# Appendix：Essential Principles (EP), and Summary of Technical Documentation (STED)

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# I. Preface

This guideline is to assist medical device entities with the compiling of required related documentation in accordance with Essential Principles (hereafter referred to as EP), and Summary of Technical Documentation (hereafter referred to as STED) for the purpose of registration for medical device licenses.

Because of a very large and wide of variety of medical device products, Ministry of Health and Welfare may require medical device entities to provide complementary documents for review if necessary, in order to ensure the safety and efficacy of medical devices.

# II. Introduction

Principal countries have been pushing towards harmonization of laws and regulations on medical devices for decades. Global Harmonization Task Force (hereafter referred to as GHTF) is founded in 1992. Since then GHTF has been dedicated in promoting standardization of medical device laws, regulations, and management systems, and establishing related guidelines for health competent authorities, medical device manufacturers, and notified bodies from various countries. Study Group 1 (hereafter referred to as SG1) established SG1-N41R9:2005《Essential Principles of Safety and Performance of Medical Devices》，which referenced European Union Directive Annex I on Essential Requirements. EP listed in this directive in detail are 17 principles concerning safety and efficacy of medical devices, requiring medical device entities to comply in evaluation of potential risks from medical devices.

SG1-N44:2008《Role of Standards in the Assessment of Medical Devices》suggests that manufacturers to adopt recognition standards of health competent authorities to evaluate and control risks factors specified by EP, in order to complete the safety and efficacy evaluation of medical devices.

GHTF SG1 established SG1-N11:2008《Summary Technical Documentation for Demonstrating Conformity with the Essential Principles of Safety and Performance of Medical Devices (STED)》for medical devices in general; established GHTF SG1-N63:2011《Summary Technical Documentation (STED) for Demonstrating Conformity with the Essential Principles of Safety and Performance of IVD Medical Devices》for IVD.

Health competent authorities of GHTF member countries such as the United States of America, the European Union, Canada, Australia, Japan, and etc., have adopted EP to evaluate the safety and efficacy evaluation of medical devices and have been pushing adoption of STED Pilot Program since 2001. Asian Harmonization Working Party (hereafter referred to as AHWP), which is composed of various Asian, the Middle-East, South Africa, and South America countries, also has adopted related guidelines within GHTF EP & STED to establish TC Common Submission Dossier Template(CSDT). CSDT has already been adopted by Association of Southeast Asian Nations (ASEAN) into draft of ASEAN Medical Devices Directive (MDD).

Medical device entities may refer to the following websites and download related GHTF guidelines:

1. GHTF official website. (http://www.ghtf.org/)
2. GHTF guideline database in Chinese. (http://ghtf.cms.itri.org.tw/)

Article 40 of the Pharmaceutical Affairs Act states, “For the manufacturing and import of medical devices, an application together with fees paid, shall be filed with the central competent health authority

for registration and market approval. No manufacturing and importation shall be allowed until a medical device permit license is approved and issued." Under the authorization of this article, Ministry of Health and Welfare establishes "Regulation on Registration of Medical Devices" and enforce related management and reviews accordingly.

To push laws and regulations of Republic of China (Taiwan) in harmonization with international laws and regulations, Food and Drug Administration of Ministry of Health and Welfare will push for adoption of EP&STED into "Regulation on Registration of Medical Devices", in the hope of synchronization and harmonization with international laws, regulations, standards, and state-of-the-art technical levels. Moreover, the groundwork for future exchange and mutual recognition of review data from foreign health competent authorities can be laid; the quality of medical device products can be ensured, and encourages medical device entities to advance their international competitiveness.

## III. Purpose

This guideline is established to assist Class III medical device entities with the registration in accordance with EP&STED, and considered as complementary rules to "Regulation on Registration of Medical Devices" and "Regulation on Registration of In Vitro Diagnostic Medical Devices".

## IV. Scope

This guideline applies to Class III medical devices listed in Annex I of "Regulations for Governing the Management of Medical Device".

## V. Glossary

1. Medical Devices mean any instruments, machines, apparatus, materials, software, reagent for in vitro use, and other similar or related articles, which is used in diagnosing, curing, alleviating, or directly preventing human diseases, regulating fertility, or which may affect the body structure or functions of human beings, and do not achieve its primary intended function by pharmacological, immunological or metabolic means in or on the human body. (Article 13 of the Pharmaceutical Affairs Act, promulgated Dec. 7, 2011.)
2. In Vitro Diagnostic Medical Devices (IVD) mean medical devices such as a diagnostic reagent, an instrument, or a system, that is used in collection, preparation, and inspection of a sample taken from a human body, with the purpose of making a diagnosis, health status, or other conditions based on the results from IVD usage. (Article 9 of "Regulation on Registration of Medical Devices", promulgated Apr. 12, 2006.)
3. Standard means a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. (GHTF SG1/N44:2008 Role of Standards in the Assessment of Medical Devices) Note: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits. (ISO/IEC Guide2:2004, definition 3.2)
4. Recognized Standard means the standard of basis that provides specific safety and efficacy essential principles. (GHTF SG1/N44:2008 Role of Standards in the Assessment of Medical Devices)

# VI. STED Application Form and Content

1. A domestic medical device firm applies for a Class III medical device registration shall submit administrative documents in accordance with Article 15 of "Regulation on Registration of Medical Devices", and STED, that include:

   ①Administrative documents:

   - One copy each of the original and photocopy of the medical device registration and market approval application form.
   - Two copies of each following item: the form for attaching outer box instruction label with all Chinese instruction leaflet catalog packaging, and labeling, instructions for use, and color pictures of the physical appearance of product.
   - A photocopy of pharmaceutical firm license as a medical device manufacturer.
   - Affidavit(A)
   - Documents verifying that the domestic manufacturing factory in conformity with the GMP for Medical Devices.

   ②STED documentation:

   Application documents for medical device EP/STED documentation shall include a complete catalog. Medical device entity shall clearly fill in applicability for every single item of the checking list in accordance with all clauses and chapters, and with respective page numbers. In the event of lack of relevant data or non-applicable in some clauses or chapters, due to the characteristics of the medical device, the medical device entity may fill in non-applicable and explain the reason.

*Sample application form catalog of a domestic medical device EP/STED for registration.*

| *EP/STED application form for registration* | *Content* | *Applicable/ Non-applicable* | *Page number* | *Reference* |
|---|---|---|---|---|
| Administrative Documents | One copy each of the original and photocopy of the medical device registration and market approval application form. | | | |
| | Two copies of each following item: the form for attaching outer box instruction label with all Chinese instruction leaflet catalog packaging, and labeling, instructions for use, and color | | | |

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| | pictures of the physical appearance of product. | | | |
| | A photocopy of pharmaceutical firm license as a medical device manufacturer. | | | |
| | Affidavit(A) | | | |
| | Documents verifying that the domestic manufacturing factory in conformity with the GMP for Medical Devices. | | | |
| STED documentation | Product description(including type, composition, and parts) | | | |
| | EP checklist | | | |
| | Risk analysis and control | | | |
| | Design and manufacture information | | | |
| | Product Verification and Confirmation | | | |
| | Sterilization *Note 1 | | | |
| | Bio-compatibility *Note 1 | | | |
| | Electrical Safety, and Electromagnetic Compatibility *Notes 1&2 | | | |
| | Software Certification *Notes 1&2 | | | |
| | Bio-compatibility for medical device derived from animal or human cell, tissue, or derivatives. *Notes 1&2 | | | |
| | Medicinal substance contained in the medical device, including compatibility between the substance and device. *Note 1 | | | |
| | Animal testing *Note 1 | | | |
| | Clinical evidence (including product efficacy evaluation and test data) *Notes 1&2 | | | |
| | Efficacy analysis *Note 2 | | | |
| | Stability *Note 2 | | | |

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| | Miscellaneous *Note 3 | | | |

*Note 1: refers to the content of product verification and confirmation that shall be submitted for medical devices in general, according to GHTF SG1-N11:2008《Summary Technical Documentation for Demonstrating Conformity with the Essential Principles of Safety and Performance of Medical Devices (STED)》

*Note 2: refers to the content of product verification and confirmation that shall be submitted for IVD, according to GHTF SG1-N63:2011《Summary Technical Documentation (STED) for Demonstrating Conformity with the Essential Principles of Safety and Performance of IVD Medical Devices》

*Note 3: In the event of the safety, efficacy, instruction of use, specification not entirely covered by product labeling and instruction leaflet, complementary documents shall be submitted as well.

2. An imported medical device firm applies for a Class III medical device registration shall submit administrative documents in accordance with Article 17 of "Regulation on Registration of Medical Devices", and STED, that include:

①Administrative documents:

- One copy of each the original and photocopy of the medical device registration and market approval application form.
- Two copies of each following item: the affixed or stapled to the label attachment form of instructions and manual with detailed Chinese translations, packaging, labels and color pictures of the physical appearance of product.
- A photocopy of pharmaceutical firm license as a medical device dealer.
- Affidavit(A)
- The original copy of the manufacture and free sale certificates of the country of origin.
- The original copy of foreign original manufacturer authorization letter.
- Documents verifying that the manufacturing factory of the imported medical device in conformity with the GMP for Medical Devices.

②STED documentation:

*Sample application form catalog of a domestic medical device EP/STED for registration.*

| *EP/STED application form for registration* | *Content* | *Applicable/ Non-applicable* | *Page number* | *Reference* |
|---|---|---|---|---|
| Administrative Documents | One copy of each the original and photocopy of the medical device registration and market approval | | | |

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| | application form. | | | |
| | Two copies of each following item: the affixed or stapled to the label attachment form of instructions and manual with detailed Chinese translations, packaging, labels and color pictures of the physical appearance of product. | | | |
| | A photocopy of pharmaceutical firm license as a medical device dealer. | | | |
| | Affidavit(A) | | | |
| | The original copy of the manufacture and free sale certificates of the country of origin. | | | |
| | The original copy of foreign original manufacturer authorization letter. | | | |
| | Certificate of domestic manufacturing plant in conformity with Good Manufacturing Practices for Medical Devices. | | | |
| STED documentation | Product description(including type, composition, and parts) | | | |
| | EP checklist | | | |
| | Risk analysis and control | | | |
| | Design and manufacture information | | | |
| | Product Verification and Confirmation | | | |
| | Sterilization *Note 1 | | | |
| | Bio-compatibility *Note 1 | | | |
| | Electrical Safety, and Electromagnetic Compatibility *Notes 1&2 | | | |
| | Software Certification *Notes 1&2 | | | |
| | Bio-compatibility for medical device derived from animal or | | | |

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| | human cell, tissue, or derivatives. *Notes 1&2 | | | |
| | Medicinal substance contained in the medical device, including compatibility between the substance and device. *Note 1 | | | |
| | Animal testing *Note 1 | | | |
| | Clinical evidence (including product efficacy evaluation and test data) *Notes 1&2 | | | |
| | Efficacy analysis *Note 2 | | | |
| | Stability *Note 2 | | | |
| | Miscellaneous *Note 3 | | | |

*Note 1: refers to the content of product verification and confirmation that shall be submitted for medical devices in general, according to GHTF SG1-N11:2008《Summary Technical Documentation for Demonstrating Conformity with the Essential Principles of Safety and Performance of Medical Devices (STED)》

*Note 2: refers to the content of product verification and confirmation that shall be submitted for IVD, according to GHTF SG1-N63:2011《Summary Technical Documentation (STED) for Demonstrating Conformity with the Essential Principles of Safety and Performance of IVD Medical Devices》

*Note 3: In the event of the safety, efficacy, instruction of use, specification not entirely covered by product labeling and instruction leaflet, complementary documents shall be submitted as well.

3. Application for medical device registration with EP/STED documentation shall provide relevant "risk analysis and control", "design and manufacture", and "product verification and confirmation" items. The degree of detail of the above-mentioned items correlate to classification of the medical device. According to GHTF guidelines, application for medical device registration with EP/STED documentation shall provide EP in principle. As for Class III medical devices, in addition to abstract description, the applicant shall submit information in detail, such as examination test report, and/or original records, and etc.

## VII. Administrative Documents

1. Each item of administrative documents shall comply "Regulation on Registration of Medical Devices", such as application form, affidavit, pharmaceutical entity license as a manufacturer, pharmaceutical entity license as a dealer, certificate of conformity with Good Manufacturing Practices for Medical Devices, FSC, and authorization letter, and etc.
2. Product label, instruction leaflet, or packaging shall comply Article 75 of the Pharmaceutical Affairs Act, and related regulations.

3. Other related application forms are available on Food and Drug Administration of Ministry of Health and Welfare website:
   http://www.fda.gov.tw/TC/site.aspx?sid=2226

## VIII. STED Documentation

About STED documentation, refer to the following guidelines:

Medical devices in general: GHTF/SG1/N11:2008《Summary Technical Documentation for Demonstrating Conformity with the Essential Principles of Safety and Performance of Medical Devices (STED)》

IVD: GHTF/SG1/N63:2011《Summary Technical Documentation (STED) for Demonstrating Conformity with the Essential Principles of Safety and Performance of IVD Medical Devices》

Key points from various chapters and/or sections of STED documentation explains as the following:

1. Product description (including type, composition, and accessory)
   (1)Medical device in general STED documentation shall include the following description:
   ⓐSummary of the medical device, including intended use.
   ⓑTargeted patient population and condition, and other considerations, such as the standard of patient selection.
   ⓒTheory of operation.
   ⓓClassification of the device, and applicable judging rule.
   ⓔExplanation of novel function.
   ⓕDescription of accessory to be used in combination with the medical, other medical device, and other non-medical device product.
   ⓖDescription or complete list of all model/version of the medical device.
   ⓗSummary of key functional elements, such as its parts/components(including software, if applicable), prescription, construct, functionality. Diagrams such as structural diagram, picture, engineering drawing shall be included if applicable, and clear indication of key parts/components including ample explanation shall be included as well.
   ⓘSummary of material that key function elements of the device contain, and summary of material that is in direct or indirect contact with the human body.
   (2)IVD STED documentation shall include the following description:
   ⓐIntended use, including inspection items; whether it is automatic or not; intended use of the instrument; quantitative or qualitative test; whether it is used in measuring, judging, or defining for specific disease, condition, or risk factors; specimen type, such as serum, plasma, whole blood, biopsy, or urine; examination subject population.
   ⓑFunctional description of IVD, such as screening, monitoring, diagnosis or assisting with diagnosis, or, judging or assisting with judging which stage of disease. Description of screening method or theory of operation of the instrument.
   ⓒExpectant user. (Professional or lay person)
   ⓓClassification of IVD, and applicable judging rule according to 《Judging Rules of IVD Classification》.

ⓔDescription of all components involved in examination, such as antibody, antigen, substrate to detect antigen-antibody complex, nucleic acid primer, buffer solution, recommended collocation quality control material or calibrator, and etc.

ⓕDescription of specimen collection and transport materials.

ⓖDescription of analytic characteristics of automatic analytic instrument and its intended use.

ⓗDescription of instrument used in automatic examination and its characteristics.

ⓘDescription of any software used. (If applicable)

ⓙDescription or complete list of all combinations or packaging of IVD. (If applicable)

ⓚDescription of accessory or any other related product used in combination. (If applicable)

(3)Product specification should explain in detail about the characteristics, scope, efficacy, and version or accessory of specification booklet of the medical device.

(4)In order to prove conformity with EP or background data, previous generation device from the same manufacturer, or same approved type by the Ministry of Health and Welfare shall be provided.

2. EP checklist:

EP checklist shall be submitted with STED documentation, in order to identify EP related to safety and efficacy of the medical device; explain whether or not all requirements apply to this medical device; In the meantime, EP checklist is also considered to be proof of conformity with EP.

A medical device entity may select any of the following methods to prove conformity with EP:

ⓐConformity with recognized standard or other standard

ⓑConformity with generally accepted industry test methods

ⓒConformity with in-plant tests

ⓓComparison with similar medical device already approved

ⓔConformity with pre-clinical trial standard or technical standard

Ministry of Health and Welfare has been announcing medical device recognized standards since 2003, and 1,002 such standards have been announced by 2011. Medical device entities can refer to the following website:

Medical device recognized standards database.

(http://mdlicense.itri.org.tw/MD2010/MDRecognized.aspx)

In addition, Ministry of Health and Welfare has been announcing 37 such pre-clinical trial standards or technical standards in total since 2009. Medical device entities can refer to the following website:

(http://www.fda.gov.tw/TC/law.aspx?cid=55&cchk=f2d99f85-142b-4517-86c1-571ecbb15758)

Ep checklist shall specify proof of conformity with complete technical documents of the medical device, and index of medical device application forms for EP/STED documentation.

EP checklist is listed in detail as the Annex I.

As for English version of Essential Principal Checklist, refer to GHTF/SG1/N11:2008《Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)-Appendix A》

3. Risk analysis and control

STED documentation shall summarize risk identified from the process of risk analysis executed by the medical device entity, and measures taken to control/reduce the risk down to a manageable level. Risk analytic activity shall conform to medical device recognized standard announced by Ministry of Health and Welfare or other international standards, and also comparable to complexity and novelty of the medical device.

Possible harm induced from IVD shall at least include risk arisen from false positive and false negative, and in-direct risk. For example, instability that could lead to erroneous results, or harm brought by the user, such as reagent contained contagious antigen.

Result of risk analysis shall provide evidence in order to support the conclusion, and whether the result is acceptable the remaining risk compared to the benefit.

Medical device STED documentation shall summarize possible risk while using the medical device, risk control measure, and related research results.

Class III medical device STED documentation shall submit complete reports on all risk control related research, in addition to the previous summaries.

4. Design and manufacturing information

(1) Design

Medical device entity shall summarize design information of the medical device, so that reviewer may acquire a general understanding about this medical device. Such content for medical device in general may include product needs, design, verification, examination, test, review plan, and records. Such content for IVD may include analysis on its key composition, like antibody, antigen, enzyme, nucleic acid primer, suggested quality control material or calibrator, and substrate for detecting antigen-antibody compound. As for Class III IVD, detailed specification of its material shall also be submitted. This section shall not be construed to replace detail information needed by quality control audit or other compliance evaluation activities.

(2) Manufacture process

Medical device entity shall summarize quality control system and manufacturing process and related activities, including design, manufacturing, assembly, final product test and packing, the explanation of manufacturing (this item may be provided with a flow-chart), so that reviewer gains a general understanding about the manufacturing process.

| Manufacturing plant information | Items | Name of document/file |
|---|---|---|
| Flow chart | In-plant:<br>Commissioned: | |
| Application plant information | Name, address, license of the medical device entity, plant registration, quality control status | |
| Commissioned plant | Name, address, license of the | |

| | | |
|---|---|---|
| information | medical device entity, plant registration, quality control status | |

This section shall not be construed to replace detail information needed by quality control audit or other compliance evaluation activities.

(3) Design and manufacture plant

Medical device entity shall summarize about the design or manufacturing plant of the medical device, not including raw material provider. In the event of quality control certificate or equivalence certificate already indicating such sites, the above-mentioned certificate may serve as an attachment to STED documentation.

5. Product verification and confirmation

Degree of detailing information on product verification and confirmation depends on the risk level, complexity, and novelty of the medical device.

Medical device EP/STED documentation filed for registration shall summarize product verification and confirmation related data, in order to prove conformity to EP. The following shall be included at least:

(1) Engineering test;
(2) Laboratory test;
(3) Simulation test;
(4) Animal test;
(5) Related citation and discussion of scientific literature on that medical device or a similar one.

General speaking, product verification and confirmation on medical device in general include:

(1) Sterilization;
(2) Bio-compatibility;
(3) Electrical Safety and Electro-Magnetic Compatibility;
(4) Software verification;
(5) Biological safety on medical device that contains animal or human cells, tissue, or derivative;
(6) Medicinal substance that medical device contains (if applicable), including compatibility of the device and that medicinal substance.
(7) Animal study on direct evidence of safety and efficacy for the medical device, particularly when no clinical trial had been done for the medical device;
(8) Clinical evidence.

Product verification and confirmation on IVD include:

(1) Specimen types;
(2) Accuracy;
(3) Traceability of calibrators and control materials;
(4) Analytical sensitivity;
(5) Analytical specificity;
(6) Range of measurement;
(7) Cut-off confirmation;

(8) Stability (specimen stability not included)

(9) Electrical Safety and Electro-Magnetic Compatibility;

(10) Software verification and confirmation;

(11) Clinical evidence.

Content of summary shall include product verification and confirmation, and related citation and discussion of literature.

| Types of Standards | Data Content |
|---|---|
| Acceptability criterion | Declaration of particular recognized standard or related certificate |
| No acceptability criterion<br>Non-recognized standard<br>Professional guideline, industrial method, or in-plant standard | Particular standard or related certificate<br>Description of application of that particular standard and theory, test method, acceptability criterion, test results and discussion |

Application for Class III medical device, in addition to previous documents, shall submit test report results in detail that include:

(1) Adopted standard, the reason for this adopted standard, and the theory;

(2) The complete test plan;

(3) Data analysis method;

(4) Acceptability criterion;

(5) The complete test report;

(6) Test results and discussion.

# Annex I : EP checklist

This Annex is based on GHTF SG1-N11:2008《Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)》

A. General requirements

| Safety and Efficacy Essential Principles(EP) of the Medical Device | If applicable for this device? | Applicable laws, regulations or standards | Evidence |
|---|---|---|---|
| 5.1<br>Beneficial effects brought by medical device use should outweigh possible risk to the patient; health and safety of the patient and user should also be safeguarded. Design and manufacture of the medical device should ensure no harm or safety issues be brought against the patient, or other users or personnel. Expectant user of certain medical devices should possess adequate professional knowledge, experience, education or training. | | | |
| 5.2<br>Design and manufacturing of medical device of the manufacturer should conform to generally recognized technology standards and EP. The manufacturer should also control risk, so that remaining risk from medical device can be lowered to an acceptable level. The manufacturer should adopt the following principles in the following order:<br>(1) To identify know harm; to estimate expectant use, and risk from possible misuse.<br>(2) To minimize risk by safe design and manufacture.<br>(3) To take appropriate measure | | | |

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| (including alarms) to minimize remaining risk.<br>(4) To inform the user of remaining risk. | | | |
| 5.3<br>Medical device should achieve manufacturer‘s planned efficacy. After design, manufacture, and packaging, the medical device still conform to all functions required by related laws and regulations. | | | |
| 5.4<br>Before manufacturer‘s designated expiry date, and appropriate maintenance according to operation manual provided by the manufacturer done to the medical device, specified characteristics and efficacy from 5.1, 5.2, and 5.3, under normal operation, shall not harm the health and safety of the patient or user or other personnel. | | | |
| 5.5<br>After design, manufacture, and packaging, under normal transport and storage status specified by operation manual, the medical device should still maintain its expected product characteristics and efficacy. | | | |
| 5.6<br>Manufacturer should ensure clinical beneficial effects brought by its medical device outweigh the adverse effects. | | | |

B. Design and manufacture requirements

| Safety and Efficacy Essential Principles(EP) of the Medical Device | If applicable for this device? | Applicable laws, regulations or | Evidence |
|---|---|---|---|

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| | | standards | |
| 5.7 Chemical, Physical and biological characteristics | | | |
| 5.7.1<br>Design and manufacture of medical device should conform to general requirements from 5.1 to 5.6, emphasizing on:<br>• Selection of material especially on toxicity, and flammability if applicable.<br>• Consideration of expected use of the medical device; Compatibility between its material and biological tissue, cell, body fluids, and specimen.<br>• If applicable, selecting material should consider characteristics such as its hardness, wear and tear, and fatigue strength. | | | |
| 5.7.2<br>Design, manufacture, and packaging of the medical device should consider its expected use; minimize pollutants and remnants and risk to the patient and personnel involved in transport, storage, and use of the medical device; especially human tissue, time of contact and frequency of contact. | | | |
| 5.7.3<br>Design and manufacture of the medical device should ensure its safety after normal use or routine procedure exposure to other material, substance, or air. If the medical device is used as drug administration, then design and manufacture should match with related rules or regulations for that drug. The | | | |

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| medical device should also maintain its efficacy as expected. | | | |
| 5.7.4<br>If the medical device contains drug, and affects human body used in combination with that drug, manufacturer should consider its expected use, and verify safety, quality and efficacy of the drug. | | | |
| 5.7.5<br>Design and manufacture of medical device should lower possible substance leakage from the medical device and harm to the human body from that. | | | |
| 5.7.6<br>Design and manufacture of medical device should consider characteristics of the medical device and its environment, and lower risk of substance inadvertently entering into the medical device, or releasing from it. | | | |
| 5.8 Contamination and microbial contamination | | | |
| 5.8.1<br>Design and manufacture of medical device manufacturing process should eliminate or minimize patient, user or other personnel's contamination risk. Design of the medical device should make them easy to operate. Reduce microbial leakage or microbial contamination during operation of the medical device if necessary. To prevent patient, user or other personnel from microbial contamination from the medical | | | |

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| device or specimen as well. | | | |
| 5.8.2<br>If the medical device includes substance taken from a biological entity, manufacturer should select a probable source, donor, and substance, in order to reduce risk of contamination. Select a confirmed deactivated, preserved, tested and control procedures source if necessary. | | | |
| 5.8.3<br>If the medical device contains non-human animal tissue, cell or substance, such animal tissue, cell or substance should match with the expected use, and conform to related laws and regulations. (Strict prohibition from using bovine products from affected area suffering from BSE announced by Council of Agriculture, Executive Yuan. Shall be positive free of BSE antigen contamination as well.) Tissue, cell, or substance from animal source should be well-preserved for health competent authority inspection. Processing, preservation, testing, and handling of animal tissue, cell, or substance should ensure the safety; the manufacturing process should process viruses or other antigens with verified decontamination or deactivation methods. | | | |
| 5.8.4<br>If the medical device contains human tissue, cell, or substance, such tissue, cell, or substance should | | | |

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| match with their expected use, and conform to laws and regulations. Tissue, cell, or other substance from a human source and related data should be well preserved for health competent authority inspection. Processing, preservation, testing, and handling of human tissue, cell, or substance should ensure the safety; the manufacturing process should process viruses or other antigens with verified decontamination or deactivation methods. | | | |
| 5.8.5<br>If the medical device is labeled as containing special microbes, design, manufacture and packaging should ensure that medical device maintains sustaining such microbes during being put on the market, transport, and storage conditions. | | | |
| 5.8.6<br>Sterilized medical device should use single use only packaging to ensure that medical device conform to transport, and storage conditions after being put on the market, may maintain sterilized status until the protective packaging damaged or broken. | | | |
| 5.8.7<br>Medical device labeled as sterilized or containing special microbes should be processed, or manufactured with proper and verified methods, and sterilized if necessary. | | | |

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| 5.8.8<br>Medical device processed by sterilization procedure should be manufactured under properly controlled conditions, such as environmental condition. | | | |
| 5.8.9<br>Packaging system of a non-sterilized medical device should maintain cleanness of the medical device. If that medical device should be sterilized before use, manufacturer should minimize risk from microbial contamination. The packaging system should also conform to the sterilization method specified by the manufacturer. | | | |
| 5.8.10<br>If the same or a similar medical device is put on the market both with sterilized and non-sterilized status, its package or label should reflect the status respectively. | | | |
| 5.9 Manufacture and environmental characteristics | | | |
| 5.9.1<br>If the medical device is designed to be used with another medical device or instrument, the combined system as a whole should conform to safety requirements, including the connecting system between them; efficacy of each of the device should not be affected. Label or operation manual should point out usage limitations to the whole system. | | | |
| 5.9.2<br>Design and manufacture of the | | | |

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| medical device should eliminate or properly reduce the following risks:<br>• related physical properties including the ratio of volume/pressure and dimensions, ergonomically risk factor if necessary;<br>• known outside influence or environmental conditions possibly cause the medical device. For example, magnetic fields, external electronics and electromagnetic effects, static discharges, pressure, humidity, temperature, change in pressure or acceleration.<br>• under normal operation condition, risk arisen from in contact to material, substance or air.<br>• risk of substance inadvertently entering the medical device<br>• risk arisen from error in specimen identification<br>• risk of interference with other research or therapeutic devices, and non-maintainable or non-adjustable medical devices, such as implants; risk arisen from old material, measurement or control mechanism lost their accuracy. | | | |
| 5.9.3<br>Design and manufacture of the medical device should lower risk of combustion or explosion under normal operation or single malfunction status, especially foe those medical devices with possible exposure to flammable substances. | | | |
| 5.9.4 | | | |

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| Design and manufacture of the medical device should ensure safety of waste handling. Waste means substances generated from non-related expected use of the medical device during design, manufacture, shipping, discarding, and etc., any stage during the product lifecycle of the medical device. For example, packaging, packaging waste, electronics parts that contain environmental hazardous materials, including medical waste. Waste-related laws and regulations, please refer to Environmental Protection Administration, Executive Yuan. | | | |
| 5.10 Diagnostic or measuring function medical device | | | |
| 5.10.1<br>If medical device with measuring function lacks adequate accuracy, major adverse effect to the patient may occur; the design and manufacture of such medical device should ensure its accuracy, precision, and stability fit for expected use. The manufacturer should specify the limitations in accuracy of its medical device. | | | |
| 5.10.2<br>Design and manufacture of a diagnostic medical device should be manufactured according to proper scientific or technological methods, possess adequate accuracy, precision, and stability in order to fit its expected use. Particular medical devices should provide their accuracy, specificity, true value, repeatability, reproducibility, | | | |

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| known interference control, and limitation in detection. | | | |
| 5.10.3<br>If efficacy of the medical device is decided by its adjustor or quality control materials, the quality control system should ensure such adjustor or quality control materials fit their measurement traceability. | | | |
| 5.10.4<br>The size of the fonts used in measurements, monitoring, or display should consider the expected use of the medical device, matching ergonomics. | | | |
| 5.10.5<br>Values displayed by the medical device should conform to current laws and regulations, or generally accepted standard units; to make users to understand easily. | | | |
| 5.11 Radiation protection | | | |
| 5.11.1<br>Abstract | | | |
| 5.11.1.1<br>Design, manufacture, and packaging should lower the probability of exposure of patient, user or other personnel to radiation. | | | |
| 5.11.1.2<br>Expected radiation | | | |
| 5.11.1.2.1<br>If the medical device is designed for a specific medical purpose resulting in a release of radiation of visible or invisible to the human eye, the user should be able to control release of the | | | |

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| medical device. Design and manufacture of the medical device should ensure the release of radiation well within tolerance level, and repeatability of related variables. | | | |
| 5.11.2.2<br>For medical device that radiates harmful visible or invisible radiation, a visual cue and/or audio alarm should be installed wherever feasible. | | | |
| 5.11.3 Unexpected radiation | | | |
| 5.11.3.1<br>Design and manufacture of the medical device should lower risk of patient, user, or other personnel from exposure to unexpected, deviated, or scattered radiation. | | | |
| 5.11.4 Operation Manual | | | |
| 5.11.4.1<br>Operation Manual of a medical device that emanates radiation should provide the following information: characteristics of emanating radiation, method for protection of patient, user, or other personnel from misuse and elimination of risk inherently arisen during installation. | | | |
| 5.11.5 Ionizing radiation | | | |
| 5.11.5.1<br>For emanating ionizing radiation medical device, the design and manufacture of the medical device should ensure that it may control absorbed dose, radiation geometric distribution, and energy distribution or quality. | | | |
| 5.11.5.2<br>For radiation diagnostic medical | | | |

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| device using ionizing radiation, the design and manufacture of the medical device should attain proper output or imagery quality the expected medical use needs, and also minimize radiation absorbed dose of patient and user. | | | |
| 5.11.5.3<br>For radiation therapeutic medical device using ionizing radiation, the design and manufacture of the medical device should ensure that, via monitoring and adjusting method, radiation absorbed dose, radiation type, and radiation energy distribution can be controlled. | | | |
| 5.12 Requirements for a medical device that is connected or attached to an energy source, | | | |
| 5.12.1<br>Medical device incorporating a programmable electronics system (including software), its design and manufacture should ensure its repeatability and reliability, and efficacy. If a single malfunction occurs to the system, proper measures should be taken to eliminate or reduce follow-up risks. | | | |
| 5.12.2<br>In the event of patient safety being monitored by an internal power supply of the medical device, that medical device should be equipped with instrument that determines power supply status. | | | |
| 5.12.3<br>In the event of patient safety being monitored by an external power | | | |

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| supply of the medical device, that medical device should be equipped with an alarming system in case of a power failure. | | | |
| 5.12.4<br>Medical device using as monitoring single or multiple clinical parameters of the patient should be equipped with proper alarming system, in order to warn the user once the condition of the patient is deteriorating or critical. | | | |
| 5.12.5<br>Design and manufacture of the medical device should minimize risk of electromagnetic interference. | | | |
| 5.12.6<br>Design and manufacture of the medical device should ensure that medical device be equipped with proper electromagnetic interference shielding capability, in order to ensure its operation. | | | |
| 5.12.7<br>Electric risk shielding. Design and manufacture of the medical device should minimize risk of electric discharge under normal use or single malfunction during normal installation and maintenance conditions. | | | |
| 5.13 Mechanical risk prevention | | | |
| 5.13.1<br>Design and manufacture of the medical device should consider mechanical risk, in order to protect patient and user from suffering from risk arisen from kinetic inertia, unstable and movable components. | | | |

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| 5.13.2<br>With the exception of vibration being the normal function, design and manufacture of the medical device should consider methods of technical development, obtainable limited vibration (especially for the vibration source), in order to minimize risk arisen from vibration of the medical device. | | | |
| 5.13.3<br>With the exception of sound being the normal function, design and manufacture of the medical device should consider methods of technical development, obtainable limited sound (especially for the sound source), in order to minimize risk arisen from sound of the medical device. | | | |
| 5.13.4<br>Design and manufacture of medical device with plugs or connectors connected to power, gas, water, or wind power generator should minimize operational risk of user. | | | |
| 5.13.5<br>In the event of medical device coming in contact with human body or surroundings (not including normal use to provide heat, or reach the temperature required), it should ensure the medical device cannot reach harmful temperature under normal use. | | | |
| 5.14 Protection from risk of providing patient with energy or substance. | | | |
| 5.14.1<br>Medical device that provides patient | | | |

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| with energy or substance, the design and manufacture should ensure the energy or substance can be setup and sustained accurately, in order to secure patient and user safety. | | | |
| 5.14.2<br>Medical device should be equipped with instrument that prevents or indicates that improper amount of energy or substance provided may cause harm. That medical device should provide preventive measures to prevent sources of energy or substance from providing harmful levels of energy or substance to the patient accidentally. | | | |
| 5.14.3<br>Description of clear operation guidelines on operating device and display functionalities. If that medical device illustrates operation guidelines or adjustment parameters on the display, such information should be easy to understand for ordinary users. | | | |
| 5.15 Protection for medical device used in patient self-test or self-monitoring. | | | |
| 5.15.1<br>Design and manufacture of the medical device should consider technical and method acknowledgement of the user, foreseeable adverse effects caused by user techniques and environmental factors, in order to ensure the medical device operate properly according to the expected used. The manufacturer should provide the user with | | | |

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| easy-to-understand and easy-to-use information. | | | |
| 5.15.2<br>Design and manufacture of the medical device should minimize risk arisen from operation error of the device or specimen, or interpretation of the results. | | | |
| 5.15.3<br>The medical device should provide user with procedure that verifies its normal operation as humanly possible. | | | |
| 5.16 Information provided by manufacturer. (including product labeling and instruction leaflet) | | | |
| 5.16.1<br>Considering training and knowledge user possesses, the user should be able to obtain required information on identifying manufacturer, in order to ensure the expected efficacy and use the medical device safely. | | | |
| 5.17 Efficacy evaluation (including clinical trials) | | | |
| 5.17.1<br>Information on efficacy evaluation of medical device should prepared according to current laws and regulations. | | | |
| 5.17.2<br>Execution of clinical trials of test subjects should conform to related medical device clinical trials laws, regulations, and Good Clinical Practices. | | | |