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

(a) for the European Community

- Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended.

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

(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).