 93/42/EEC

1. Sections 1 and 5 of Annex 8 to Directive 90/385/EEC and of Annex XI to Directive 93/42/EEC shall be interpreted as including the following elements:

1.1. The conformity assessment body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The conformity assessment body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer.

1.2. That conformity assessment body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The conformity assessment body shall have procedures in place that effectively ensure identification, investigation and resolution of any case in which a conflict of interests may arise, including involvement of its staff in consultancy services in the field of medical devices prior to taking up employment with the body.

1.3. That conformity assessment body, its top management and the personnel responsible for carrying out the conformity assessment tasks shall not:

(a) engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;

(b) offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide or have offered or provided, during the last three years, consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards Union requirements for the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude conformity assessment activities for manufacturers and economic operators mentioned above or general training activities relating to medical device regulations or related standards that are not client specific.

1.4. The conformity assessment body's top level management and its assessment personnel shall be impartial. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number or the results of assessments carried out.

1.5. When a conformity assessment body is owned by a public entity or institution, the Member State shall ensure and document the independence of the conformity assessment body and the absence of any conflict of interests between, on the one hand, the designating authority and/or competent authority and, on the other hand, the conformity assessment body.

1.6. The conformity assessment body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity in its conformity assessment activities.

1.7. The requirements of points 1.1 to 1.6 do not preclude exchanges of technical information and regulatory guidance between a body and a manufacturer seeking their conformity assessment.