UNITED ARAB EMIRATES

MINISTRY OF HEALTH

دولة الإمارات العربية المتحدة
وزارة الصحة

Registration of Manufacturer of Medical Device

Medical Devices Manufacturers must be registered with UAE Ministry of Health before they can market their devices in the UAE.

Companies wishing to export medical devices to UAE must have a local UAE REPRESENTATIVE or DISTRIBUTOR who holds Medical Store licensed from Ministry of Health. Imported medical Devices are subject to local registration requirements.

All the manufacturers of Class I, Class II a, Class II b, Class III and Active Implantable Devices has to be registered with UAE Ministry of Health. Examples of the Devices in the above said classes are provided below for guidance.

The UAE local distributor must submit a registration application to MOH Drug Control Department (***see attached application***).

A registration number will be given when an application is approved. This number will be valid for a 5 years period unless significant changes are made to the approved application data.

The Director General can cancel the registration number, if any of the following takes place:

a. Based on the request of the applicants;

b. Based on evaluation or monitoring, following products may fail to meet the criteria because:

- **(1)** they are not safe or are harmful to health,
- **(2)** the quality is substandard,
- **(3)** they differ from the approved label; this includes using a brand name which is originally owned by another rightful party.
- **(4)** If submitted documents prove to be untrue

The Director will notify the registration holder in writing of the cancellation.

Applications are considered complete if application forms and enclosures are filled up correctly according to the instructions.

Application forms must be signed by the head of the company, the director or technical representative as indicated in the agency agreement. Indicate name of place, date, complete name of responsible person and company's seal.

The exoneration process: 8-12 weeks after submission of complete documents

- ***(The application must be clearly typed <u>in English</u> and submitted by the Local agent/ Manufacturer along with all the related documents <u>in a file</u>).***

(All information required should be expressed in a legible, in terms that are easily understood, be either in Arabic or in English)

UNITED ARAB EMIRATES

MINISTRY OF HEALTH

دولة الإمارات العربية المتحدة
وزارة الصحة

Particular of Medical Device Company

Company Name:	
City:	Country of origin:
Street:	
Web site:(*if available*)	Post Code:
Contact Name:	Email:
Telephone:	Fax:
Business registration number in country of origin:	Validity:

Name of the competent authority that issued the business License :

Contact person: Telephone:

Fax:

Email:

Please tick the type of products manufactured by the company

☐ ***Medical Device***
- □ ***Active Implantable Medical Device***
- □ **Non Invasive Medical Device**
- □ **Invasive Medical Device**

☐ ***In-Vitro Diagnostic Medical Device***

☐ **Tissues of Animal Origin**

☐ **Other , Please specify**

Manufacturing Facility

Please complete the following information about each facility / location included in this assessment.

Manufacturing sites

City:	Country:
Address:	

Post Code:
Tel: Fax: Email:
No. of employees (for Medical devices) at the manufacturing site
Brief description of the facility and principal activities occurring at this site: (Further details may be attached on a separate sheet)
Site No. 2
Manufacturing sites
Address: Post Code:
Tel: Fax: Email:
Brief description of the facility and principal activities occurring at this site: (Further details may be attached on a separate sheet)

UNITED ARAB EMIRATES

MINISTRY OF HEALTH

دولة الإمارات العربية المتحدة
وزارة الصحة

Details of the Authorized Representation	
Name:	
Address	Country:
Emirate:	City:
Postal Code:	
Contact person:	
Tel:	Fax:
Email:	
Please list the activities of the authorized representative within UAE	

Details of the Local Distributor	
Name of Medical Store:	
Address	
Emirate:	City:
Postal Code:	
Contact person:	
Tel:	Fax:
Email:	
Medical Store License No.:	
Expiry Date :	

Quality Management System (QMS)

Please tick below the standards with which the QMS complies:
ISO 13485: IEC 60601-1 etc…

Certified by …….. (certification body)

Validity: ……..

☐ Others…….(Please specify)

Certified by …….. (certification body)

Validity: ……..

Does the scope of certification of the QMS include ***Design & Development*** Controls?

☐ Yes ☐ No

If yes please mention the name & type of certification:

Does the manufacturer outsource any process (e.g., design & Development, manufacturing, warehousing, sterilization, etc.)

☐ Yes ☐ No

If yes please fill the information mentioned below:

Indicate the outsourced process below:

Name of Facility

Address

City: Country:

Postal Code:

Enter the details of Notified Body approval of quality system for sterilization or measuring function relevant to the device(s)

*Please list any Certifications currently held by company

Type Certification	Certified by:

Countries that Devices are approved and sold

Country	*Devices Name* *(Please list only max. 5 devices if available)*	*Authority that issued the approval for marketing*

Devices of the Company		
Please list five device products that applicant is manufacturing		
Class I		
Class IIa & Class IIb		
Class III		

Others	

8- Declaration

I hereby declare that all the information I have provided is correct and all the attached documents are genuine; I will inform the Ministry about any changes to this information.

Name of Applicant *(Manufacturer)*
Signature:
Date:

Accreditation of Company

Companies (both domestic and foreign) and their distributors (importers) of medical devices must **register their establishments with the Drug Control Depart*m*ent.**

Company is an operator of an establishment who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a medical device intended for marketing within UAE is required to register. This includes their manufacturing site, contract manufacturer, and contract sterilizers, specification developers, re packagers or re labelers, re processors of single-use devices, re-manufacturers, and manufacturers of components or accessories that are sold or leased directly to the end user.

If the company has multiple manufacturing sites, each Manufacturing location should be identified and registered with indicate the facility where the manufacturing step is carried out as follows:

- Design
- Production
- Sterilization (if applicable)
- Packaging
- Labelling
- Final Release.
- Warehousing & dispatch.

If all steps for involved with a particular stage are undertaken by the company at a single manufacturing facility, it is sufficient to identify the manufactures facility and indicate that all steps.

A company shall demonstrate compliance with ISO 13485 issued by recognized conformity assessment body.

Manufactures of Classes IIb, III devices shall have a full quality management system that includes design and development. Manufactures of class I, IIa devices shall have a quality management system that need not include design and development activities.

The company shall inform the Drug Control Department any major changes of his quality management system and change of certification of his quality management system e.g. change of the scope of certification or suspension or withdrawal of certification by the conformity assessment body.

The Company must prepare provision for audit plan and provide all documents necessary and related to contract manufactures / sterilizers that it employs.

Contract Sterilizers, Contract Device Manufacturers and Finished Device Manufacturers

Contract sterilization and contract manufacturing are considered an extension of the finished device manufacturer's process. The manufacturing site of the finished device is ultimately responsible for assuring that validations, operations, process controls, quality assurance checks, etc. are appropriate, adequately documented and correctly performed.

Contract sterilizers and contract manufacturers of finished devices are considered manufacturers for the purpose of applying the accreditation.

Contract sterilizers and contract manufacturers of finished devices are subject to those parts of the Quality System regulation that apply to the operations that are performed.

The finished device manufacturing site bears overall responsibility for the safety and effectiveness of the finished device and must control all contractors.

For contract sterilization, the written agreement, between the company and contract sterilizer, required may be referenced to determine how the parties have defined their respective responsibilities. For other contract manufacturers, any written agreements used as part of supplier controls may be referenced to determine how the parties have defined their activities and respective responsibilities.

Documentation for Company Registration

1. ***The company requesting Registration shall make application in writing by completing an official form, which is to be signed by duly authorized representative in the company.***
2. ***Company Business License includes their manufacturing site issued by the competent authority in country of origin***
3. ***General Information on Manufacturing Site and quality management system follows.***
4. ***organization of Quality Assurance system (flow chart)***
5. ***Notarized copies of Quality management's certificates.***
6. ***Notarized copies of conformity certificates of foreign authorities held by the manufacturer.***
7. ***For class I (non-sterile) manufacturer GMP certificate/Certification by Notified body approved by the Regulatory authority of Country of origin is required***
8. ***For classes IIb & III manufacturer: Notarized Copies of the Design Examination or Type Examination certificates issued by notified body.***
9. ***Notarized copy of complete essential principle checklist that accredited by the manufacturer.***
10. ***Report of Recent audit by other auditing organization includes the non-conformities points and evidence of closed out.***

For Sterilization process: full verification that processes are appropriate to produce sterile products including the controlled condition; records of process for each sterilization batch are maintained and traceable to each batch; review the validation includes qualification of sterilizer. Determine that the process is operating within specific limit; if the sterilization process is software controlled, determine that that the software is validated; determine that the equipment used has been adjusted, calibrated and maintained.

11. Copies of certification and documents certifying conformity to :Sterile manufacture

12. Site Master File for each manufacturing site

13. Corrective action programme and supporting documentation.

14. Post marketing surveillance planning.

15. Documented Procedures Established

a) Complaint Handling

b) Reportable adverse Incidents in UAE (A Copy of the documented procedure shall be submitted together with this application)

c) Recall (A Copy of the documented procedure shall be submitted together with this application)

16. Statements that Manufacturer will undertake to provide evidence of established and systems for distribution records, complaint handling, adverse Incident reporting and product recall. (in case of all classes)

17. General profile contains the following Information

a) Company name, address, including the corporate structure as well as all company names of the company and its manufacturing site used

b) contact name, telephone, fax numbers and e-mail addresses

c) total number of employees (all shifts) covered by the scope of the audit

d) product range and class of medical devices being manufactured (The class of a medical device may differ from one regulatory authority to another)

e) types of medical devices sold and/or planned to be sold in the UAE and/or GCC regions for which the regulatory requirements will be assessed, including a complete list of authorizations (e.g., licenses) issued for those medical devices (where applicable)

f) Location and function of each site to be included.

g) a list of activities performed at each site

h) Any special manufacturing processes, e.g., software, sterilization, etc

3.3.3. Authorized Representative

The basic need to have an 'authorized representative' arises because, where a company is based outside the UAE, the Drug Control Department need to be able to contact an entity or person who is based within UAE, and who acts on behalf of the manufacturer.

A notarized agreement documentation stating the appointment of the local authorized representative by the company may be provided.

The representative must file an evidence of Power of Attorney from the company which authorizes him to speak for his principals. The original power of Attorney is to be legalized

The authorized representative required commitment for the following tasks:

- The Authorized Representative is responsible towards the Ministry of Health, representing the company in Drug Control Department.
- The Authorized Representative is obliged to submit Medical Device Reports on behalf of the manufacturer. Failure to meet deadlines, or any other inconsistencies, may have serious repercussions, both for him self and the manufacturer.
- The Authorized Representative must be appointed in writing, by contract; all duties and responsibilities ought to be clearly defined and assigned.
- The Authorized Representative may face liability claims resulting either from device malfunction or serious complaint!
- The Authorized Representative must at all times be available to interact between the Medical device company &, the Ministry of Health.
- The authorized representative required to notify Drug Control Department of any new models of medical devices they market in UAE.
- The Authorized Representative requires the 'Person' is capable to make qualified pre-submission judgment (in the event of an incident) on behalf of the Medical Device company
- The Authorized Representative should be in a position to ensure that he provides qualified and trained (Regulatory Affairs) personnel to cover the responsibilities entailed.
- The Authorized Representative Can advise accurately on all the Regulatory issues of Labeling, including The Label itself, Product Inserts, Inner and Outer Packaging, Instructions for Use and Advertising …etc
- Can they demonstrate knowledge of the additional requirements of the ISO 13485 series of standards, including the new ISO 9001:2000
- Can advice on effective implementation of all Regulatory Procedures, including Adverse and Near Incident Reporting, Advisory Notice Issue (including Product Recall), Post Market Feedback, Complaint Handling and Significant Change Notifications
- They prepared to participate fully, if required, in all Post Sales Issues (Post Market Feedback, Incident Reporting, Product Recall and Complaint Handling)

The Distributor can be acting as the authorized representative

The Import of Medical Devices through Distributor that licensed from ministry of health drug control department has to comply with a code of practice issued by the Drug Control Department.

The main consideration is whether or not an existing distributor of manufacturer's products can effectively fulfill the regulatory responsibilities alongside their marketing activities.

Taking full consideration of the responsibilities of the local representative.

Change of Local Authorization Representative

Foreign Companies are free to make any changes desired or necessary for their required Local Representative. All foreign company are, however, required to report all such changes, including changes in the new local representative name, address or phone number, to Drug Control Department within ten (30) business days. The new rule allows a foreign company's representative to report those kinds of changes directly to Drug Control Department. However, foreign firms are advised to duplicate that reporting effort to ensure compliance.

Documentation

Representation Agreement, where the manufacturer indicates that the importer is their representative in the country. (The representative should be exclusive distributor)