

ANNEX IX

CRITERIA FOR THE DESIGNATION OF NOTIFIED BODIES

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.