SECTORAL ANNEX ON MEDICAL DEVICES

1. PURPOSE

1.1. This Mutual Recognition Agreement (MRA) annex on conformity assessment and compliance certification pertaining to medical devices has been developed by Canada and the EEA EFTA States to enhance bilateral medical device regulatory cooperation while facilitating global trade and maintaining the same high standards of health and safety in both jurisdictions.

1.2. Furthermore, this Annex calls for the development of an infrastructure for on-going communications/consultations between Regulatory and/or Designating Authorities and Conformity Assessment Bodies of each Party to enable regulators to determine and maintain the equivalence of their medical device conformity assessment capabilities and to develop a cooperative approach to post-market vigilance.

2. SCOPE AND COVERAGE

2.1. This Annex applies to all medical devices which in Canada or in each of the EEA EFTA States are subject to conformity assessment procedures, including scientific technical evaluations of high risk medical devices and quality systems assessments, by a Conformity Assessment Body.

2.2. The product coverage shall be as determined by the relevant legislation of each Party, which is:

(a) for the EEA EFTA States:

- Directive 90/385/EEC (EEA Agreement, Annex II, Chapter X, point 7) of 20 June, 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended.
- Directive 93/42/EEC (EEA Agreement, Annex II, Chapter IX, point 27a as inserted by Decision No 7/94) of 14 June, 1993 concerning medical devices, as amended.

(b) for Canada:

- The Food and Drugs Act and Medical Devices Regulations (proposed for promulgation 1998) as amended from time to time;
- the Canadian Electrical Code (as it relates to medical devices);
- the Radiation Emitting Devices Act and Regulations as amended from time to time (as they relate to medical devices).