It shall not, however, apply to the following products:

-       in vitro diagnostic medical devices,

-       devices incorporating, as an integral part, a substance which, if used separately, may be considered to be a medicinal product,

-       breast implants,

-       medical devices incorporating tissues of human or animal origin. However, medical devices incorporating tissues of animal origin and where the device is intended to come into contact with intact skin only, will be included within the scope of this Sectoral Annex.

Canada, on the one hand, and each of the EEA EFTA States, on the other, may, however, decide by common agreement, to extend the application of this Annex to the aforementioned or any other medical devices to the extent that such provisions are included in the Mutual Recognition Agreement in relation to conformity assessment between Canada and the European Community.

3.   CONFIDENTIALITY

3.1.   Each Party will protect from public disclosure any non-public confidential technical, commercial and scientific information, including trade secrets and proprietary information provided by the other Party.

3.2.   Each Party reserves the right to make public the results of any conformity assessment reports in situations in which public health and safety may be affected.

4.   RESOLUTION OF DIVERGENT VIEWS

4.1.   Divergent views which have not been resolved between the regulatory authorities for medical devices will be referred to the Joint Sectoral Group for resolution. In the event that the Joint Sectoral Group is unable to resolve these divergent views, the concerned Party may bring the matter to the attention of the Joint Committee.

5.   MANAGEMENT MECHANISM

5.1.   A Joint Sectoral Group will be established for the purposes of management of this Sectoral Annex. Its role will be to make decisions concerning the definition, establishment, and evaluation of conformity assessment procedures and programmes, the establishment of the "two-way" alert programme, the management of the confidence building period and the definition of a