The Parties shall enter into the operational phase provided that there is representation of each Party's CABs in Attachment II.

The Agreement will also be re-examined at the end of the transitional period to take account of the regulatory evolution of each Party. Consideration shall be given to a single submission/evaluation/quality systems assessment which simultaneously satisfies the requirements of each jurisdiction.

## 7. OPERATIONAL PHASE

### 7.1. General Obligations

The provisions of this Section will apply only to conformity assessment carried out in the Parties' respective territories by Conformity Assessment Bodies recognized under this sectoral Annex.

The European Community and Canada agree that, for medical devices covered by this Annex, each Party will recognize the conclusions of the conformity assessment carried out by the other Party and the certificate of compliance granted by the Conformity Assessment Body of the other Party, without further re-assessment.

For evaluation against European requirements, Health Canada or other Conformity Assessment Bodies designated by Canada shall establish the conclusions of completed conformity assessments as referred to in the Active Implantable Medical Device and the Medical Device Directives, and issue the appropriate certificate of compliance. The responsible authorities in the European Community will, without any further re-assessment, accept the certification as evidence of compliance with the premarket requirements of the relevant European Directives.