UNITED ARAB EMIRATES

MINISTRY OF HEALTH

دولة الإمارات العربية المتحدة
وزارة الصحة

UAE Medical Devices Registration Guideline

DEFINITIONS

MEDICAL DEVICE (MD):

The term "medical device" in general includes all products used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap but excludes drugs, and as a rule does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means.

MEDICAL DEVICES includes the following three main TYPES:

A- *MEDICAL DEVICE (MD):*

Means "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnose, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury of handicap,
- Investigation, replacement or modification of the anatomy or of a Physiological process, Control of conception ,

and, which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means " (EU Medical Device Directive,93/42/EEC, and Global Harmonization Task Force).

B- *ACTIVE IMPLANTABLE MEDICAL DEVICE (AIMD)*

Powered Implantable Medical Devices e.g. pacemakers etc

C*- 'IN VITRO DIAGNOSTIC DEVICE (IVD)'* but does not include any device that is used in relation to animals (veterinary applications).

Any medical device which is a reagent product, calibrator, control material, kit, instruments, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- Concerning a physiological or pathological state of health of disease, or
- Concerning a congenital abnormality or
- To determine the safety and compatibility with the potential recipients or to monitor therapeutic measures

This includes a specimen receptacle for the primary containment and preservation of specimens derived from the human body but not a product for general laboratory use, unless that product, in view of their characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination.

'ACCESSORY'

Means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

'MANUFACTURER'

Means the natural or legal person with responsibility for the design manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this guideline to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name.

'INTENDED PURPOSE'

Means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

'PLACING ON THE MARKET'

Means the first making available in return for payment or free of charge of a device with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

'PUTTING INTO SERVICE'

Means the stage at which a device is ready for use on the Community market for the first time for its intended purpose.

UAE Medical Devices Registration Guidelines

ARTICLE 1
PREFACE

Medical Device Regulation in UAE will be supervised and directed by Drug Control Dept / MOH. Classification, requirements and evaluation of Medical Devices in UAE will be mainly simulation of rules and regulations recognized by the international regulatory benchmarks, which are mainly:

A- UAE Pharmacy Law No 4 for 1983
B- Global Harmonization Task Force (GHTF) for Medical Device ,
C- EU Medical Device Directives 93/42/EEC, EU .in Vitro Diagnostic Device Directive (IVDD) 98/79/EC and EU Active Implantable Medical Device Directive (AIMDD) 90/385/EEC.
D- US FDA (United State Food & Drug Administration)
E- Australia TGA

The regulation of medical devices in UAE is aimed to maintain a balance between ensuring product safety, quality and effectiveness and providing the public with timely access to medical devices and preventing the entrance of unsafe or ineffective devices into the UAE market.

ARTICLE 2
SCOPE

2.1 These guidelines shall apply to medical devices and their accessories. For the purposes of these guidelines, accessories shall be treated as medical devices in their own right.

2.2 Where a device is intended to administer a medicinal product, that device shall be governed by this guideline, without prejudice to the corresponding regulations for registration of medicinal products for human use set by the Drug Control Dept.
If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by corresponding regulations for registration of medicinal products for human use set by the Drug Control Dept.
The relevant essential requirements of Annex I shall apply as far as safety and performance related device features are concerned.

2.3 Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and which is liable to act upon the body with action ancillary to that of the device, that device must be assessed and authorized in accordance with this guideline

2.4. This guideline does not apply to
a) active implantable devices
b) medicinal products
c)cosmetic products

d) human blood, human blood products, human plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells;
e) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin;
f) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.
g) Medical Devices not in direct contact with human beings, not used for channelling blood products or not in direct contact with open wounds.

ARTICLE 3
ESSENTIAL REQUIREMENTS

The Medical devices must meet the essential requirements set out in Annex 2 which apply to them, taking account of the intended purpose of the devices concerned.

ARTICLE 4
CLASSIFICATION

5.1. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex 3. Classification will be extremely claim sensitive

5.2. According to the class of the concerned product and the available bench mark regulatory bodies' approvals, the committee on Medical Device registration will decide to approve its registration through either one or two stages registration procedure.

ARTICLE 5
MEDICAL DEVICE REGISTRATION COMMITTEE

6.1 The manufacture or its local authorized representative is required to apply for the Committee on Medical device registration at the Technical Section of the Drug Control Dept of MOH to register their medical devices prior to first placement on the local market. Only Medical Devices a valid Registration certificate will be allowed to be placed in the market given that they are covered within the scope of this guideline.

6.2 The application to Register a medical device in UAE must be made by the device manufacturer or its local authorized representative who is explicitly designated by either the local or foreign manufacturer, to act and to be addressed by DCD in UAE, on behalf of the manufacturer, with regards to the latter's legal obligations and responsibilities.

The Committee will briefly review the MD in concern and it will decide if it will be either exempted from further evaluation or otherwise to issue the applicant an official letter requesting submission of more documents
The Committees decision will be made according to set criteria, which in turn depends on the classification of the product according to the EU rules for classifying of MD mentioned in Annex 2.

Further Verification and full evaluation by the committee on medical Devices: Evidence of safety and effectiveness must be submitted to the committee to support the placement of the concerned MD on the UAE market.

ARTICLE 6
REGISTRATION FILE

7.1 The manufacturer or its local authorized representative is required to maintain objective evidence on the safety and effectiveness of the medical device. The objective evidence is used to assess the quality, safety and effectiveness of the medical device for its intended use, to identify the risk involved when for the medical condition and to ensure that these risk are acceptable when weighed against its benefits

7.2 The committee will go through each application, where it will use the support documents submitted for monitoring of misleading claims -if any -associated with the device.

7.3 The required documents and information are summarized in table 1 below classified according the stages involved in the registration procedure

Table 1

List of closures required for MD Registration
Enclosure A: *Application form* filled ,stamped and signed by the manufacturer
Enclosure B: *Manufacturer Certificates*
☐ Copies of all certificates related to ISO certification of ISO 9001:2000 standards. The ISO 13485:2003 standard attested and authenticated
☐ GMP original Certificate issued by the relevant health authorities at country of origin attested and authenticated
Enclosure C: *Regulatory Approval*
☐ Copies of all certificates, documentation and letters of regulatory approval/clearance to manufacture, sell, import and export the medical device
Enclosure D: *Post-market Requirement*
☐ Provide evidence of established procedures and systems for Distribution Records, Complaint Handling, Adverse Incident Reporting and Recall.
Enclosure E: *Product Information*
☐ Device Description, Intended Use, Indications, Instructions of Use, Contraindications, Warnings, Precautions, Potential Adverse Events, Alternative Therapy, Device Labelling with a copy of the device label.
☐ Specifications of materials used in device manufacturing and packaging.

List of closures required for MD Registration
Enclosure F: Declaration of Conformity
☐ Copies of certification and document certifying conformity to product standards, safety and effectiveness requirements and quality systems in design and manufacturing.
☐ Quality Plan
☐ Manufacturing Process
Enclosure G: *Status of Device Distribution*
☐ Date of first introduction & use, list of countries where it is marketed and details of the regulatory status (e.g. marketing approval, product recall, product ban, etc.). A summary of the "mandatory" reported problems with the device since the introduction of the device in the market.
Enclosure H: *Safety and Effectiveness Data*
☐ Risk Assessment comprising of risk analysis, evaluation and reduction measures.
☐ Detailed information on Safety and Effectiveness Studies, which includes pre-clinical and clinical studies, process validation studies, software validation studies where appropriate, and literature studies, with Summary of Studies, Conclusions drawn from those studies and Bibliography of published reports dealing with the device.
☐ Objective evidence on the biological safety of the device, if it contains animal or human tissue or their derivative.
Enclosure I*: Human clinical data*
☐ Peer-reviewed scientific literature dealing with the device, and the written report
☐ Results and Conclusions of Human Clinical Studies
Enclosure J: *Stability Studies*
Enclosure K*; Quality Control lab requirements*
☐ Specifications ☐ Analysis method ☐ Analysis requirements
Enclosure J: Price certificate
☐ Ex- factory price ☐ CIF price ☐ Wholesaler price in country of origin ☐ Retail price in country of origin

7.4 Receipt of the application and application Number:
The Receipt form will include a checklist for support documents submitted by applicants to indicate the type of support documents that have been submitted in the application by placing a tick on the appropriate check box. The omission of required data or the provisions of incorrect information can delay the evaluations process. The Officer in Charge at the Technical Section of Drug Control dept will sign the receipt and keep a copy after giving it a serial number which will serve as an ID for the application for the purpose of follow up.

7.5 Table of contents
The contents page must precede the Enclosures of support documents, and should list the titles of the documents sets submitted under each enclosure.

7.6 Declaration by the applicant should be submitted declare that:

1. insures that all submitted documents are true
2. will be fully responsible for the product and post market plan submitted for complain handling or recall
3. c-will fully comply with the requirements of the Drug control dept after the placing the product in the market.

7.7 All documents, including certificates, should be in English or Arabic and to be according to explanation in Annex 1

ARTICLE 7
CERTIFICATE OF A MEDICAL DEVICE

8.1 When the medical Device proves its safety efficacy and compliance with all the essential requirements and gets approval of the committee on medical Devices it will be granted a Registration certificate which in turn entitles the applicant to import and freely sell the registered medical device given that the said applicant will comply with all the post marketing requirements in article nine.

8.2 A registration certificate will be valid for 5 years unless significant changes are made to the approved application data.

8.3 The Drug control dept can cancel the registration certificate if any of the following takes place:

8.3.1 Based on the request of the applicant
8.3.2 Based on non compliance with the manufacturer's obligations set in article nine.
8.3.3. The product proved to be not safe or harmful to health
8.3.4 The quality became substandard to that in the time of the application
8.3.5 They differ from the approved label
8.3.6 If Intellectual property rights of other similar product is violated.

8.4 The Director of Drug Control Dept will notify the registration holder in writing of the cancellation.

ARTICLE 8
POST-MARKET REQUIREMENTS AND OBLIGATIONS
MEDICAL DEVICE VIGILANCE SYSTEM

9.1 The purpose of a Medical Device Vigilance System is to minimize risk to the health and safety of patients, users and others by reducing the like hood of a serious incident involving a medical device being repeated. Close cooperation among the DCD, manufactures and practicing medical professionals is necessary to achieve an effective vigilance system

9.2 Manufacturers and local authorized representatives must also meet post-market requirements that consist of:

9.2.1 Maintain Distribution Records

The manufacturers, local authorized representatives, importers and distributors are required to keep distribution records to facilitate the accountability and traceability of a medical device. This ensures that the device distribution channels in UAE, including medical device exports from UAE, are identifiable

9.2.2 Maintain Complaint Handling procedures and records

The manufacturers and local authorized representative are required to maintain records of problem report relating to the safety of the device, including any consumer complains and perform corrective action if necessary.

9*.2.3 Maintain Adverse Incident reporting procedures and records*

The manufacturers and local authorized representative are required to notify the DCD of any adverse events related to a failure of the device or a deterioration of its effectiveness, or any inadequacy in its labelling or in its directions for use, which has resulted in the death or a serious deterioration in the state of health of a patient, users or other person, or could potentially lead to such consequences due to its recurrence.

9.2.4 Have Recall procedures in place

The manufacturers and local authorized representatives are to establish and implement documents, procedures that will enable them to carry out effective and timely investigations of reported problems and recalls; and maintaining records of incident reports and of actions taken in response to these reports. Given that defective or potentially defective medical devices should either be removed from the market or measures are taken to correct the problem in an effective and timely fashion.

9.3 The device manufacturer or its local authorized representative must submit the documents for the following post-market procedures in applying to place the medical device on the UAE market.

9.4 If a particular establishment has already submitted its post-market procedures in one product application. it need not repeat this submission in subsequent applications provided(a) proper reference are made to the documents submitted in the earlier application and (b) there are no additional requirements and no changes made to the procedures .

ARTICLE 9
IMPLEMENTATION

The implementation of the above articles and attached Annexes (Annex1, Annex2 and Annex 3 will be effective instantly after this guidance issue.

ANNEX 1
THE SUPPORT DOCUMENTS REQUIERD TO BE AVAILABLE IN REGISTRATION FILE

1.1 Application Form

A Standard form is available at the Drug Control Dept containing general medical device details. Such information will include the device name, applicant's company name and address, application date, indication for the types of documentation submitted.

Each form is to be used for only one medical device application. Applicants are required to complete and sign on the hard copy of the Application form(s). Applications submitted with incomplete application forms will be rejected.

1.2 Declaration by Applicant

Serves to obtain affirmation from the applicant that the submitted documents and data are correct and accurate. Applicants are required to complete and sign on the hard copy of the declaration form. Applications submitted with incomplete forms will be rejected.

Alternatively, a notarized agreement documentation stating the appointment of the local authorized representative by the manufacturer may be provided.

1.3 Enclosure of support documents

The submitted documents must be grouped according to their appropriate Enclosures based on the alphabetical allocations indicated in table 1above, support documents in the receipt. These Enclosures should be submitted in separated sections and indexed appropriately.

The scope of summary technical information submitted should correspond to the risk-based classification of the medical device. The DCL may request for additional data depending on the particular circumstance of the device.

1.4 Regulatory Approval

Medical devices with prior approval from recognized regulatory agencies

Medical device approvals or clearance from recognized regulatory authority, for example, from FDA (USA), EU (European Union), TGA (Australia) TPP (Canada) and/or MLHW (Japan) can be used to abridge the evaluation process for medical devices to be marketed in UAE.

Evidence of regular approval or clearance of the medical device in the form of certification and/or relevant documents must be provided, as original authenticated documents.

(i) US FDA clearance / approval

Certification for Foreign Government

The Certificate for Foreign Government is a written certification that a company or its devices are in compliance with US law.

(ii) EU Medical Device

EC Design Examination Certificate

Manufactures of Class lll medical devices must lodge with the notified body an application for examination of the design dossier relating to the product, which he plans to manufacture. The certification must contain the conclusions of the examination, the conditions of validity, the data needed for identification of the

approved design and, where appropriate, a description of the intended purpose of the product.

EC Type Examination Certificate
EC Type Examination is the procedure whereby a notified body ascertains that a representative sample of the production covered fulfils the relevant provisions of the EU Medical Device Directive. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, the conditions of validity and the data needed for identification of the type approved.

EC Certification for quality System/GMP
The manufacturer must ensure application of a quality approved for the design, manufacturer and final inspection of the products concerned. The applications for assessment of quality system must be lodged with a notified body , which examines the quality system and issues an EC Certificate if it finds that the full quality assurance system with the provisions of the various EU Medical Device Directives .

EC Declaration of Conformity
The declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations of the application, ensure and declares that the product concerned meet the provisions of the EU Medical Device Directive at every stage, from design to final inspection.

(iii) Australia TGA approval/clearance
Medical devices that are not excluded and exempted from the operation of the Therapeutic Goods Act 1989 are regulated under:

A- Registrable Devices
These therapeutic devices have to be 'Registered' in the Australian Register of Therapeutic Goods [ARTG] and have to undergo extensive pre-market evaluation before they can be supplied in Australia. Manufacturers are required to submit data to establish the quality, safety and effectiveness of their device for review by the TGA.
B- Listable Devices
These therapeutic devices have to be 'listed' in the ARTG, but don't have to undergo extensive pre-market evaluation before supply. Test certification and/or acceptable evidence of Good manufacturing Practice (GMP) are also required for some products.

(iv) Canada TPP clearance/approval
All medical devices must meet the safety and effectiveness requirements. Class II, III or IV medical device can only be sold or imported if the manufacturer of the device holds a license to device. Class II medical devices are manufactured according to the quality system standard CAN/CSA ISO 13488-98 and, Class III and IV devices are designed and manufactured according to the quality system standard CAN/CSA ISO 13485-98.

(v) Japan MHLW clearance /approval
Medical devices are regulated by the Pharmaceutical Affairs Law, which is enforced by the Japanese Ministry of Health, Labour and Welfare (MHLW).

1.5 Post-Market Requirement:

To provide the following:

1) Complaint Handling procedures and corrective measures to be taken in case of safety related incidents.
2) Post marketing surveillance plans and vigilance systems to be incorporated by the manufacturers and local authorized representative are required to notify the DCD of any adverse events related to a failure.
3) Recall procedures and plans.
4) Written commitment to:
   - ✓maintain distribution records that facilitate device tracking
   - ✓obtain feedback on design and product improvements
   - ✓To notify DCD of any adverse incident involving a medical device that has or might have led to a death or serious deterioration in health.
   - ✓Take corrective actions including recall of the devices where appropriate

1.6 Product Information

This requires a description of the device, intended use and instructions of use. Product information is manifested in the form of device labelling which must accompany each device. This includes any physician's manual, pack labelling, and promoting material and product brochure containing information on indications, contraindications, warnings, potential adverse effects and alternative therapy.

1.6.1 Device Description

Besides a general description of the device, a more detailed description of the device attributes is necessary to explain how the device functions, the basic scientific concepts that form the foundation for the device, the component materials and accessories used in its operation as well as packaging . A complete description of each functional component, material or ingredient of the device should be provided, with labelled pictorial representation of the device in the form of diagrams, photographs or drawing as, appropriate.

1.6.2 Intended Use

This means the use for which the medical device is intended for which it is suited to the data supplied by the manufacturer in the instruction as well as the functional capability of the device.

1.6.3 Indications

This is a general description of the disease or condition that the device will diagnose, treat, prevent cure, or mitigate includes a description of the target patient population for which the device is intended.

1.6.4 Instruction of Use

These are all necessary information from the manufacturer including the procedures, methods, frequency, duration, quantity and preparation to be followed for safe use of the medical device. Instruction needed to use the device in a safe manner shall, to the extent possible, be included on the device itself and/or on its packaging.

1.6.5 Contraindications

This is a general description of the disease or condition and the patient population for which the device should not be used for the purpose of diagnose, treating, curing or mitigating. Contraindications are conditions under which the

device should not be used because the risk of use clearly outweighs any possible benefit.

1.6.6 Warnings

This is the specific hazard alert information that a user needs know before using the device.

1.6.7 Precautions

This alerts the user to exercise special care necessary for the safe and effective use of the device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life-threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the device of the use or misuse and the care necessary to avoid such effects.

1.6.8 Potential Adverse Effects

These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/ user, or side effects from the use of the medical device, under normal conditions.

1.6.9 Alternative Therapy

This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the device is intended.

1.6.10 Device Labelling

This is the description and information t literature that accompanies the device any time while it is held for sale or shipped, such as any physician's manual, pack labelling, promotional material and product brochures etc.

1.6.11 Physician's Manual

The physician's manual is also otherwise known as the user manual, operator’s manual, prescriber's manual or reference manual. It contains directions under which the physician or end-user can use a device safely and for its intended purpose. This should include information on indications, contraindications, warnings, precautions, potential adverse effects, alternative therapy and the conditions that should be managed during normal use to maintain the safety and effectiveness of the device.

1.6.12 Pack Labelling

This is printed, written or graphic product information provided on or attached to one or more levels of packaging, including the outer packaging or the outside container wrapper. Any pack labelling which is not provided on the outer packaging must be easily legible through this outer packaging.

1.6.13 Promotional Material

This is any mode or medium of disseminating product information for advertising and/or labelling purpose (s) , for example all forms of printed (e.g. posters, tags, brochures, pamphlets, circulars, booklets, instruction books, direction sheets, etc .) , written or graphic product information and description, including those transmitted by means of print, radio and television mass media .

1.6.14 Specifications of materials used in device manufacturing and packaging

The material identifications and specifications must be provided including raw materials and components. The information must include complete chemical, biological and physical characterization of all component materials.

1.7 Declaration of Conformity

A declaration of conformity is required consisting of the manufacturer's declaration that the medical device complies with the quality, safety and effectiveness requirements. The manufacturer can only prepare a declaration of conformity after appropriately performing a critical design review minimizing risk and documenting the objective evidence into a summary technical file. Certification to demonstrate this compliance should also be submitted.

Compliance with recognized standards may be used, if the manufacturer chooses, to demonstrate the relevant quality, safety and effectiveness requirement of the medical device. Documentation should include the standards itself, how it was applied, deviations, test results other outputs and the certification obtained.

If devices contain biological materials, the devices and manufacturing processes must be designed in such ways as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. Materials of animal origin must form animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the material. Safety with regards to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.

The manufacturer can provide a declaration of product conformity in the form as appropriate product certification. For example CE mark is a declaration by the manufacturer that the product meets all the appropriate of the relevant legislation including those relating to safety and, where required has been assessed accordingly. The declaration of conformity to good manufacturing practices requires that each manufacturer established and maintains a quality system that is appropriate for the specific medical device(s)designed or manufactured and is certified through a third party-attestation. The Authority reserves the right to inspect and audit a manufacturing site for the purpose of monitoring compliance to the appropriate good manufacturing practice.

Quality plan

Quality Plan sets out the quality practices, resources and sequence of activities relevant to the device including service along with type of inspection equipment record requirement.

This quality plan would outline the design and process control material characterization. The plan may be presented as a narrative or in the form a flow diagram.

Manufacturing Process

Manufacturing Process for the device should be provided in the form of a list of resources and activities that transform inputs into the desired output. The manufacturing process should include the appropriate equipment specifications, manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing packaging,

labelling storage product distribution, appropriate installation, and maintenance and servicing. Sufficient details must be provided to enable a person generally familiar with quality system to judge the appropriateness of the controls in place. The sterilization method and processing should be included if any.

If multiple facilities are involved in the manufacture of a device, the applicable information for each facility must be submitted. Firms that manufacture or process the device under contract to the manufacturer may elect to submit all or a portion of the manufacturing information applicable to their facility directly to the Authority in the form of a master file. The manufacturer should inform these contractors of the need to supply detailed information on the device.

1.8 Status of Device Distribution

A summary of marketing history of the device is requested. The manufacturer or its local authorized representative must provide a list of countries where the device is currently being introduced and sold, its date of instruction and details of the regulatory status (e.g. marketing approval, product recall, product ban, etc.). The manufacturer or its local authorized representative must also provide a summary of reported problems related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use, and has led to the death or serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur. These incidents require 'mandatory ' problem reporting that the manufacturer had submitted to the relevant regulatory authorities.

1.9 Safety and Effectiveness Data

The safety and effectiveness requirements must be applied as a function of the risk inherent with a given product. This enclosure requires a summary of all studies that the manufacturer relies on to ensure that the device meets the safety and effectiveness requirements, as well as the conclusions drawn from those studies. This includes evaluation of those risks against the claimed benefits of the device and the method used to reduce risk to acceptable levels. The studies must be organized into the following sub-sections and reported as appropriate. An introductory summary should accompany each study presented.

Risk Assessment

A list of possible hazard for these devices must be prepared. Indirect risks from medical devices including IVD may result from device- associated hazards, such as instability, which lead to erroneous results, or from user-related hazards, such as infectious reagents. The evaluation of these risks against the claimed benefits of the device and the method used to reduce risk to acceptable levels must be described. The individual or organization that carries out the risk analysis must be clearly identified. The technique used to analyse risk must be specified, to ensure that it is appropriate for the device and the risk involved.

Pre-clinical and clinical studies

Details must be provided on all biocompatibility tests conducted on the materials used in a device. At a minimum, tests must be conducted on samples from the finished, sterilized device. All materials that are significantly different must be characterized. Information describing the tests, the results and the analyses of data must be presented.

Complete pre-clinical physical test data must be provided, as appropriate. The report must include the objectives, methodology, results and manufacturer's conclusion of all physical studies of the device and its components. Physical testing must be conducted to predict the adequacy of device response to physiological stresses, undesirable conditions and forces, lone-term use and all known and possible failure modes.

Pre-clinical animal studies used to support the probability of effectiveness in human must be reported. These studies must be undertaken using good laboratory practices. The objectives, methodology, results analysis and manufacture's conclusion must be presented. The study conclusion should address the device's interactions with animal's fluids and tissues and the functional effectiveness of the device in the experimental animal model(s). The rationale (and limitations) of selecting the particular animal model should be discussed.

Clinical evidence of effectiveness may comprise device-related investigations conducted in UAE or other countries. It may be derived from relevant publications in peer-reviewed scientific literature .The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusion on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.

Process Validation Studies

The results of all process validation studies must be presented. When the results of a particular process cannot be verified by subsequent observation, that the process must be validated to obtain objectives evidence. This applies to sterilization processes as well.

The procedures for monitoring and controlling the process parameters of validated process must be fully described. For example, the type of process, details of the equipment and process parameters employed in sterilization must be specified. Process validation data must include sterility tests data and methods, culture media, time and temperature of incubation, controls, number or samples examined and frequency of testing. Pyrogen test data and methods are required , including frequency of testing , number of units tested methods of testing , data from test results or a substantial rational for not conducting this kind of testing . Toxicity test methods and data must be described. If the sterilizer is toxic or produces toxic residues, test data and methods for establishing that post-process sterilizer and/or are within acceptable limits must be presented.

Software validation studies, if applicable

The correctness of a software product is another critical product characteristic that cannot be fully verified in a finished product. The manufacturer and/or device sponsor must provide evidence that validates the software design development process. This information should include the results of all verification, validation and testing performed in-house and in a user's environment to final release, for all of the different hardware configurations identified in the labelling. As well as representative data generated from both testing environments.

Literature Studies

Copies are required of all literature that the manufacturer is using to support safety and effectiveness. These will be a subset of the bibliography of references. General bibliographic references should be device-specific as supplied in chronological order. Care should be taken to ensure that the references are timely and relevant to the current application.

Devices Containing Biological Material

Results of studies substances the adequacy of the measures taken with regards to the risks associated with transmissible agents must be provided. This will include viral clearance results for known hazards. Donor screening concerns must be fully addressed and methods of harvesting must also be fully described. Process validation results are required to substantiate that manufacturing procedures are in place to minimize biological risks.

1.10 Human Clinical Data

Human clinical data needs to be submitted in the evaluation of higher risks medical devices and forms a part of the application criteria. In order to demonstrate compliance with the safety and effectiveness requirements, the human clinical data provided may be in the following forms:

- A compilation of the relevant peer-reviewed scientific literature currently available on the intended purpose of the device and the techniques employed with , if appropriate , a written report containing a critical evaluation of the compilation ;
- The results and conclusion of a specifically designed clinical investigation.

Scientific Literature

Critical analysis and evaluation of scientific literature are broad concepts, which include any experience gained from as establishment device already on the market used in clinical practice. This includes data on the materials or type of design used in the particular device and data on the type of medical procedures used.

Designed Clinical Investigations

A designed clinical investigation on human subjects is performed on the basis of an appropriate protocol with well-defined objectives under the guidelines of good clinical practices. It involves procedures that are appropriate to the device under examination .The clinical investigation should be performed under circumstances that are similar to the intended conditions of use. The approval of ethics review committee and patient consent must be sought before conducting a clinical investigation, in observation of the Declaration of Helsinki.

The DCD/ Technical section relevant committee as it will be decided by the classification committee will review the device information submitted to ensure that the devices meets the safety, quality and effectiveness requirements.

Information to justify the safety, quality and effectiveness of the medical device should be provided by the manufacturer or its local authorized representative, who is responsible for the accuracy of the information submitted and for matters consequent upon supply of the devices such as reporting adverse incidents, maintaining distribution records, facilitating tracking of certain implanted devices and establishing written procedures regarding investigating incidents and devices from the market .

Annex 2
Essential Requirements for Medical devices

2.1 General Requirements

- MD when used under the conditions and for the purpose intended, it will not compromise the clinical condition or the safety of the patients, users and where applicable, other persons.
- The devices must achieve the performance intended by the manufacturer
- The lifetime of the device as indicated by the manufacturer shouldn't be affected when the device is subjected to the stresses which can occur during normal conditions of use
- Any undesirable side effects must constitute acceptable risks when weighed against the benefits intended.

2.2 Chemical and Physical Properties

- Non-toxic and where appropriate, non-inflammable materials should be used.
- Materials used should be compatible with biological tissues cells and body fluids, taking account of the intended purpose of the device.

Risk posed for person involved in the transport, storage and use of the devices and to the patients by the contaminants and residues should be minimized by its design, manufacturing method and packing.

2.3 Infection and Microbial Contaminations

- The devices and manufacturer processes must be designed in such a way as to minimize the risk of infection to the patient. The design must be of easy handling and where necessary, minimize contamination of the device by the patient or vice versa during use.
- Sterile device must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure to remain sterile under the storage and transport conditions laid down, until the protective packaging is damaged or opened.
- Devices labelled sterile must have been sterilized by an appropriate, validated method.
- Packaging system for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and
- If the devices are to be sterilized prior to use, the risk of microbial contamination must be minimized.
- The packs and/or label of the device must distinguish between products sold in similar sterile packaging.

2.4 Construction and Environmental Properties

- If the device is intended for use in combination with other devices or equipments, the connection system must be safe and must not impair the specified performance of the devices; any restrictions on use must be indicated on the label or in the instruction leaflet.
- The design, manufacturer and packaging of a medical device shall minimize any risk to a patient, user of other person from reasonably hazard, including

(a) Flammability or explosion ;
(b) Presence of a contaminate or chemical or microbial residue;
(c) Radiation
(d) Electrical , mechanical or thermal hazards : and
(e) Fluid leaking from or entering into device
(f) Vibration generated by the devices, noise emitted

- The terminal and connections to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risk
- Accessible parts of the devices and their surrounding must not attain potentially dangerous temperatures under normal use.

2.5 Labelling Requirements

1. Any labelling artwork should be approved during the Registration process
2. Any deviation from the approved set of labels will lead to suspension of the registration approval.
3. All information required be easily understood by the intended user and must be English and preferably Arabic. For self testing IVD and Devices used by patients it is a must.
4. Instructions for use are not required for class I and II devices if these devices can be used safely without such instruction.
5. Medical devices must be labelled with the following information:

a) The name and address of the manufacturer
b) The identifier of the device, including the identifier of any medical device that is part of a system, test kit. Medical device group , medical device family device group family
c) Where appropriate , the batch code
d) Where appropriate, an indication that the device is for single use.
e) If the contents are not readily apparent, an indication of what the package contains expressed in terms appropriate to the device, such as the size net weight length volume or number of units ;
f) The expiry date of the device, if any, determined by the manufacturer on the basis of the component with the shortest projected useful life;
g) Unless self-evident to the intended user, the medical conditions , purpose and uses for which the device is manufactured , sold or represented, including the performance specifications of the device if those specifications are necessary for proper use ;
h) The directions for use, unless directions are not required for the device to be used safely and effectively; the condition for transporting and storing the device /or handling conditions applicable to the device; any special operating instruction; any warning and/or precaution to take.
i) A medical device that is to be sold in a sterile condition shall be manufacturer and sterilized under appropriately controlled conditions, and the sterilization method used shall be validated. Declaration that the device is sterile should be in the form a label.
j) An indication of the time limit for implanting the device safely.

ANNEX 3
CLASSIFICATION OF MEDICAL DEVICES

3. 1 Risk Based Classification

The control of medical devices will be based on a risk assessment and risk management.
The level of regulatory control applied to the medical device is proportional to the degree of perceived risk associated with the device. The requirements of the review process differ for each class, type and technology of medical device. Medical devices may be classified into 4 classes: Class l (low risk). lla and llb (medium risk) or lll (high risk) according to the European Union classification rules.

3.2 Basic definitions

The classification rules are based on terms related to duration of contact with the patient degree of invasiveness and the part of the body affected by use of the device.

*3.2.1 Time (*Duration*):*

Transient
Normally intended for continuous use for less than 60 minutes
Short term
Normally intended for continuous use for not more than 30 days
Long term
Normally intended for continuous use for more than 30 days
Concept of continuous use
Concepts of duration such as transient short term and long term are defined in terms of continuous use. Continuous must be understood as an uninterrupted actual use for the intended purpose.

3.2.2 Invasiveness

Invasive devices
A device which in whole or in part penetrates inside the body . either through a body orifice or through the surface of the body.
Body orifice
Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening such as a stoma.
Surgically invasive device
An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

For the purposes of this Directive devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

There are two exceptions to this:
A surgically crested stoma used in colostomy and ileostomy or permanent tracheostomy is considered to be a natural body orifice. Therefore devices introduced to into such a stoma are not surgically invasive. A surgically created opening to allow access to the circulatory system in contrast should

not be considered to be such a "natural body orifice". Devices introduced into such an opening are surgically invasive.

A device that administers energy to the body should not be considered as invasive if only energy penetrates the body and not the device itself. Energy as such a device and therefore it cannot be classified. Only the device generating the energy must be classified. However, if a device administers a substance, whether this substance is a medicine or a medical device, such a substance must be assessed in its own right (e.g. substances administered by a jet injector).

Any device which in whole or in part penetrates inside the body either through a natural body orifice or through the surface of the body is an invasive device. A surgically invasive device always implies that it enters through an artificially created opening. This can be a large opening such as a surgically incision, or it can be a pinprick opening created by a needle. Therefore surgically gloves and needles used with syringes are surgically invasive.

3.2.3 Implantable device

Any device which is intended:

- to be totally introduced into the human body or
- to replace an epithelial surface or the surface of the eye

By surgical intervention which is intended to remain in place after the procedure Any device intended to be partially introduced into human body through surgical intervention and intended to remain I place after the procedures for at least 30 days is also considered an implantable device.

One of the key elements in defining what an implantable device is, is the concept of "procedure" .thus as implantable device must remain in the patient after the procedures. a "procedure" must be understood in this context to include the surgical procedure during which the implant is placed into the body and the immediate post-operative care is associated with the procedures . The "procedure" does not extent to the conclusion of the therapeutic treatment, e.g. the removal of an implant must be considered to be another "procedure" thus a plate used to reduce a fracture of the bone is an implant even if it is taken out after the fracture has healed. In this case the placing of the plate and its explanation are tow different surgical procedures.

Some partially implanted devices are deemed to be implants. For instance if an operation is carried out to specifically to place an infusion port into the body then such as infusion port would remain for least 30 days after the procedure and consequently be an implant .

However, a suture used for skin wound closure that is taken out prior to 30days is not an implant

3.3 Application of Rules

In terms of further interpretation of the decision rules, the following should be considered :

- It is the intended and not the accidental use of the device that determines the class of the device. if a medical practitioner uses the device in a manner not intended by the manufacturer this does not change the class of the device for purpose of conformity assessment .
- It is the intended purpose assigned by the manufacturer to the device that determines the class of the device and not the class assigned to other similar products.
- as an alternative to classifying the system as a whole the determination of the class of a particular device may be made with respect to the simplest configuration that can still be considered , in view of its proper functional features, as a device in its own right . A device that is part of a system may be classed as a device in its own right rather than classifying the system as a whole. Similarly combination devices with parts that have different functional purpose may be analysed separately with respect to each of these parts for instance a drainage device will have an invasive tube and non-invasive collections device. These components may be classified separately.
- Accessories must be classified separated from their parent device.
- If a given device can be classified according to several rules, then the highest possible class applies.
- If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use. Classification of the device will have to be determined on the basis of claims contained in the information provided with the device. The manufacturer must be sufficiently specific in that regard. If the manufacturer wants to avoid the particular higher classification, then it must clearly on the labelling the intended purpose in such a way that device falls into the lower class. The manufacturer must provide as a minimum requirement either appropriate positive or negative indications for use.
- For a device to be "specifically intended" for the purpose referenced in a particular classification rule, the manufacturer must clearly indicate that the device is intended for such a specific purpose in the information accompanying the device. Otherwise it is deemed to intended to be used principally for the purpose that is accepted in general medical practice.
- Multi-application equipment such as laser printers and identification cameras, which may be used in combination with medical devices, are not medical devices unless their manufacturer places them on the market with specific intended purpose as medical devices.
- Standalone software, e.g. software which is used for image enhancement is regards as driving or influencing the use of a device and so falls automatically into the same class. Other standalone software, which neither is nor regarded as driving or influencing the use of a device is classified in its own right.

3.4 Rules Used For Classification

Non- Invasive Devices

Rule 1

All non-invasive devices are in class I, unless one of the rules set out hereinafter applies

Rule 2

All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in class II:

If they may be connected to an active medical device in Class II or higher class,
If they are intended for use for storing or channelling blood or other liquids or for storing oranges, parts of organs or body tissues , in all other cases they are in Class I

Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class III unless the treatment consists of filtration, centrifugation or exchanging of gas, heat in which case they are in Class II

Rule 4

All non-invasive devices that come into contact with injured skin:

- Are in Class I if they are intended to be used a mechanical barrier, for compression or for absorption of exudates,
- Are in class III if they are to be used principally with wounds, which have breached the dermis and can only heal by secondary intent ,
- Are in Class in II in all other cases, including devices principally intended to manage the micro-environment of a wound.

Invasive Devices

Rule 5

All invasive devices with respect to body orifices, other than surgically devices and which are not intended for connection to a medical device

- Are in Class I if they are intended for transient use
- Are in class II if they are intended for short-term use expect if they used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I,
- Are in class III if they are intended for long-term use, except if they are in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membranes, in which case they are in Class II.

All invasive devices with respect to body orifices other than surgically invasive devices, intended for connection to an active medical device in Class II or a higher class, are in class II.

Rule 6

All surgically invasive devices intended for transient use are in Class II unless they are:

- Intended specifically to diagnose , monitor or correct of the heart or the central circulatory system through direct contact with these parts of the body, in which case they are in Class IV ,
- Reusable surgically instruments in which case are in class I
- Intended to supply energy effect to be wholly or mainly absorbed in which case they are in Class III ,
- Intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III ,
- Intended to administer medicines by means of a delivery system, if this system, if this done in a manner that is potentially hazardous taking account of the mode of application in which they are in Class III.

Rule 7

All surgically invasive devices intended for short-term use are in Class II unless they are intended:

- Either specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class IV ,
- Or specifically for use in direct contact with the central nervous system, in which they are in Class IV,
- Or to supply energy in the form of ionizing radiation in which case they are in Class III,
- Or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IV,
- Or to undergo chemical change in the body , except if the devices are placed in the teeth , or to administer medicines , in which case they are in Class III.

Rule 8

All implantable devices and long-term surgically invasive devices are in Class III unless they are intended:

- To be placed in the teeth, in which case they are in Class II,
- To be used in direct contact with the heart , the central circulatory system or the central nervous system in which case they are in Class IV,
- To have a biological effect or to be wholly or mainly absorbed in which they are in Class IV ,
- Or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IV.

Additional Rules Applicable to Active Devices

Rule 9

All active therapeutic devices, intended to administer or exchange energy are in class II unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the human nature, the density and site of application of the energy, in which case they are in Class III.

All active devices intended to control or monitoring the performance of active therapeutic devices in Class III, or intended to influence the performance of such devices are in Class II.

Rule 10

Active devices intended for diagnose are in Class II:

- If they are intended to supply energy which will be absorbed by the human body , except for devices used to illuminate the patient's body, in the visible spectrum
- If they are intended to image in vivo distribution of radiopharmaceuticals
- If they are intended to allow direct diagnose or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters , where the nature of variations is such that it could result immediate danger to the patient for instance variations in cardiac performance , respiration, activity of CNS ; in which case they are in Class III.

Active devices intended to emit ionizing radiation and intended for diagnose and therapeutic interventional radiology including devices which control or monitor such devices or which directly influence their performance, are in Class III.

Rule 11

All active devices intended to administer and/or remove medicines; body liquids other substances to or form the body are in Class II unless this is done in a manner

This is potentially hazardous, taking account of the nature of the substances involved , of the part of the body concerned and of the mode of application in which case they are in Class III.

Rule 12

All other active devices are in Class I.

Special Rules

Rule 13

All devices incorporating, as integral part a substance that if used separately can be considered to be a medicinal product, which is liable to act on the human body with action ancillary to that of the devices, are in Class IV.

Rule 14

All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class III , unless they are implantable or lone term invasive devices in which case they are in class IV .

Rule 15

All devices intended specifically to be used for disinfecting, cleaning, rising or when appropriate, hydrating contact lenses are in Class III.

All devices intended specifically to be used for disinfecting medical devices are in Class II.

This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.

Rule 16

Non-active devices specifically intended for recording of X-ray diagnose images are in class II .

Rule 17

All devices manufactured utilizing tissues or derivatives rendered non-viable are Class IV except where such devices are intended to come into contact with intact skin only

Rule 18

By derogation from other rules, blood bags are in Class III .

UNITED ARAB EMIRATES

MINISTRY OF HEALTH

دولة الإمارات العربية المتحدة
وزارة الصحة

APPLICATION FOR REGISTRATION OF MEDICAL DEVICE PRODUCT

[A] Detail of local Distributor			
Authorized Distributor			
Contact person			
Email:			
Street:			
District:			
City:			
P.o Box:			
Tel:		Fax:	
Detail of Drug Store			
No. of License		Date of Renewal	

[B] Detail of the Manufacturer			
Name of Manufacturer			
Contact person			
Email:			
City :		Country:	
P.o Box:			
Tel:		Fax:	
Name & address of competent authority that issue the manufacturing license			
Manufacturing License Number:			
Date of Establishment			
Turnover			

[D] Quality System Standard			
Certificate of the same validity as the GMP medical device Standard *(Please tick √)*			
□ISO 13485 □ISO 13488 □ EN 46001 □EN 46002 *If Others please specify*……			
For European Union Organization that inspect the factory and examine the certificate *(Please tick √)* □ BSI □ G-med □ mdc □ NSAI □ TűV PS □ TűV Rheinland			
Name of the Notified Body that Issued the Certificate			
Address			
City:		Country:	
Tel:		Fax:	
Contact person			
Email:			
Certificate Number:			
Validity of Certificate;			

[C] Detail of the Marketing Authorization Holder (MAH)			
Name of Marketing Authorization Holder			
Contact person			
Country:		City:	
P.o Box:			
Tel:		Fax:	
Email:			

[E] Detail of the Product	
Name of the Product	
Description of the device *(state type, appearance, material, purpose, & mechanism of action)*	
Sterilization Requirement	□ Sterilized □ Sterilization before use □ Partial Sterilization □ Not Required
Does the Medical device contain any of the animal or human derivatives	□Yes □No *If Yes, please define the substance that included and its source:……..*
What is the intended purpose /use of the device	
Potential Adverse Effects	
Contraindications	
Warnings	

A List of The Components of the Device	Ingredients	Quantity
Instructions for use of the device *(state claims as made in product information, including any claims related to the added substance)*		
Shelf life / Storage conditions		

[F] Detail of Conformity Assessment	
Is the product marketed in the country of origin?	□Yes □No
If yes, When was the device introduced on the market? Please write the registration No:	

List Certification / Approval held for product and locations (e.g. CE certificate, FDA, TGA…etc)

Approvals	Agency (s)	Year

The Mode of dispensing of the Medical device in the country of origin
The classification of the Medical device in the country of origin (please Tick √)
□Class I □Class II □Class III □Class VI *If Others please specify*…… ……

[G] DECLARATION BY APPLICANT
(Please read the following Declaration before signing)

In making this application we declare that:

1- We certify that all of the information provided above is true & correct. If the information is incorrect, we are willing to accept denial of permission or termination of this case. we are willing to accept legal responsibility
2- We are in Conformance with the requirements of the Drug Control Regulations with respect to the medical device.
3- We undertake to keep the approved Quality System adequate & efficacious.
4- We Undertake and accept obligation to notify the Drug Control Department of the following incidents immediately on learning of them:
   [a] Any malfunction or deterioration in the characteristics and/or performance of a device as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state or health.
   [b] Any technical or medical reason connected with the characteristics or performance of a device leading, for the reasons referred to in subparagraph [a] to systematic recall of devices of the same type by the manufacturer

Full name of the MAH:

Signature:

Name and Designation of Signatory:

Seal of the company

To be signed by the Managing Director/ of the MAH or an equivalent person