Sectoral Annex Medical Devices

In special cases, particularly in emergency situations, all those involved in the implementation of this Sectoral Annex will endeavour to provide all documentation requested by the Party of Parties concerned in an expeditious manner.

7.4 Two-way Alert System

The Joint Sectoral Group will ensure that an efficient and effective "two-way" Alert System is in place at all times. Elements of such a system are described in Attachment 4. Canada, on the one hand, and each of the EEA EFTA States, on the other, shall notify the other Party concerned of any confirmed problem reports, corrective actions, or recalls related to products that it has evaluated under the terms of this Agreement. Each Party will respond to special requests for information on particular devices and will ensure that its Designated Authorities and Conformity Assessment Bodies make available relevant information on these devices, as requested.

It shall be the responsibility of the Regulatory Authorities covered by this Sectoral Annex to ensure that any suspension or cancellation (total or partial) of a certificate of compliance is immediately communicated to the Party or Parties concerned.

7.5 Fees

The regime of registration or conformity assessment fees is determined by the location of the manufacturer. The cost recovery programmes and the fees pertaining to the issuance of a certificate of compliance in each jurisdiction will remain the responsibility of that jurisdiction. Conformity assessment fees will not be charged by Canada or any of the EEA EFTA States to manufacturers located on the territory of the other Party concerned, where the conformity assessment was conducted by a Conformity Assessment Body located in the concerned Party's territory.

7.6 Monitoring of the Agreement

The continuous monitoring of the equivalency of designation processes and conformity assessments for each Party's requirements that have been determined to be equivalent at the conclusion of the confidence building program, and any subsequent decisions concerning that equivalence, must be made according to mutually developed and managed equivalence maintenance and implementation activities. This will be managed by the Joint Sectoral Group.

The Parties will undertake to hold regular consultations, within the Joint Sectoral Group set up under this Sectoral Annex to ensure the continued relevancy and accuracy of this Sectoral Annex. The Regulatory/Designating Authorities and Conformity Assessment Bodies will organize meetings to discuss specific