

ANNEX IX

CRITERIA FOR THE DESIGNATION OF NOTIFIED BODIES

1. The notified body, its director and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer or user of the devices which they inspect, nor the authorised representative of any of these persons. They may not be directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This in no way precludes the possibility of exchanges of technical information between the manufacturer and the body.
2. The notified body and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications.

Should the notified body subcontract specific tasks connected with the establishment and verification of the facts, it must first ensure that the subcontractor meets the provisions of the Directive. The notified body shall keep at the disposal of the national authorities the relevant documents assessing the subcontractor's qualifications and the work carried out by the subcontractor under this Directive.

3. The notified body must be able to carry out all the tasks assigned to such bodies by one of Annexes III to VII and for which it has been notified, whether these tasks are carried out by the body itself or on its responsibility. In particular, it must have the necessary staff and possess the facilities needed to perform properly the technical and administrative tasks entailed in assessment and verification. This includes the availability of sufficient scientific staff within the organisation who possess adequate experience and knowledge necessary to assess the biological and medical functionality and performance of devices for which it has been notified, in relation to the requirements of this Directive and, in particular, with Annex I requirements. The notified body must also have access to the equipment necessary for the verifications required.
4. The inspection staff must have:
 - sound vocational training covering all the assessment and verification operations for which the body has been designated,
 - satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections,
 - the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.
5. The impartiality of the inspection staff must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of the inspections.
6. The body must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.
7. The staff of the inspection body are bound to observe professional secrecy with regard to all information gained in the course of their duties (except vis-à-vis the competent

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administrative authorities of the State in which their activities are carried out) under this Directive or any provision of national law putting it into effect.