Technical Requirements for the Initial Registration of Medical Devices under Class C in Accordance with the CSDT Template

1. Executive Summary. The executive summary shall include the following information:
    a. an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT;
    b. the commercial marketing history;
    c. the intended uses and indications in labeling;
    d. the list of regulatory approvals or marketing clearances obtained;
    e. the status of any pending request for market clearance; and
    f. the important safety/performance related information.
2. Relevant essential principles and method/s used to demonstrate conformity, if applicable. (See Annex K)
3. Device description with the following information:
    a. Intended use
    b. Indications of use
    c. Instruction for use
    d. Contraindications
    e. Warnings
    f. Precautions
    g. Potential adverse effects
    h. Alternative therapy (practices and procedures)
    i. Materials. A description of the materials of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device.
    j. Other Relevant Specifications to include the following:
        j.1 The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors
        j.2 If applicable, other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging.
    k. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)
4. Summary of Design Verification and Validation Documents:
    The validation documents shall consist of the following:
    a. Declaration/Certificates of Conformity to the product standards issued by the manufacturer
    b. Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance, such as a listing of and conclusions drawn from published

reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles;

c. data summaries or tests reports and evaluations covering the following appropriate test reports, whichever is applicable:
    c.1 Engineering test
    c.2 Laboratory test
    c.3 Biocompatibility test
    c.4 Animal Test
    c.5 Simulated Use
d. Clinical evidence for the following:
    d.1 Implantable devices
    d.2 Newly introduced devices
    d.3 Devices incorporating new materials coming into contact with the patient.
    d.4 Existing materials applied in a body part not previously exposed to that material, and for which no prior chemical experience exists.
    d.5 An existing device that is modified and the modification might affect safety and effectiveness.
e. Software validation studies, if applicable.
f. Biological evaluation, if applicable.

5. Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging)
6. Risk assessment consisting of risk analysis, evaluation and reduction measures.
7. Physical Manufacturer information
    a. Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device.
    b. A brief summary of the sterilization method should be included.