READER'S GUIDE TO THE SUMMARY BASIS OF DECISION - MEDICAL DEVICES

1.0 Device and Application Information: Basic information regarding the application including device name, date of application, manufacturer, biological material, drug material (if applicable), intended use, and the date the license was issued.

2.0 Notice of Decision: A one-page summary of the authorization of the device including the date of authorization, device description and principles of its operation, a brief description of the supporting clinical (human) studies upon which authorization was based, the indication, contraindications and a paragraph summarizing the benefit/risk profile. A paragraph will also be provided outlining acceptability under the *Medical Device Regulations*.

3.0 Scientific and Regulatory Basis for Decision: Represents the bulk of the document and provides information supporting Health Canada's decision to authorize the device on the basis of quality (chemistry and manufacturing), safety, and effectiveness data submitted.

Device-Specific Detailed Information: Health Canada's assessment of the following information: principles of operation, description of the device, components of the device, materials used in the device and packaging, as well as reagent characterization. If the device contains a medicinal substance or drug, a description and the technical requirements of the substance or drug are included.

Devices Containing Biological Material: Health Canada's assessment of the measures taken to mitigate risks associated with animal or human tissue or their derivative if being used in the device.

Safety and Effectiveness: An overview of the study designs and the results of the studies which have figured significantly in Health Canada's decision. The reader will find information related to sterilization, manufacturing and quality control, pre-clinical studies, and clinical effectiveness and safety of the device. The section also provides validation of the software and the labelling material used with the device.

List of Standards: A list of the standards used in the manufacture and design of the device plus the recognized standards from Health Canada for which a declaration of conformity was provided.

Method of Sterilization: The type of sterilization process used, the level of sterility, and the validation of the process used.

Manufacturing and Quality Control: Methods used in, and the facilities and controls used for, the manufacture, processing, packaging, storage and, where appropriate, the installation of the device. Information regarding process validation, as well as statements relating to the quality plan and quality system certification is also included.

Pre-clinical Studies: Health Canada's assessment of the non-human studies performed to evaluate the effectiveness and safety of the medical device. This information includes assessments of physical tests (to predict the adequacy of device response to physiological stresses, undesirable conditions and forces, long-term use), biocompatibility tests (to ensure the device does not produce a toxic or immunological response in living tissue, including those related to leachables, impurities, or metabolites), tests in animals (device maneuverability, performance and pathology information), in-vitro diagnostic tests (sensitivity, specificity, interference and assay performance), and stability/shelf life tests, where appropriate.

Clinical Effectiveness and Safety: An overview of the human studies and the results of the clinical data that figured significantly into Health Canada's decision. Included are analysis of clinical effectiveness and safety, clinical studies in special populations, and, for near-patient *in vitro* diagnostic devices, investigational tests conducted with the intended user population and under conditions simulating expected conditions of use. Adverse events observed during investigational testing and post-market actions including incident reports are discussed, and precautions or contraindications are included.

4.0 Benefit/Risk Assessment: A summary of the quality, safety and effectiveness of the device. Factors affecting the risk/benefit assessment are discussed. Risks inherent with the use of the device are described along with strategies for mitigating the risks. Readers may also find information regarding infectious reagents and a comparison with a licenced device.

5.0 Application Milestones: A list of the steps taken within the application process along with the date of decision.