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Ministry of Health

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مركز سلامة الدواء
Drug Safety Center

Guideline on Requirements of Class C & D In Vitro Diagnostics Device Registration in Sultanate of Oman

Drug Safety Center

2025

First Edition

Document Title	Guideline on Requirements of Class C and D In-Vitro Diagnostics Device Registration in Sultanate of Oman
Document Type	Guideline
Directorate/Institution	Drug Safety Center
Targeted Group	All Local In Vitro Diagnostic Device Establishment
Document Author	In Vitro Diagnostic Device Registration Section Task Force
Designation	In Vitro Diagnostic Device Registration Section Task Force
Document Reviewer	Eng. Faiza Alzadjali
Designation	Director of Medical Device Control Department
Release Date	October 2025
Review Frequency	Every 3 years

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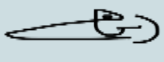
Signature		**Signature**	
Date	**26/10/2025**	**Date**	**18/11/2025**

Acknowledgments

The preparation of this guideline was undertaken by In Vitro Diagnostic Device Registration Section/ Medical Device Control Department. The Drug Safety Center extends its sincere gratitude to all staff members of the section for their dedicated efforts. Special acknowledgment is given to the members of the In Vitro Diagnostic Device Registration Section Task Force for their invaluable contributions, in particular:

- Eng. Amani Al Ghielani
- Eng. Badria Al Wahibi

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Acronyms:

MOH	Ministry of Health
DSC	Drug Safety Center
MDCD	Medical Device Control Department
MD	Medical Device
IVD	In Vitro Diagnostic
ISO	International Organization for Standardization
QMS:	Quality Management System
GMDN	Global Medical Device Nomenclature
HS code	Harmonized System
PSUR	Periodic Safety Update Report
PMCF	Post-market clinical follow-up
CFG	Certificate of foreign government
CDNE	Certificate for medical device not exported from the United States

Definitions

In Vitro Diagnostic (IVD) Device	In Vitro Diagnostic (IVD) medical device means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body, including blood and tissue donations, solely or principally to provide information: • Concerning a physiological or pathological state; • Concerning a congenital abnormality; • Concerning the predisposition to a medical condition or a disease; • To determine the safety and compatibility with potential recipients; • To predict treatment response or reactions; • To define or monitor therapeutic measures. This includes kits, reagents, calibrators, control materials, specimen receptacles, software, and related instruments, apparatus, systems or other articles.
High-Risk In-vitro diagnostic devices **Class D**	High Individual Risk and High Public Health Risk.
Moderate –High In-vitro diagnostic device **Class C**	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.
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 IVD or medical device with the intention of making the IVD or medical device available for use, under his name; whether or not such a IVD or 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 IVD or medical device to enable that IVD or medical device to achieve its intended purpose.
Accessories to In-vitro diagnostic device	Means an article which, is intended specifically by its manufacturer to be used together with an IVD medical device to enable that device to be used in accordance with its intended use as an IVD medical device. Or to augment or extend the capabilities of that device in fulfilment of its intended use as an IVD medical device.
Verification	confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.
Validation	Validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.
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.

CHAPTER ONE

Introduction

In Vitro Diagnostic devices are required to be registered to cater the 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 for the registration of Class C moderate –high & Class D high risk In-vitro diagnostic 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.

Purpose

The purpose of this guidance is to describe the procedures and general requirements for the submission of Class C& D In-vitro diagnostic device registration.

Scope

This guidance applies to the following products:

- High Risk In-Vitro Diagnostic Devices, Class D, **Annex II List A**
- Moderate - High Risk In-Vitro Diagnostic Devices, Class C , **Annex II List A**

Structure

This is the first version of this guidance and it consists of several chapters. Chapter one covers a brief introduction to the guideline as well as the purpose, scope and structure. Chapter two explains the general requirements of in-vitro diagnostic device registration. Chapter three covers the requirements of moderate –high & high risk in-vitro diagnostic device registration. Chapter four comprises of the document history and version control table, references and appendixes.

CHAPTER TWO

General Requirements

1. Registration requirements shall be presented in a clear, organized, readily, searchable and unambiguous manner.
2. Apply for registration through the online portal.

   https://moh.gov.om/ar/%D8%A7%D9%84%D8%AE%D8%AF%D9%85%D8%A7%D8%AA/?classification=2404&category=9285
3. To fulfil the prerequisite of the IVD registration, applicant must complete the Initial approval of wholesale Activity, local establishment approval and Manufacturer registration (Fees applies).
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:

- **Drug Safety Center has the right to request more requirements as per product type if needed.**
- **In case of any variation in the IVD Devices the manufacturer shall apply through variation services after the registration is complete**
- **IVD Device Dossier File Sections Requirements:**
  - Class D / High -Risk In-vitro diagnostic device (all sections required).
  - Class C / Moderate - High Risk In-vitro diagnostic device (all sections except 5 & 6).

Requirements of moderate - high & high risk In-vitro diagnostic device registration:

Section 1: Application type

This section includes the type of application whether the device is medical device or IVD, name of the device, the risk classification of the device, device grouping, device Category and which jurisdiction the device follow.

Regulatory jurisdiction the device follows:

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

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:

- Legal manufacturer Details (legal manufacturer name, manufacturer registration status, legal manufacturer country/city, Tel no, Fax no, Email, QMS Certificate number, QMS Certificate expiry date)
- All information will be gathered from previous step which is MD manufacturer registration.
- **For more details, refer to the guideline GD 22 (**Guidance Document GD 22: Requirements of Medical Device Manufacturer Registration in Sultanate of Oman)

Section 3: IVD Device information

This section defines the IVD device and accessories information, and IVD device grouping/bundling. The following points shall be submitted.

IVD Device information:

- Trade / Brand name.
- Model name / number.
- Serial number
- IVD device risk classification.
- Intended use.
- IVD device category.
- Manufacturer device ID (identification number).
- Is the device intended to be for Single Use?
- Is this Product Sterile?
- Countries Where the Device Used.
- GMDN.
- Nomenclature code if different than GMDN
- HS code
- Method of Traceability.
- Shelf life in months (if applicable)
- Storage condition. (Manufacturer recommendation).
- First year sold
- Warnings
- Active ingredient
- Principles of operation/mode of action (how it works/ operates)
- Picture or drawing of the device which should be details (include sufficient explanation to understand the drawing)
- Description of any devices required to operate the device (IT infrastructure, laptop, mobile smart phone) if applicable.
- Declaration (does the device require any specific declaration to be made such as containing animal tissue / medicines/human blood derivatives)

IVD device grouping/ bundling:

This field describes which grouping / bundling to be filled as per Annex (1) 50 product maximum in one application, and it include Product name, manufacturer name, trade brand name, model number, risk classification and category. Refer to bundling and grouping guidance for more information.

- IVD Device Single
- IVD Device Family
- IVD Device System
- IVD Family of Systems
- IVD Device test Kit
- IVD Device Cluster
- IVD Groping/SET

Note: If the device has accessories, they may be included with the device within the same registration application, unless they are marketed separately

IVD Device Accessories information:

In case there are any accessories it will including the following:

- Accessories Name.
- Risk classification.
- Serial Number.
- Description of accessories.
- GMDN.
- Model No.
- Device Identifier.
- Batch/ Lot/ reference no.
- Label.
- Catalogue.
- IFU.

Section 4: Device Labeling

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

- Instruction for Use (IFU).
- Label on the Device.
- Product Labels and Packaging
- Promotional materials /catalogue

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 Principal 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.

Section 6: Summary of design Verification & Validation

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

- **Design Stages**
  - Reference to design procedure.
  - Description of design stages
  - Confirmation of the verification and validation conducted on the device
- **Manufacturing processes**

- Manufacturing information to include:
- Manufacturing process flow
- Manufacturing specifications including in process testing

- Final inspection and acceptance criteria
- Manufacturing validation

- **Manufacturing Structure**

- Name and address of place where design was carried out (all sites and subcontractors).
- Name and address of place where manufacturing is carried out (all sites andsubcontractors).
- Detail of suppliers including identification of critical suppliers.
- Confirmation of subcontractor contracts (if applicable).

Section 7: Product Verification and Validation

This section provides product certificates if product follow EU jurisdiction:

- **IVD high risk** (class D)

- CE certificate
- Full Quality Assurance / Equivalent.
- Design Examination / Equivalent.
- Batch verification
- Type Examination / Equivalent.
- Production Quality Assurance / Equivalent.
- Others

- **IVD moderate to high (class C)**

- Full Quality Assurance / Equivalent.
- Type Examination / Equivalent.
- EC Verification / Equivalent.
- Production Quality Assurance / Equivalent.
- Others

This section provides product certificates if product follow US jurisdiction:

- **IVD high risk** (class D):

- PMA
- Other

- **IVD moderate to high (class C)**

- PMA
- 510K
- Others

Section8: Clinical evidence

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

- Clinical performance
- Analytical performance
- Stability testing.
- Shelf-life testing.
- Software validation

Section 9: Post Market control

In Vitro diagnostics 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:

- The conclusions of the benefit-risk determination
- The main findings of the post-market clinical follow-up (PMCF)
- 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.
- Manufacturers of high risk devices (C&D) shall update the PSUR at least annually.

Section 10: Status of device distribution

In this section the establishment of IVD devices should:

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

Section 11: Declaration of conformity

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

- Product Name
- Model number
- Classification
- Statement that the declaration is issued under the sole responsibility of the manufacturer
- Issued/signed stamped from manufacturer.

Section 12: Benefit-Risk Analysis and risk management

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

CHAPTER THREE

Responsibilities:

Department and section staff	Support the review, evaluation, and processing of Moderate-High and High-Risk IVD registration applications in accordance with the applicable regulatory requirements.
Department Directors and Section Heads	Supervise and ensure compliance with the registration procedures, approve recommendations, and provide oversight for all Moderate-High and High-Risk IVD registration activities.
QASM Section	Monitor quality assurance aspects, safety, and post-market surveillance related to registered Moderate-High and High-Risk IVD.
DG-DSC	Oversee implementation of the regulatory framework, ensure alignment with national and international standards, and endorse final decisions on Moderate-High and High-Risk IVD registrations.

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial Release	October 2025
2		
3		

References:

International Medical Device Regulators Forum (IMDRF). (2024). *IMDRF/GRRP WG/N78:2024 – CSDT: Common Submission Dossier Template for Medical Devices and IVD Medical Devices.*

International Medical Device Regulators Forum (IMDRF). (2018). *IMDRF/GRRP WG/N47:2018 – Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices.*

International Medical Device Regulators Forum (IMDRF). (2016). *IMDRF/GRRP WG/N19:2016 – Definitions of the Terms Manufacturer, Authorized Representative, Importer and Distributor.*

International Medical Device Regulators Forum (IMDRF). (2014). *IMDRF/GRRP WG/N26:2014 – Principles of Medical Devices Classification.*

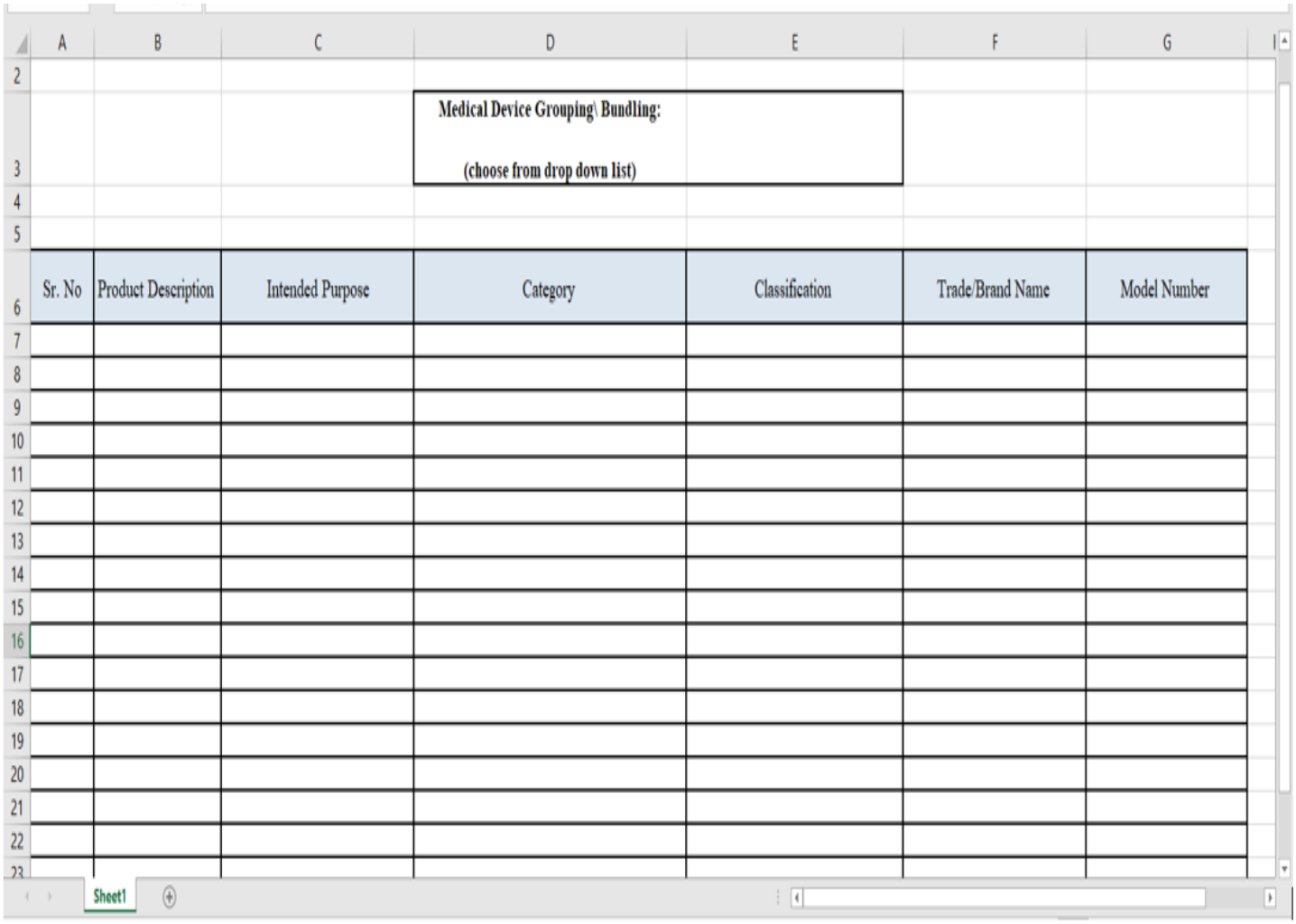
International Medical Device Regulators Forum (IMDRF). (2023). *IMDRF/GRRP WG/N52:2023 – Labelling for Medical Devices, including In Vitro Diagnostic Medical Devices (IVDs).*

World Health Organization (WHO). (2017). *Global Model Regulatory Framework for Medical Devices including In Vitro Diagnostic Medical Devices.* Geneva: World Health Organization.

Annexes

Appendix 1: Medical Device Grouping /Bundling

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



Medical Device Grouping\ Bundling:

(choose from drop down list)

Sr. No	Product Description	Intended Purpose	Category	Classification	Trade/Brand Name	Model Number

Sheet1

Appendix 2: Essential Principles of Safety and Performance for Medical Devices

Essential Principal Checklist	
Device:	

Essential Principal	Applicable to the device?	Standards Applied	Method of Conformity	Identity of Specific Documents
5.1 General Requirements				
5.1.1 Medical devices and IVD medical devices should achieve the performance intended by their manufacturer and should be designed and manufactured in such a way that, during intended conditions of use, they are suitable for their intended purpose. They should be safe and perform as intended, should have risks that are acceptable when weighed against the benefits to the patient, and should not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons.				
5.1.2 Manufacturers should establish, implement, document and maintain a risk management system to ensure the ongoing quality, safety and performance of the medical device and IVD medical device. Risk management should be understood as a continuous iterative process throughout the entire lifecycle of a medical device and IVD medical device,				

requiring regular systematic updating. In carrying out risk management manufacturers should: a) establish and document a risk management plan covering each medical device and IVD medical device; b) identify and analyze the known and foreseeable hazards associated with each medical device and IVD medical device; c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; d) eliminate or control the risks referred to in point (c) in accordance with the requirements of points 5.1.3 and 5.1.4 below; e) evaluate the impact of information from the production and postproduction phases, on the overall risk, benefit-risk determination and risk acceptability. This evaluation should include the impact of the presence of previously unrecognized hazards or hazardous situations, the acceptability of the estimated risk(s) arising from a hazardous situation, and changes to the generally acknowledged state of the art. f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of points 5.1.3 and 5.1.4 below.				

5.1.3 Risk control measures adopted by manufacturers for the design and manufacture of the medical device and IVD medical device should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, manufacturers should control risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers should, in the following order of priority: a) eliminate or appropriately reduce risks through safe design and manufacture b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users				
5.1.4 The manufacturer should inform users of any relevant residual risks.				
5.1.5 In eliminating or reducing risks related to use, the manufacturer should: a) appropriately reduce the risks related to the features of the medical device and IVD medical device and the environment in which the medical device and IVD medical device are intended to be used (e.g. ergonomic/usability features, tolerance to dust and humidity) and				

	b) b) give consideration to the technical knowledge, experience, education, training and use environment and, where applicable, the medical and physical conditions of intended users..				
5.1.6	The characteristics and performance of a medical device and IVD medical device should not be adversely affected to such a degree that the health or safety of the patient and the user and, where applicable, of other persons are compromised during the expected life of the device, as specified by the manufacturer, when the medical device and IVD medical device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained and calibrated (if applicable) in accordance with the manufacturer's instructions.				
5.1.7	IVD medical devices should be designed, manufactured and packaged in such a way that their characteristics and performance, including the integrity and cleanliness of the product and when used in accordance with the intended use, are not adversely affected by transport and storage (for example, through shock, vibrations, and fluctuations of temperature and humidity), taking account of the instructions and information provided by the manufacturer. The performance, safety, and sterility of the medical device and IVD medical device should be sufficiently maintained				

	throughout any shelf-life specified by the manufacturer.				
5.1.8	IVD medical devices should have acceptable stability during their shelf-life, during the time of use after being opened (for IVDs, including after being installed in the instrument), and during transportation or dispatch (for IVDs, including samples).				
5.1.9	All known and foreseeable risks, and any undesirable side-effects, should be minimized and be acceptable when weighed against the evaluated benefits arising from the achieved performance of the device during intended conditions of use taking into account the generally acknowledged state of the art.				

5.2 Clinical Evaluation			
5.2.1 Where appropriate and depending on jurisdictional requirements, a clinical evaluation may be required. A clinical evaluation should assess clinical data to establish that a favorable benefit-risk determination exists for the medical device and IVD medical device in the form of one or more of the following: a) clinical investigation reports (for IVDs, clinical performance evaluation reports) b) published scientific literature/reviews c) clinical experience			
5.2.2 Clinical investigations should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. These principles protect the rights, safety and well-being of human subjects, which are the most important considerations and shall prevail over interests of science and society. These principles shall be understood, observed, and applied at every step in the clinical investigation. In addition, some countries may have specific regulatory requirements for pre-study protocol review, informed consent, and for IVD medical devices, use of leftover specimens.			
5.3 Chemical, Physical, and Biological Properties			
5.3.1 Regarding chemical, physical, and biological properties of a medical device and IVD medical device, particular attention should be paid to the following: **a)** the choice of materials and substances used, particularly with respect to: - toxicity; - biocompatibility; and IMDRF GRRP WG/N47 FINAL: 2018 31 October 2018 Page 15 of 35 -flammability; **b)** the impact of processes on material properties;			

c) where appropriate, the results of biophysical or modelling research whose validity of which has been demonstrated beforehand; **d)** the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance; **e)** surface properties; and **f)** the confirmation that the device meets any defined chemical and/or physical specifications.			
5.3.2 Medical devices and IVD medical devices should be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to users and patients, taking account of the intended purpose of the medical device and IVD medical device, and to the persons involved in the transport, storage and use of the medical device and IVD medical device. Particular attention should be paid to tissues of users and patients exposed to those contaminants and residues and to the duration and frequency of exposure.			
5.3.3 The Medical devices and IVD medical device should be designed and manufactured in such a way as to appropriately reduce the risks posed by substance egress (including leaching and/or evaporation), degradation products, processing residues, etc. Special attention should be given to leaking or leaching of substances, which are carcinogenic, mutagenic or toxic to reproduction.			
5.3.4 The medical device and IVD medical device should be designed and manufactured in such a way as to appropriately reduce the risks posed by the unintentional ingress of substances into the device, taking into account the medical device and IVD medical device and the nature of the environment in which it is intended to be used.			

5.3.5 Medical devices and IVD medical devices and their manufacturing processes should be designed in such a way as to eliminate or to appropriately reduce the risk of infection to users and all other persons who may come in contact with the IVD medical device. The design should: a) allow for easy and safe handling b) appropriately reduce any microbial leakage from IVD medical device and/or microbial exposure during use; c) prevent microbial contamination of IVD medical device or its content (e.g., specimens); and/or d) appropriately reduce the risks from unintended exposure (e.g., cuts and pricks (such as needle stick injuries), eye splashes, etc.).			
5.4 Chemical, Physical, and Biological Properties			
5.4.1 Where necessary, Medical devices and IVD medical devices should be designed to facilitate their safe cleaning, disinfection, sterilization, and re-sterilization by the user, as appropriate.			
5.4.2 Medical devices and IVD medical devices labeled as having a specific microbial state should be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.			
5.4.3 Medical devices and IVD medical devices, delivered in a sterile state should be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It should be ensured that the integrity of that			

packaging is clearly evident to the final user (for example, through the use of tamper-proof packaging).			
5.4.4 Medical devices and IVD medical devices labelled as sterile should be processed, manufactured, packaged, and sterilized by means of appropriate, validated methods. The shelf-life of these medical devices and IVD medical devices should be determined by validated methods.			
5.4.5 Medical devices and IVD medical devices intended to be sterilized, either by the manufacturer or user, should be manufactured and packaged in appropriate and controlled conditions and facilities.			
5.4.6 Where the medical devices and IVD medical devices are provided non-sterile and are intended to be sterilized prior to use: a) the packaging system should minimize the risk of microbial contamination and should be suitable taking account of the method of sterilization indicated by the manufacturer; and b) the method of sterilization indicated by the manufacturer should be validated.			
5.4.7 For medical devices and IVD medical devices placed on the market in both sterile and non-sterile conditions, the label should clearly distinguish between these versions.			
5.5 Considerations of Environment and Conditions of Use			
5.5.1 If the medical device or IVD medical device is intended to be used in combination with other medical devices or IVD medical devices and/or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the medical device or IVD medical device. Any known restrictions on use applying to such combinations should be indicated on the label			

and/or in the instructions for use. Any connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, should be designed and manufactured in such a way as to remove or appropriately reduce all possible risks, including incorrect connections or safety hazards.			
5.5.2 Medical devices and IVD medical devices should be designed and manufactured in consideration of the intended environment and conditions of use, and in such a way as to remove or appropriately reduce the: **a)** risks of injury to the users or other persons in connection with its physical and ergonomic/usability features; **b)** risks of user error due to the design of the medical device or IVD medical device user interface, ergonomic/usability features, and the environment in which the medical device or IVD medical device is intended to be used; **c)** risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, and/or variations in pressure and acceleration; **d)** risks associated with the use of the medical device or IVD medical device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during intended conditions of use; **e)** risks associated with the possible negative interaction between software and the information technology (IT) environment within which it operates and interacts; **f)** environmental risks from unexpected egress of substances from the medical device or IVD medical device during use, taking into account the medical device or IVD medical device and the nature of the environment in which it is			

intended to be used; **g)** the risk of incorrect identification of specimens/samples/data and the risk of erroneous results due to, for example, confusing color and/or numeric coding on specimen receptacles, removable parts and/or accessories used to perform the analysis, test, or assay as intended; and **h)** the risks of interference with other medical devices or IVD medical devices normally used in diagnosis, monitoring or treatment.			
5.5.3 Medical devices and IVD medical devices should be designed and manufactured in such a way as to remove or appropriately reduce the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to medical devices and IVD medical devices whose intended use includes exposure to or in association with flammable or explosive substances or substances which could cause combustion.			
5.5.4 Medical devices and IVD medical devices should be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively. Specifically, **a)** When maintenance is not possible, for example, with implants, the risks from ageing of materials, etc. should be appropriately reduced. **b)** When adjustment and calibration are not possible, for example, with certain kinds of thermometers, the risks from loss of accuracy of any measuring or control mechanism are appropriately reduced.			
5.5.5 Medical devices and IVD medical devices that are intended to be operated together with other medical devices or IVD medical devices or products should be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.			
5.5.6 Medical devices and IVD medical devices should be designed and manufactured in such a			

	way as to appropriately reduce the risk of unauthorized access that could hamper the device from functioning as intended or impose a safety concern.			
5.5.7	Any measurement, monitoring or display scale functions of medical devices and IVD medical devices should be designed and manufactured in line with ergonomic/usability principles, taking account of the intended purpose, users and the environmental conditions in which the medical devices and IVD medical devices are intended to be used.			
	Medical devices and IVD medical devices should be designed and manufactured in such a way as to facilitate their safe disposal or recycling and the safe disposal or recycling of related waste substances by the user, patient or other person. The instructions for use should identify safe disposal or recycling procedures and measures.			
5.6	**Protection against Electrical, Mechanical, and Thermal Risks**			
5.6.1	Medical devices and IVD medical devices should be designed and manufactured in such a way as to protect users against mechanical risks connected with, for example, resistance to movement, instability, and moving parts.			
5.6.2	Medical devices and IVD medical devices should be designed and manufactured in such a way as to appropriately reduce the risks arising from vibration generated by the medical devices or IVD medical 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.			
5.6.3	Medical devices and IVD medical devices should be designed and manufactured in such a way as to appropriately reduce 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.			
5.6.4	Medical devices and IVD medical devices should be designed and manufactured in such a way as to appropriately reduce the risk related to the failure of any parts within the device that are intended to be connected or reconnected before or during use.			
5.6.5	Accessible parts of medical devices and IVD medical 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.			
5.7	**Active Medical Devices and IVD Medical Devices and Medical Devices Connected to Them**			
5.7.1	For active medical devices and IVD medical devices, in the event of a single fault condition, appropriate means should be adopted to eliminate or appropriately reduce consequent risks.			
5.7.2	Medical devices and IVD medical devices where the safety of the patient depends on an internal power supply should be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical.			
5.7.3	Medical devices and IVD medical devices where the safety of the patient depends on an external power supply should include an alarm system to signal any power failure.			
5.7.4	Medical devices and IVD medical 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.			
5.7.5	Medical devices and IVD medical devices should be designed and manufactured in such a			

	way as to appropriately reduce the risks of creating electromagnetic interference which could impair the operation of any devices or equipment in the intended environment.			
5.7.6	Medical devices and IVD medical devices should be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.			
5.7.7	Medical devices and IVD medical devices should be designed and manufactured in such a way as to appropriately reduce the risk of accidental electric shocks to the user or any other person, both during normal use of the medical device or IVD medical device and in the event of a single fault condition in the medical device or IVD medical device, provided the medical device or IVD medical device is installed and maintained as indicated by the manufacturer.			
5.8	**Medical Devices and IVD Medical Devices that Incorporate Software or are Software as a Medical Device**			
5.8.1	Medical devices and IVD medical devices that incorporate electronic programmable systems, including software, or are software as a medical device, should be designed to ensure accuracy, reliability, precision, safety, and performance in line with their intended use. In the event of a single fault condition, appropriate means should be adopted to eliminate or appropriately reduce consequent risks or impairment of performance.			
5.8.2	For medical devices and IVD medical devices that incorporate software or are software as a medical device, the software should be developed, manufactured and maintained in accordance with the state of the art taking into account the principles of development life cycle (e.g., rapid development cycles, frequent changes, the cumulative effect of changes), risk management (e.g., changes to system, environment, and data), including information security (e.g., safely implement updates),			

verification and validation (e.g., change management process).			
5.8.3 Software that is intended to be used in combination with mobile computing platforms should be designed and developed taking into account the platform itself (e.g. size and contrast ratio of the screen, connectivity, memory, etc.) and the external factors related to their use (varying environment as regards level of light or noise).			
5.8.4 Manufacturers should set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorized access, necessary to run the software as intended.			
5.8.5 The medical device and IVD medical device should be designed, manufactured and maintained in such a way as to provide an adequate level of cybersecurity against attempts to gain unauthorized access.			
5.9 Medical Devices and IVD Medical Devices with a Diagnostic or Measuring Function			
5.9.1 Medical devices and IVD medical devices with a diagnostic or measuring (including monitoring) function should be designed and manufactured in such a way as to provide, among other performance characteristics, sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. a) Where applicable, the limits of accuracy should be indicated by the manufacturer. b) Whenever possible, values expressed numerically should be in commonly accepted, standardized units, and understood by users of the medical device or IVD medical device. While generally supporting the convergence on the global use of internationally standardized measurement units, considerations of safety, user familiarity and established clinical practice			

may justify the use of other recognized measurement units. c) The function of the controls and indicators should be clearly specified on the medical device and IVD medical device. Where a medical device or IVD medical 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 d) the patient.			

5.10 Labeling			
5.10.1 Medical devices and IVD medical devices should be accompanied by the information needed to distinctively identify the medical device or IVD medical device and its manufacturer. Each medical device and IVD medical device should also be accompanied by, or direct the user to any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the medical device or IVD medical device itself, on the packaging or in the instructions for use, or be readily accessible through electronic means (such as a website), and should be easily understood by the intended user.			
5.11 Protection against Radiation			
5.11.1 Medical devices and IVD medical devices should be designed, manufactured and packaged in such a way that exposure of users, other persons, or where appropriate, patients, to radiation is appropriately reduced in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic and therapeutic purposes.			
5.11.2 The operating instructions for medical devices and IVD medical devices emitting hazardous or potentially hazardous radiation should contain detailed information as to the nature of the emitted radiation, the means of protecting the users, other persons, or where appropriate, patients, and ways of avoiding misuse and of appropriately reducing the risks inherent to transport, storage and installation.			
5.11.3 Where medical devices and IVD medical devices are intended to emit hazardous, or potentially hazardous, radiation, they should be fitted, where possible, with visual displays and/or audible warnings of such emissions.			
5.11.4 Medical devices and IVD medical devices should be designed and manufactured in such a way that that the exposure of users, other			

	persons, or where appropriate, patients, to the emission of unintended, stray or scattered radiation is appropriately reduced. Where possible and appropriate, methods should be selected which reduce the exposure to radiation of users, other persons, or where appropriate, patients, who may be affected.			
5.11.5	For medical devices and IVD medical devices emitting hazardous or potentially hazardous radiation and that require installation, information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure should be specified in the operating instructions.			
5.11.6	Where medical devices and IVD medical devices are intended to emit hazardous, or potentially hazardous, radiation, accessible to user, they should be designed and manufactured in such a way as to ensure that the quantity, geometry, energy distribution (or quality), and other key characteristics of the radiation emitted can be appropriately controlled and adjusted and, where appropriate, monitored during use. Such medical devices and IVD medical devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.			
5.12	**Protection against the Risks posed by Medical Devices and IVD Medical Devices intended by the Manufacturer for use by Lay Users**			
5.12.1	Medical devices and IVD medical devices for use by lay users (such as self-testing or near-patient testing intended for use by lay users) should be designed and manufactured in such a way that they perform appropriately for their intended use/purpose taking into account the skills and the means available to lay users and the influence resulting from variation that can be reasonably anticipated in the lay user's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay user to understand and apply when using the medical device or IVD medical device and interpreting the results.			

5.12.2 Medical devices and IVD medical devices for use by lay users (such as self-testing or near-patient testing intended for use by lay users) should be designed and manufactured in such a way as to: a) ensure that the medical device and IVD medical device can be used safely and accurately by the intended user per instructions for use. When the risks associated with the instructions for use cannot be mitigated to appropriate levels, these risks may be mitigated through training. b) appropriately reduce the risk of error by the intended user in the handling of the medical device or IVD medical device and, if applicable, in the interpretation of the results.			
5.12.3 Medical devices and IVD medical devices for use by lay users (such as self-testing or near-patient testing intended for use by lay users) should, where appropriate, include means by which the lay user: a) can verify that, at the time of use, the medical device or IVD medical device will perform as intended by the manufacturer, and b) is warned if the medical device or IVD medical device has failed to operate as intended or to provide a valid result.			
5.13 Medical Devices and IVD Medical Devices Incorporating Materials of Biological Origin			
5.13.1 For medical devices and IVD medical devices that include tissues, cells, or substances of animal, plant, or bacterial origin or their derivatives, which are non-viable or rendered non-viable the following should apply: **a)** where appropriate, taking into account the animal species, tissues and cells of animal origin, or their derivatives, should originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals may need to be retained by			

manufacturers depending on jurisdictional requirements. **b)** sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, should be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regards to viruses and other transmissible agents should be addressed by implementation of validated state of the art methods of elimination or inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the medical device or IVD medical device.			
5.13.2 For Regulatory Authorities, which regulate products manufactured utilizing tissues, cells, or substances of human origin or their derivatives as medical devices or IVD medical devices, the following should apply: **a)** donation, procurement and testing of the tissues and cells should be done in accordance with jurisdictional requirements; and **b)** processing, preservation and any other handling of those tissues and cells or their derivatives should be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by appropriate methods of sourcing and by implementation of validated state of the art methods of elimination or inactivation in the course of the manufacturing process.			
5.13.3 For medical devices and IVD medical devices manufactured utilizing biological substances other than those referred to in Sections 5.13.1 and 5.13.2 (for example, materials of plant or bacterial origin), the processing, preservation, testing and handling of those substances should be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regards to viruses and			

other transmissible agents should be addressed by appropriate methods of sourcing and by implementation of validated state of the art methods of elimination or inactivation in the course of the manufacturing process. Other requirements can apply in specific regulatory jurisdictions.			
7.1 Chemical, Physical and Biological Properties			
7.1.1 With regards to chemical, physical, and biological properties for IVD medical devices, attention should be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyze or marker to be detected and measured (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.			
7.2 Performance Characteristics			
7.2.1 IVD medical devices should achieve the analytical and clinical performances, as stated by the manufacturer that are applicable to the intended use/purpose, taking into account the intended patient population, the intended user, and the setting of intended use. These performance characteristics should be established using suitable, validated, state of the art methods. For example: **a)** The analytical performance can include, but is not limited to, a. Traceability of calibrators and controls b. Accuracy of measurement (trueness and precision) c. Analytical sensitivity/Limit of detection d. Analytical specificity e. Measuring interval/range f. Specimen stability **b)** The clinical performance, for example			

diagnostic/clinical sensitivity, diagnostic/clinical specificity, positive predictive value, negative predictive value, likelihood ratios, and expected values in normal and affected populations. **c)** Validated control procedures to assure the user that the IVD medical device is performing as intended, and therefore the results are suitable for the intended use.			
7.2.2 Where the performance of an IVD medical device depends on the use of calibrators or control materials, the traceability of values assigned to such calibrators or control materials should be ensured through available reference measurement procedures or available reference materials of a higher order.			
7.2.3 Wherever possible, values expressed numerically should be in commonly accepted, standardized units and understood by the users of the IVD medical device.			
7.2.4 The performance characteristics of the IVD medical device should be evaluated according to the intended use statement which may include the following: **a)** intended user, for example, lay user, laboratory professional; **b)** intended use environment, for example, patient home, emergency units, ambulances, healthcare centers, laboratory; **c)** relevant populations, for example, pediatric, adult, pregnant women, individuals with signs and symptoms of a specific disease, patients undergoing differential diagnosis, blood donors, etc. Populations evaluated should represent, where appropriate, ethnically, gender, and genetically diverse populations so as to be representative of the population(s) where the device is intended to be marketed. For infectious diseases, it is recommended that the populations selected have similar prevalence rates.			

Appendix 3: Procedure Flowchart