

For evaluating against Canadian requirements, the European CABs shall establish the conclusions of the examination and submit to Health Canada an abbreviated supporting report and certificate of compliance which includes such conclusions. Based on these documents, and without any further re-assessment, Health Canada will accept the certification as evidence of compliance with the premarket requirements of the Canadian Medical Devices Regulations.

Each Party shall make available to the other Party, upon reasoned request, any information which has been reviewed as part of the assessment of a medical device for the purpose of issuing certificates of compliance.

Each Party reserves the right, at any time, to question information with respect to the designation process or the performance of conformity assessments against the requirements of its regulatory regime. Furthermore, each Party reserves the right to conduct its own conformity assessments for reasons identified to the other Party. Justification for such action shall be based on documented evidence and notification is to be provided in advance to the other Party. Recourse to this action should be an exception.

#### 7.2. Procedures for Designation of CABs

The procedures to be followed by the Designating Authorities of each Party in designating CABs shall respect the criteria laid down in the other Party's regulations or guidelines (non-binding guidance is provided in Attachment V).