1. PURPOSE

1.1. This Mutual Recognition Agreement (MRA) Annex on conformity assessment and compliance certification pertaining to medical devices has been developed by the European Community and Canada 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 the European Community are subject to conformity assessment procedures, including scientific technical evaluations of high risk medical devices and quality systems assessments, by a Conformity Assessment Body.