Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical affair and Drugs Control

Medical Device Control Department

Guidance Document GD3: Requirements of Moderate -High &High Risk Medical Devices Registration in Sultanate of Oman

By: Medical Device Control Department
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Contents

1. Introduction

Medical devices are required to be registered to cater for regulatory requirements. Regulation is enforced in Oman via ministerial decree 113/2020. This will ensure that products entering the market are safe and efficient.

This guidance document is meant to assist applicants in the registration of moderate –high & high risk medical devices and medium high devices in sultanate of Oman.

Applicants are strongly encouraged to familiarize themselves with the criteria and requirements for review processes outlined in this guidance and the other relevant guidance documents before submitting their applications.

2. Purpose

The purpose of this guidance is to describe the procedures and general requirements for the submission of moderate –high & high risk medical device dossier.

3. Scope

This guidance applies to the following products:

High Risk Medical Devices

Moderate- High medical devices

4. Definition

Medical Device: Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices,
- Providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

High-Risk Medical Device: High Individual Risk and High Public Health Risk.

Medium –High Medical devices: **Moderate-to high** individual Risk and **moderate-to** high Public Health Risk.

Registration: the process by which a party submits information to the Regulatory Authority in a jurisdiction, regarding the identification and establishment location(s) of the manufacturer and other parties, responsible for supplying a medical device(s) to the market in that jurisdiction.

Listing: the process whereby a party submits information to the Regulatory Authority in a jurisdiction, regarding the identification of a medical device(s) that is or will be supplied to the market in that jurisdiction.

Label: means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices.

Manufacturer: means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

Accessories: Means a product intended specifically by its manufacturer to be used together with a medical device to enable that medical device to achieve its intended purpose.

Accessory to a medical device: means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use.

Risk: Combination of the probability of occurrence of harm and the severity of that harm.

Intended use / purpose: the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

5. Abbreviations

ISO: International Organization for Standardization
QMS: Quality Management System
GMDN: Global Medical Device Nomenclature
HS code: Harmonized System
AATB certificate: American Association of Tissue Banks Certificate

6. General Requirements:

1. Medical Devices shall not be imported, placed on the market, and/or put into service within Oman unless it is listed in medical device control department database. This can be done through the website: https://www.moh.gov.om/ar/web/dgpadc/-13
2. Registration requirements shall be presented in a clear, organized, readily, searchable and unambiguous manner.
3. Apply for registration through the online portal.
4. Payment of fees should be made according to Risk-classification.
5. Applications with the incorrect risk classification of devices may result in the re-submission of the applications according to the appropriate risk class.

Note:

- **The applicant is required to submit the requirements in dossier format according to sections as below.**
- **DGPA &DC has the right to request more requirements as per product type if needed.**
- **In case of any variation in the Medical Devices the manufacturer shall:**
  -Prepare, hold and update related "Technical Documentation" that confirm to local regulation requirements and submit accordingly.

7. Medical Device Dossier File Sections Requirements:

- High risk (all sections required).

- Moderate - High (all sections except 5 & 6).

7.1 Section 1: Application type

This section includes the type of application whether Medical device or IVD, the risk class of the device and device grouping.

7.2 Section 2: Manufacturer information

This section includes name, physical site address and details of legal manufacturer, quality management system used and the certificates e.g. (ISO 13485) for the manufacturer.

And the following:

- Audit report for the manufacturer.
- Manufacturing/ Production process.
- Manufacturer Layout.
- Authorization Letter from Manufacturer/ Commerce Agency Certificate.
- Sub-Site information (Name, Country, Postal Address, Physical address, Telephone#, Fax #, and Email Address)
- Sub-contractors Name
- Sub-contractors (Subcontractors Services Details)

7.3 Section 3: Medical Device information

This section defines the medical device and accessories information, Medical device grouping/bundling and regulatory jurisdiction. The following points shall be documented.

7.3.1 Regulatory jurisdiction the device follows:

- KSA(MDMA)
- USA
- EU
- Canada
- Australia
- Japan
- Others (specify)

7.3.2 Medical device grouping/ bundling.

This section describes which grouping / bundling to be filled as per **Annex (1),** refer to bundling and grouping guidance for more information.

- Single
- Family
- System
- Systems
- Procedure pack

7.3.3 Medical Device information:

7.3.3.1 Trade / Brand name.
7.3.3.2 Model name / number.
7.3.3.3 Medical device classification.
7.3.3.4 Intended use.
7.3.3.5 Description of accessories.
7.3.3.6 Medical device category.
7.3.3.7 Manufacturer device identification number[1]
7.3.3.8 Format of device identification number that appear in labeling for traceability purpose[2]
7.3.3.9 GMDN.
7.3.3.10 Nomenclature code if different than GMDN
7.3.3.11 HS code
7.3.3.12 Shelf life (if applicable)
7.3.3.13 Storage condition (follow the label and manufacturer recommendation).
7.3.3.14 Year first sold
7.3.3.15 Warnings
7.3.3.16 Principles of operation/mode of action (how it works/ operates)
7.3.3.17 Picture or drawing of the device which should be details (include sufficient explanation to understand the drawing)
7.3.3.18 Description of any devices required to operate the device (IT infrastructure, laptop, mobile smart phone) if applicable.
7.3.3.19 Declaration (does the device require any specific declaration to be made such as containing animal tissue / medicines/human blood derivatives)

[1] Manufacturer device identification number: Code or reference number
[2] Format of device identification number that appear in labeling for traceability purpose: which system used for traceability purpose

7.4 Section 4: Device Labeling

This section of registration requirements shall include a full set of:

- Labels for the device.
- Packaging which includes the instructions for use (IFU).
- Any promotional material if applicable.

7.5 Section 5: Essential Principles & evidence of conformity

This section intended to demonstrate how the manufacturer has met the essential principles of safety and performance. The Essential Principle Checklists **Annex (2).** Can be used to demonstrate this and should form this section of the registration requirements. Alternative formats are allowed as long as all essential principles have been considered as follows:

- All applicable essential principles have been identified and conformity has been validated by evidenced.
- All non-applicable essential principles have a rationale detailing why they are not applicable.
- The precise identity of the controlled documents offering evidence of conformity with each essential principle is documented.

7.6 Section 6: Summary of design Verification & Validation documents

This section provides details on the device design and how it is manufactured. This section shall include:

7.6.1 Full device description

7.6.1.1 Device technical drawings (clearly labelled and explained)
7.6.1.2 Information to describe the function and assembly of the device
7.6.1.3 Applied Part (explanation of which parts of the devices contact the human body either directly or indirectly, Identification of the contact materials.
7.6.1.4 For instruments, a description of major subsystems, analytical technology such as operating principles and control mechanisms, dedicated computer hardware and software.
7.6.1.5 For instruments and software, an overview of the entire system.
7.6.1.6 For software, a description of the data interpretation methodology, namely the algorithm.

7.6.2 Design Stages

7.6.2.1 Reference to design procedure.
7.6.2.2 Description of design stages
7.6.2.3 Confirmation of the verification and validation conducted on the device

7.6.3 Manufacturing processes

Manufacturing information to include:

7.6.3.1 Manufacturing process flow
7.6.3.2 Manufacturing specifications including in process testing
7.6.3.3 Final inspection and acceptance criteria
7.6.3.4 Manufacturing validation

7.6.4 Manufacturing structure

7.6.4.1 Name and address of place where design was carried out (all sites and subcontractors)
7.6.4.2 Name and address of place where manufacturing is carried out (all sites and subcontractors)
7.6.4.3 Detail of suppliers including identification of critical suppliers
7.6.4.4 Confirmation of subcontractor contracts (if applicable)

7.7 Section 7: Product Verification and Validation

This section provides product certificates:

1. Full quality assurance / Equivalent
2. Design examination certificate / Equivalent
3. TSE free certificate (if biological)
4. AATB certificate (if from US) (if biological)
5. Others

7.8 Section 8: Clinical evidence

This section provides clinical evidence about the products and shall include:

- Clinical evaluation report

7.9 Section 9: Post Market control

Medical device manufacturers shall prepare a periodic safety update report (PSUR) for each device and where relevant for each category or group of devices summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. Post-market Surveillance Plan is a proactive and systematics process to collect information.

Throughout the lifetime of the device concerned, that PSUR shall set out:

1. The conclusions of the benefit-risk determination
2. The main findings of the Post-market clinical follow-up (PMCF)

3. The volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.
4. Manufacturers of high risk devices (C&D) shall update the PSUR at least annually.

7.10 Section 10: Status of device distribution

In this section the establishment of medical devices should:

- List the countries where the device is marketed with evidence and /or a letter issued by the legal manufacturer conforming the product distribution list.
- Submit free sale certificate from competent authority or certificate of foreign government CFG if the product from USA and CDNE (certificate for medical device not exported from the United States).

7.11 Section 11: Declaration of conformity

This section of registration requirements includes declaration of conformity from manufacturer and it is containing:

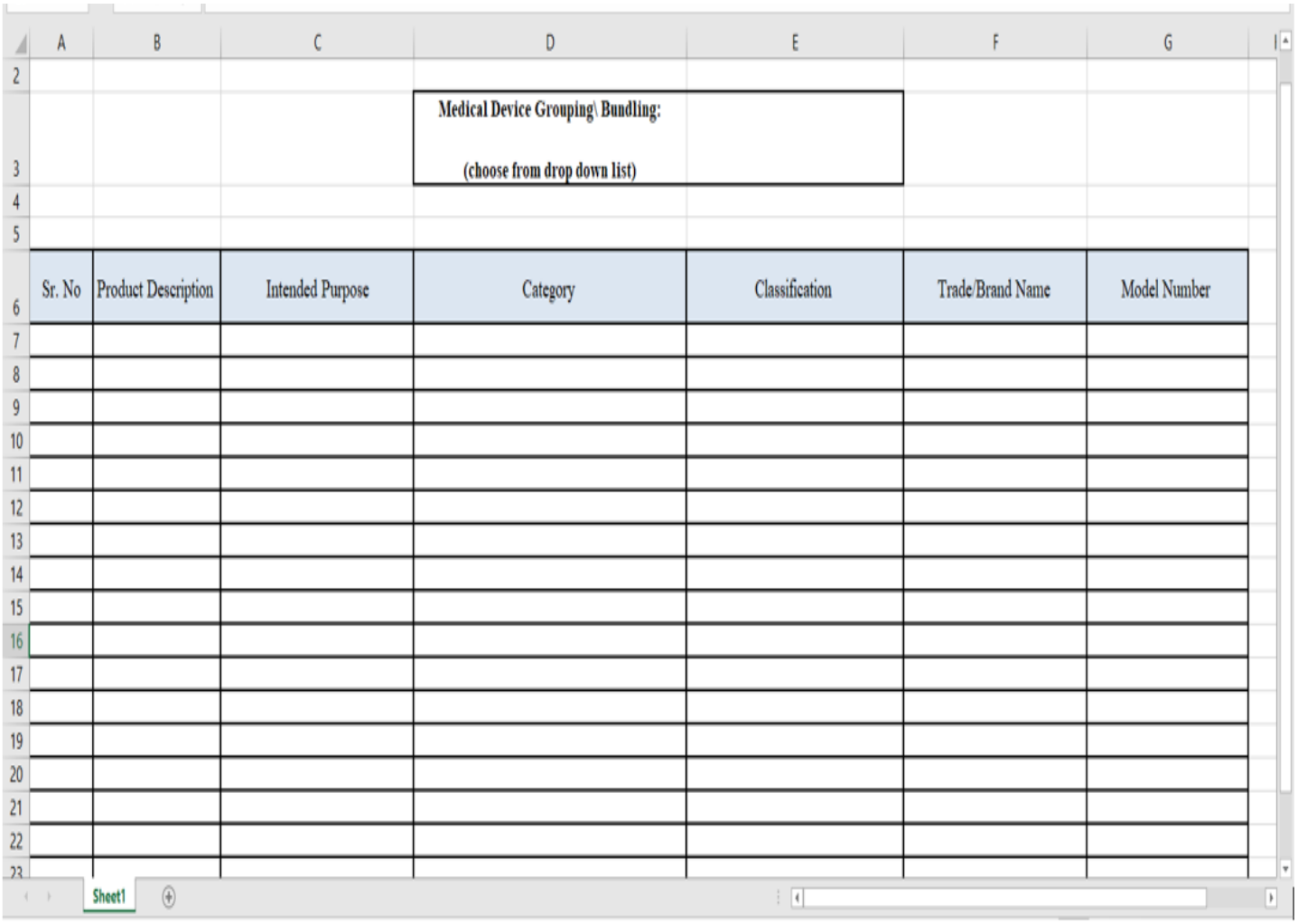
1. Product Name
2. Model number
3. Classification
4. Statement that the declaration is issued under the sole responsibility of the manufacturer
5. Issued/signed stamped from manufacturer.

Note: All Dossier sections requirements should be documented and filled in the online platform.

Annexes

Annex (1) Medical Device Grouping /Bundling

Please refer to the Guidance Document on grouping & bundling for medical devices



	A	B	C	D	E	F	G
2							
3				Medical Device Grouping\ Bundling: (choose from drop down list)			
4							
5							
6	Sr. No	Product Description	Intended Purpose	Category	Classification	Trade/Brand Name	Model Number
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Sheet1

Annex (2) Essential Principles of Safety and Performance for Medical Devices

Essential Principal Checklist	GHTF
Device:	

Essential Principal	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
5. General Requirements			
5.1 Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
5.2 The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: ▪ identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse, ▪ eliminate risks as far as reasonably practicable through inherently safe design and manufacture, ▪ reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms, ▪ Inform users of any residual risks.			
5.3 Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
5.4 The characteristics and performances referred to in Clauses 5.1, 5.2 and 5.3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.			
5.5 The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.			
5.6 The benefits must be determined to outweigh any undesirable side effects for the performances intended.			
Design and Manufacturing Requirements			
5.7 Chemical, physical and biological properties			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 5.1 to 5.6 of the 'General Requirements'. Particular attention should be paid to: ▪ the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, ▪ the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device, ▪ The choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.			
The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.			
Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the device.			
The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.			
5.8 Infection and microbial contamination			
The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should: ▪ allow easy handling, and, where necessary: ▪ reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use, ▪ Prevent microbial contamination of the device, or specimen where applicable, by the patient, user or other person.			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, and test and control procedures.			
In some jurisdictions products incorporating tissues, cells and substances of non-human origin may be considered medical devices. In this case, such tissues, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
In some jurisdictions products incorporating human tissues, cells and substances may be considered medical devices. In this case, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			
Devices labelled as having a special microbiological state should be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.			
Devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.			
Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.			
Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.			
The packaging and/or label of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.			
5.9 Manufacturing and environmental properties			
If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.			

Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: ▪ the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; ▪ risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration; ▪ the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use; ▪ the risks of accidental penetration of substances into the device; ▪ the risk of incorrect identification of specimens; ▪ the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; ▪ Risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			
Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.			
Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.			
5.10 Devices with a diagnostic or measuring function			
Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.			
Diagnostic devices should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular the design should address sensitivity, specificity, trueness, repeatability, and reproducibility, control of known relevant interference and limits of detection, as appropriate.			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through a quality management system.			
Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.			
Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device. **Note:** While SG1 generally supports convergence on the global use of internationally standardised measurement units, considerations of safety, user familiarity, and established clinical practice may justify the use of other recognised measurement units.			
5.11 Protection against radiation			
General			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
5.11.1.1 Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.			
Intended radiation			
5.11.2.1 Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.			
5.11.2.2 Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.			
Unintended radiation			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
5.11.3.1 Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.			
Instructions for use			
5.11.4.1 The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.			
Ionizing radiation			
5.11.5.1 Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.			
5.11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
5.11.5.3 Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.			
5.12 Requirements for medical devices connected to or equipped with an energy source			
5.12.1 Devices incorporating electronic programmable systems, including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.			
Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.			
Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health			
Devices should be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.			
Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.			
Protection against electrical risks Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained as indicated by the manufacturer.			
5.13 Protection against mechanical risks			
Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.			
Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.			
Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.			
Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.			
5.14 Protection against the risks posed to the patient by supplied energy or substances			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.			
Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.			
The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.			
5.15 Protection against the risks posed to the patient for devices for self-testing or self-administration			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Such devices should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment. The information and instructions provided by the manufacturer should be easy for the user to understand and apply.			
Such devices should be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.			
Such devices should, where reasonably possible, include a procedure by which the user can verify that, at the time of use that the product will perform as intended by the manufacturer.			
5.16 Information supplied by the manufacturer			

Essential Principal	Applicable to the device?	Method of Conformity	Identity of Specific Documents
5.16.1 Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood. **Note:** Further information is provided in *SG1/N009 Labelling for Medical Devices* and in SG1/N043 *Labelling for Medical Devices (revised).*			
5.17 Performance evaluation including, where appropriate, clinical evaluation			
All data generated in support of performance evaluation should be obtained in accordance with the relevant requirements applicable in each jurisdiction.			
Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent.			

References:

List	Links
High Risk Medical Device Dossier File Sections Requirements **(CSDT requirement)**	http://www.ahwp.info/sites/default/files/AHWP_Common_Submission_Dossier_Template.pdf http://www.ahwp.info/sites/default/files/AHWP-WG1-CSDT%20Guidance_FINAL.pdf
Definitions	https://www.who.int/medical_devices/full_deffinition/en/ http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n065-listing-of-medical-devices-100827.doc http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n065-listing-of-medical-devices-100827.doc http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n70-2011-label-instruction-use-medical-devices-110916.pdf http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n055-definition-terms-090326.doc http://www.imdrf.org/docs/ghtf/final/steering-committee/procedural-docs/ghtf-sc-n4-2012-definitions-of-terms-121109.pdf http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.docx http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.docx http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n70-2011-label-instruction-use-medical-devices-110916.pdf