TR-002:2021(E)

Medical Device Administrative Control System (MDACS)

Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)

Technical Reference: TR-002

中華人民共和國

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Department of Health

The Government of the Hong Kong Special Administrative Region

The People's Republic of China

Revision History

Version Number	Date of Revision	Summary of Revisions	Reference Number
0	13 Oct 2006	• First issue of TR-002	TR-002:2006(E)
1	30 Sep 2021	• Update document format; and • Rename of Medical Device Control Office to Medical Device Division	TR-002:2021(E)

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1. Purpose

1.1 This guidance document provides guidance on Summary Technical Documentation (hereafter abbreviated to STED) for demonstrating conformity to the *Essential Principles of Safety and Performance of Medical Devices* (hereafter abbreviated to 'Essential Principles'). It describes the format for a STED (see Clause 5.0 below) and provides general recommendation on the content of the formatted elements (see clause 6.0 below).

2. Scope

2.1 This document applies to all the medical devices that fall within the scope of the Medical Device Administrative Control System as defined in clause 3.2 of GN-01 Overview of the Medical Device Administrative Control System.

2.2 The annexes provide important supplementary information including a conformity checklist, and additional recommendations for STEDs that must be submitted to a Conformity Assessment Body for review/validation/approval, such as for a cover page, an executive summary, a sample test report format, and a sample table of contents.

2.3 This document does not recommend any new or additional technical documents above and beyond what should be created by the manufacturer to comply with existing requirements to demonstrate conformity to the Essential Principles.

2.4 The format of the STED recommended herein is based upon the goal to strive for the least burdensome means to demonstrate conformity to the Essential Principles for all classes of medical devices.

2.5 Requirements for post-market vigilance or adverse incident reporting are outside the scope of this document.

3. Definitions

3.1 **Summary Technical Documentation (STED):** a summary of technical documentation held for conformity assessment purposes.

3.2 **Technical File/Technical Documentation:** documentation required to assess conformity of the medical device with the regulations.

3.3 **Essential Principles:** Essential Principles of Safety and Performance of Medical Devices

3.4 **MDD:** Medical Device Division

3.5 **CAB:** Conformity Assessment Body

4. Intended use of the STED and its preparation

4.1 The STED is intended for conformity assessment purposes. The manufacturer creates the STED to demonstrate to a CAB that the subject medical device is in conformity with the Essential Principles. The STED can be a real or virtual set of documents, at the discretion of the manufacturer.

4.2 For listing of medical devices and/ or local manufacturers under the Medical Device Administrative Control System, the manufacturer is required to conduct conformity assessment according to the Essential Principles before placing the device on the Hong Kong market. In certain cases (mostly determined by the risk class of the device), the STED may need to be reviewed/ approved by a Conformity Assessment Body before the applicable device is placed on the market.

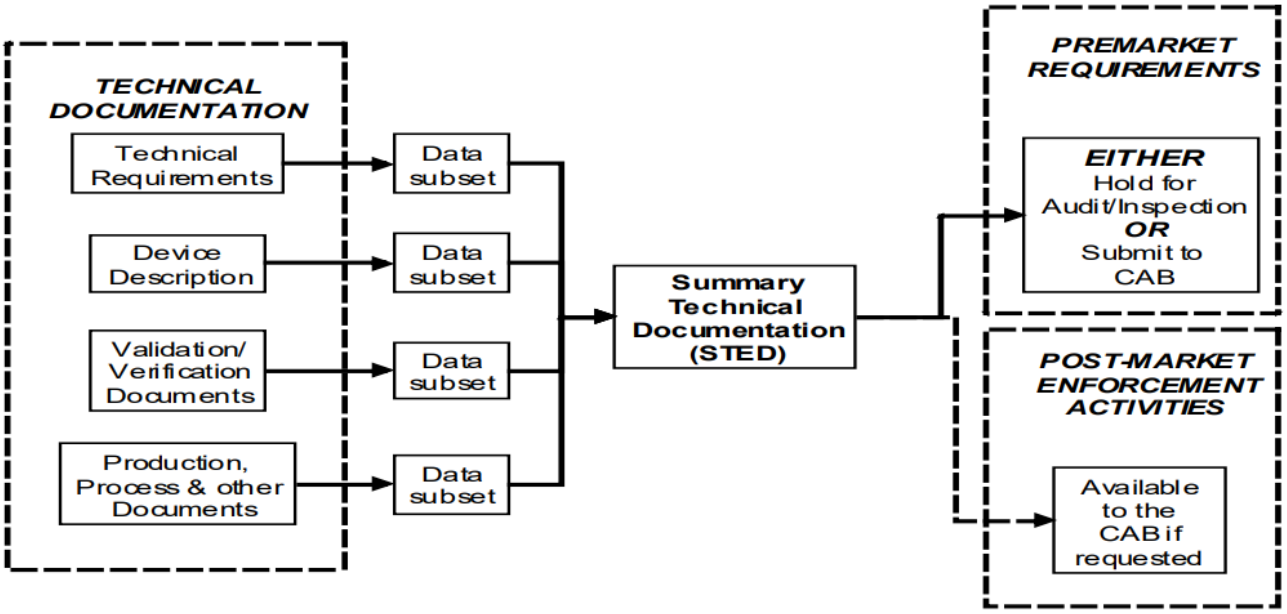
4.3 The class of the device will affect the necessary format and content of the STED and also whether or not the STED needs to be submitted to a Conformity Assessment Body for review and approval or validation before placing the device on the market. The extent of that conformity assessment and the required resulting documentation vary according to device class, increasing with higher class.

4.4 The manufacturer determines the type and detail of the total technical documentation they believe are needed to demonstrate conformity to the Essential Principles. The manufacturer holds this documentation.

4.5 As Figure 1 illustrates, the manufacturer derives the content of an STED from the total technical documentation which it has already prepared and is holding to confirm and record that the medical device is in conformity with the Essential Principles.

4.6 Further information is given in Annex A and Annex B.

Figure 1: Source and Application of the STED



4.7 As Figure 1 further illustrates, the assessment of conformity to the Essential Principles by a CAB may be required before a medical device is marketed ("pre-market"), or conformity may be audited after the medical device has been marketed ("post-market").

4.8 Medical devices that typically have a high degree of risk are those that require pre-market conformity assessment. In such cases, documentation is required to be provided to a Conformity Assessment Body for review/approval. It is intended that the STED be such documentation. For further information on STEDs provided to CAB for review/approval, see Annex B.

5. Format for Summary Technical Documentation

5.1 Basic Format

5.1.1 It is recommended that the STED be formatted as shown in the left-hand column of the table below. The right hand column indicates where expanded guidance on each recommended clause can be found elsewhere in this document.

Summary Technical Documentation	Location in this document of expanded guidance
Essential Principles and evidence of conformity	Clause 6.1
Device description	Clause 6.2

Summary documents of design verification and validation	Clause 6.3
Labelling	Clause 6.4
Risk analysis	Clause 6.5
Manufacturing information	Clause 6.6

5.2 How to Apply the Basic Format when a Pre-market Submission is not Required

5.2.1 The respective clauses of the STED may be in any of the forms shown below, at the discretion of the manufacturer.

5.2.2 In consideration of the least burdensome means to demonstrate post-market conformity, the manufacturer has the following options for the STED:

Option 1: STED based on total documentation. When the total technical documentation is held in a central location and it is contained in a concise file or volume of a relatively few number of pages, then the manufacturer may choose to designate this record as also the STED for post-market assessment purposes. Ideally, this file or volume should be in the format as described in Clause 5.1.

Option 2: STED based on summary documentation. The manufacturer may choose to create the STED as a summary of source documents and formatted as described in Clause 5.1.

Option 3: Abbreviated STED. The manufacturer may choose to use the Essential Principles Conformity Checklist (MD-CCL) as the primary method to document conformity for post-market assessment purposes. When completed, this checklist will point to or reference the identity of the documents used to demonstrate conformity of each relevant Essential Principle. This method may be useful if the source documents consist of many pages and if they are held in more than one location. The Essential Principles Conformity Checklist (MD-CCL) can be obtained from the MDD or downloaded from the MDD website.

Option 4: Combination STED. The manufacturer may choose to create the STED containing a combination of the above options, i.e. (1) some complete source documents, (2) summaries of some source documents, and/or (3) references to source documents.

5.3 How to Apply the Basic Format when a Pre-market Submission is Required

5.3.1 Where (for a particular higher risk class) the STED is provided to the CAB for conformity assessment before placing the device on the market, it is recommended that the above clauses be preceded by a cover page and an executive summary (see Annex B).

6. Guidance on the Elements of the STED

6.1 Relevant Essential Principles and Method Used to Demonstrate Conformity

6.1.1 General

6.1.1.1 The STED should identify the Essential Principles of Safety and Performance of Medical Devices that are applicable to the device.

6.1.1.2 The STED should identify the general method used to demonstrate conformity to each applicable Essential Principle. The methods that may be used include compliance with recognized or other standards, state of the art or internal industry methods, comparisons to other similar marketed devices, etc.

6.1.1.3 The STED should identify the specific documents related to the method used to demonstrate conformity to the Essential Principles. For example, when the manufacturer uses international or other standards to demonstrate conformity with the Essential Principles, the STED should identify the full title of the standard, identifying numbers, date of the standard, and the organization that created the standard. When the manufacturer uses other means, such as internal standards, the STED should describe the means.

6.1.2 Essential Principles and Evidence of Conformity

6.1.2.1 It is recommended that the evidence of conformity be provided in the

Essential Principles Conformity Checklist (MD-CCL) with supporting documentation available for review as required.

6.2 Device Description

6.2.1 The STED should summarize or reference or contain (according to the option selected by the manufacturer in Clause 5.2) the following device description data, to the extent appropriate to the complexity and risk class of the device:

6.2.1.1 General Information

(a) the functional purpose of the device (intended use);

(b) the intended patient population(s) and medical condition(s) to be diagnosed and/or treated by the device (indications for use) and other considerations such as patient selection criteria;

(c) the reasonably foreseeable medical conditions for which the device is not to be used (contraindications);

(d) a general description of the device including its principles of operation, (capabilities, the inputs to the device and outputs);

(e) an explanation of any novel features;

(f) the accessories, and other devices or equipment which are intended to be used in combination with the device;

(g) the variants of the device to be marketed including, if the STED is to be provided to the CAB for review, the parameters of the range of variants;

(h) a general description of each of the functional parts/components of the device with labelled pictorial representations of the device (e.g. diagrams, photograph, drawing(s)), clearly indicating each part, including sufficient explanation to understand the drawings and diagrams;

(i) other information as needed to provide a description of the device, e.g., for an implant, a description of the anatomical location of the device in the body, attachment mechanisms for the device, including diagrams or illustrations of the implant in situ;

(j) comparisons to other devices to establish conformity to the Essential Principles. This could include, for example, information on previous designs of the same type of device or comparisons to other related devices.

NOTE: For simple, low risk devices, the above information will typically be contained

in already existing sales brochures, instructions for use, etc.

6.2.1.2 Materials

(a) a description of the materials of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles.

6.2.1.3 Specifications

(a) the functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic devices, reliability and other factors;

(b) other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles.

6.2.1.4 Other Descriptive Information

(a) other important descriptive characteristics not detailed above, to the extent necessary to demonstrate conformity with the relevant Essential Principles (for example, the biocompatibility category for the finished device).

6.3 Summary of Design Verification and Validation Documents

6.3.1 General

6.3.1.1 The STED should summarize or reference or contain (as determined by need for a submission and the option selected by the manufacturer in Clause 5.2) design verification and design validation data to the extent appropriate to the complexity and risk class of the device.

6.3.1.2 Such documentation should typically include:

(a) declarations/certificates of conformity to the “recognized” standards listed as applied by the manufacturer; and/or

(b) summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance[1].

EXAMPLE: The completed Essential Principles Conformity Checklist that a recognized test standard was used as part of the method to demonstrate

[1] See Annex **B.4** for a **recommended** format **and content** of a test report.

conformity to one Essential Principle. Clause 6 of the STED would then include a declaration of conformity to the standard, or other certification permitted by the CAB, and a summary of the test data, if the standard does not include performance requirements.

6.3.1.3 The data summaries or tests reports and evaluations would typically cover, as appropriate to the complexity and risk class of the device:

(a) a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the device with reference to the Essential Principles;
(b) engineering tests;
(c) laboratory tests;
(d) biocompatibility tests;
(e) animal tests;
(f) simulated use;
(g) software validation.

A recommended test report format and content is shown in Annex B.4.

6.3.2 Clinical Evidence

6.3.2.1 The STED should indicate how any applicable requirements of the Essential Principles for clinical evaluation of the device have been met. Where applicable, this evaluation may take the form of a systematic review of existing bibliography, clinical experience with the same or similar devices, or by clinical investigation. Clinical investigation is most likely to be needed for higher risk class devices, or for devices where there is little or no clinical experience.

6.4 Labelling

6.4.1 The STED should summarize or reference or contain (as determined by need for a submission and the option selected by the manufacturer in Clause 5.2) the following labelling data to the extent appropriate to the complexity and risk class of the device, which is generally considered as “labelling”:

6.4.1.1 labels on the device and its packaging;

6.4.1.2 instructions for use;

6.4.1.3 other literature or training materials;

6.4.1.4 instructions for installation and maintenance;

6.4.1.5 Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform.

6.5 Risk Analysis

6.5.1 The STED should summarize or reference or contain (as determined by need for a submission and the option selected by the manufacturer in Clause 5.2) the results of the risk analysis. This risk analysis should be based upon international or other recognized standards, and be appropriate to the complexity and risk class of the device.

6.6 Manufacturing Information

6.6.1 The STED should summarize or reference or contain (e.g. whether submitted or according to the option selected by the manufacturer in Clause 5.2) documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the device.

7. Enquiries

7.1 Enquiries concerning this document and the MDACS should be directed to:

Medical Device Division
Department of Health
Telephone number: 3107 8484
Facsimile number: 3157 1286
Email address: mdd@dh.gov.hk
Website: www.mdd.gov.hk/

7.2 All latest versions of published documents and application forms for MDACS are available at MDD website.

8. References

8.1 GHTF Proposed Document: SG1/N011R17 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)

8.2 Department of Health. Overview of the Medical Device Administrative Control System. Guidance Notes GN-01.

8.3 Department of Health. Conformity Assessment Framework and Conformity Assessment Bodies. Guidance Notes GN-04.

Annex A

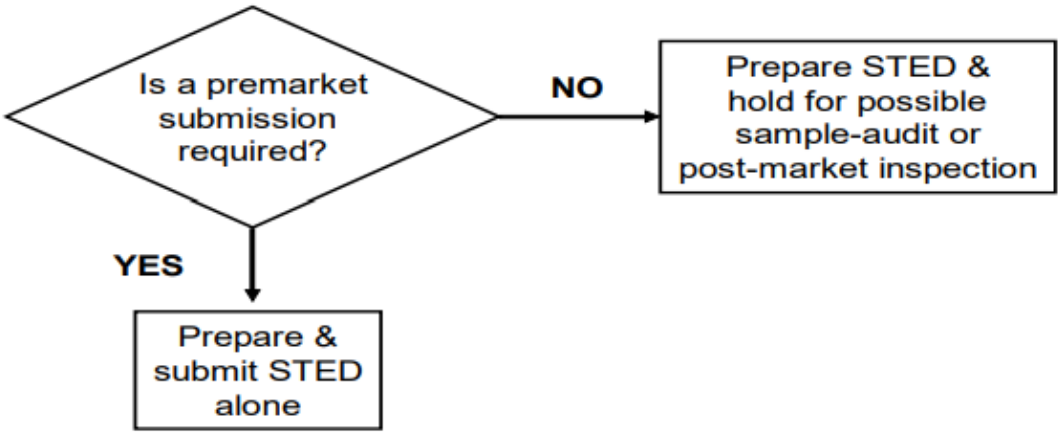
Decision Process to Determine Whether to Use the STED

A person intending to introduce a new device should first determine if documentation must be provided for conformity assessment purposes before placing on the market.

Even when provision to a CAB is not required for conformity assessment purposes prior to the marketing of the device, the STED can be used for post-market conformity assessment.

See Figure 2 below for a flow chart of this process.

Figure 2: Decision Making Process



Annex B

Additional Recommendations for STEDs provided to CAB for review/approval

B.1 General

When conformity assessment by a CAB to the Essential Principles is required before a device is marketed ("pre-market"), then the manufacturer should provide the STED in the format described in Clause 6 (see also Annex A for deciding when to use the STED).

Even when conformity assessment by a CAB to the Essential Principles is not required before a device is marketed, the CAB may still request that the manufacturer demonstrate conformity after it is marketed ("post-market"). Post-market assessment may be carried out by means of providing the STED to the CAB or by audit of the STED by the CAB at the manufacturer's facilities. Special circumstances may necessitate the examination of documentation supporting the STED.

EXAMPLE: For a Class II device the CAB may request that the manufacturer provide documentation demonstrating conformity to the Essential Principles after the device is marketed. The manufacturer may provide documentation in any one of the four forms described as Options 1 – 4 in Clause 5.2 unless the CAB stipulates the need for a specific form or documents.

B.2 Cover Page

A covering letter should be at the beginning of a STED provided to CAB for review/approval. The covering letter will explain the purpose of the STED.

B.3 The Executive Summary

An executive summary provides an overview of the medical device and helps to orient the reviewer. Where the STED is provided to CAB for review/approval, the executive summary may be included in a cover page or it may be a separate clause of the STED.

It is recommended that the executive summary include at least the following information:

- an overview of the STED, 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 STED; and
- a commercial marketing history of the device including, for example, the countries in which the device is sold, the intended uses and indications in labelling, status of any pending requests for market clearance, important safety or performance related information such as recalls and adverse

effects encountered.

B.4 Recommended Test Report Format

A test report should include, as applicable:

i) Report title and other identifying information.

ii) Name and address of facility performing the test.

iii) Name of the responsible person involved.

iv) Dates that testing was initiated and completed.

v) Study plan, results, and conclusions, including, for example:

- the study objective and test hypothesis;
- a description of the test system used including relevant specifications (a diagram may be helpful);
- a description of the differences between the test samples and final specifications, if any;
- deviations from test plan, if any;
- a comprehensive summary of the data in the form and manner specified by the CAB which will allow an independent assessment;
- statistical evaluation of the test results, where appropriate;
- bibliography of all references pertinent to the report.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