Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

Guidance Document GD: 1 Medical Device Listing

Dept. of Medical Device Control

1. Purpose:

This document is intended for use by Regulatory Authorities (RAs) and the parties responsible for providing listing information to such authorities, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. It seeks to strike a balance between the responsibilities of RAs to safeguard the health of their citizens and their obligations to avoid placing unnecessary burdens upon the industry.

2. Reference:

The guideline is abstracted and summarised by use of GHTF guidance document (GHTF/**SG1/N065:2010**).

(Global Harmonisation Task Force currently known as IMDRF (International Medical Device Regulators Forum))

3. Definitions

1. **Contact details:** means a postal address in a format that allows physical location to be established together with a telephone number and e-mail address.
2. **Listing:** the process whereby a party submits information to the Regulatory Authority in a jurisdiction, regarding the identification of a medical device(s) that is or will be supplied to the market in that jurisdiction.

4. Abbreviations:

RA : regulatory authority

5. Medical Device Listing

5.1 General

Listing provides information on medical devices that are or will be, supplied to the market that is within the RA's jurisdiction.

The RA should identify unambiguously which parties are required to provide it with listing information.

Providing listing information to the RA does not remove from the party providing such information (i.e. the listing party) its obligation to comply fully with all the other regulatory requirements that apply to it within the jurisdiction.

5.2 Parties subject to listing requirements

Medical device manufacturers, authorised representatives, importers and distributors may be subject to listing requirements.

While retaining responsibility, any party required to provide listing information may contract another party to complete the listing process on its behalf.

5.3 Timing of listing

A listing party providing information to an existing database should submit all necessary information to the RA when it supplies the device to the market for the first time.

Note: When the medical device listing database is first established, some of the devices subject to listing requirements will already be on the market. In this situation, the party providing listing information should be allowed a reasonable period of time to comply with the new listing requirements.

5.4 Information to be submitted for listing purposes

For the purposes of listing, the listing party should provide the following:

1. An indication of whether the listing party is a manufacturer, an authorised representative, an importer, or a distributor of medical devices supplied to the market of the jurisdiction where the information is being collected

2. specifying the format, mechanism and frequency with which the listing information is to be provided;
3. designating the language(s) requirements for the submitted listing information;
4. providing a mechanism that allows incorporation of either a new entry or updated information, into a searchable database, and ensuring such entries are incorporated within 30 days of the information being provided;
5. the development, maintenance and security of the database containing the entrusted data;
6. ensuring the recorded data reflects accurately the information provided by the registering party;
7. assigning, for internal data management purposes
8. specifying whether only itself and the listing party has access to the listing information, or whether some or all of the information held may be accessed by others, e.g. purchasers of medical devices, while taking care to safeguard commercially sensitive information.
9. On a periodic basis, not more frequent than annually, requesting each listing party to confirm that the information provided for listing purposes continues to be accurate.

5.5 Role of the listing party

The listing party is required to:

1. provide the RA with the listing information specified
2. attest to its accuracy;
3. update the information provided within 30 calendar days of becoming aware of the occurrence of any change, or when requested to do so by the RA, in order to maintain the accuracy of the listing database;
4. Respond to the RA's request to confirm that the information provided for device listing purposes continues to be accurate.

5. Name and contact details of the registered place of business of the listing party together with the name and post held of the person within that organisation responsible for the provision of listing information.
6. Where the listing party is an authorised representative, an importer or a distributor of medical devices it should provide the name and contact details of the registered place of business of the manufacturer(s) of the medical device(s) for which it is providing listing information together with the name and post held of the person responsible for the provision of listing information within the manufacturer's organisation.
7. Where the listing party has contracted another party to complete the listing process on its behalf the name and contact details of the place of business of that other party, together with the name and post held of the person providing the required information.
8. Information sufficient to identify each medical device for which listing information is required.
9. A device code, allocated through an internationally recognised coding system[1] , for each medical device for which listing information is required.
10. An indication that the information provided is either a new entry or an update of previously submitted information. If the second situation applies, the listing code previously allocated to the medical device should be provided.
    i. **Note:** the RA may retain an archive of medical devices that are no longer being supplied to the market.
11. The date when the listing information is submitted.

5.6 Role of the Regulatory Authority

The RA is responsible for:

- identifying which of the parties listed is required to provide information to it; specifying the information it requires from the listing party

1 Coding system such as The Global Medical Device Nomenclature (GMDN) which provides the use of generic descriptors for the identification of medical devices and other healthcare related products. The nomenclature system is managed by the GMDN Agency. The code is based on the international standard EN ISO 15225.

Listing for medical devices

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Director medical device control

DGPA&DC

MOH, Oman

Guidance Document GD1: Medical Device Listing

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4. **Abbreviations:**

Definition of listing

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

Medical Device Listing

General

- Listing provides information on medical devices that are or will be, supplied to the market that is within the RA's jurisdiction.
- The RA should identify unambiguously which parties are required to provide it with listing information.
- Providing listing information to the RA does not remove from the party providing such information (i.e. the listing party) its obligation to comply fully with all the other regulatory requirements that apply to it within the jurisdiction.

Parties subject to listing requirements

- Medical device manufacturers, authorised representatives, importers and distributors may be subject to listing requirements.
- While retaining responsibility, any party required to provide listing information may contract another party to complete the listing process on its behalf.

Timing of listing

- A listing party providing information to an existing database should submit all necessary information to the RA when it supplies the device to the market for the first time.
- Note: When the medical device listing database is first established, some of the devices subject to listing requirements will already be on the market. In this situation, the party providing listing information should be allowed a reasonable period of time to comply with the new listing requirements.

Information to be submitted for listing purposes

- An indication of whether the listing party is a manufacturer, an authorised representative, an importer, or a distributor of medical devices supplied to the market of the jurisdiction where the information is being collected. (Type of Establishment)

Information to be submitted for listing purposes

- ensuring the recorded data reflects accurately the information provided by the registering party;
- assigning, for internal data management purposes
- On a periodic basis, not more frequent than annually, requesting each listing party to confirm that the information provided for listing purposes continues to be accurate.

Role of the listing party

- provide the RA with the listing information specified
- attest to its accuracy;
- update the information provided when requested to do so by the RA, in order to maintain the accuracy of the listing database;

Role of the listing party

- Respond to the RA's request to confirm that the information provided for device listing purposes continues to be accurate.
- Name and contact details of the registered place of business of the listing party together with the name and post held of the person within that organisation responsible for the provision of listing information.
- Where the listing party is an authorised representative, an importer or a distributor of medical devices it should provide the name and contact details of the registered place of business of the manufacturer(s) of the medical device(s) for which it is providing listing information together with the name and post held of the person responsible for the provision of listing information within the manufacturer's organisation.

Role of the listing party

- Where the listing party has contracted another party to complete the listing process on its behalf the name and contact details of the place of business of that other party, together with the name and post held of the person providing the required information.
- Information sufficient to identify each medical device for which listing information is required.
- A device code, allocated through an internationally recognised coding system , for each medical device for which listing information is required.
- An indication that the information provided is either a new entry or an update of previously submitted information. If the second situation applies, the listing code previously allocated to the medical device should be provided.

Role of the listing party

The date when the listing information is submitted.

- 1 Coding system such as The Global Medical Device Nomenclature (GMDN) which provides the use of generic descriptors for the identification of medical devices and other healthcare related products. The nomenclature system is managed by the GMDN Agency. The code is based on the international standard EN ISO 15225.

- https://www.gmdnagency.org/Services/GMDN

Role of the Regulatory Authority

- identifying which of the parties listed is required to provide information to it; specifying the information it requires from the listing party

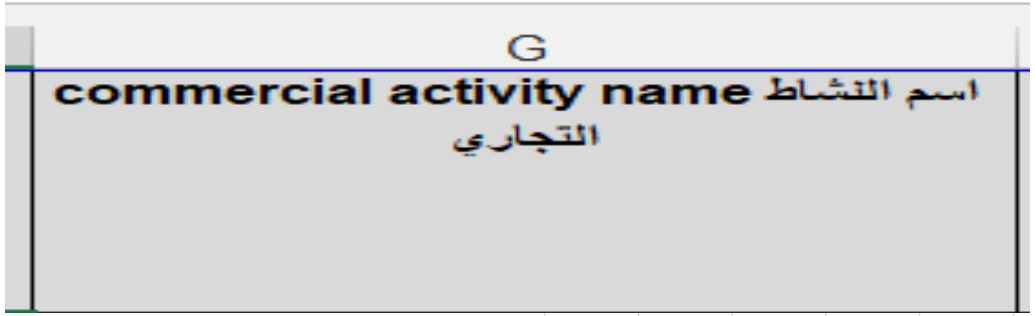
Required Product listing in Oman

- Sent on excel template to all companies dealing with Medical Devices .
- Has 2 parts :
  - Establishment details
  - Product details

Establishment Name اسم المنشأة	Commercial Activity Type نوع النشاط التجاري	commercial activity name اسم النشاط التجاري	Governorate محافظة
albareeq medical co	(choose from list)	كما هو مذكور في السجل التجاري	Dhofar

Wilaya الولاية	Area Name المنطقة	Latitude احدثيات العرض	Longitude احداثيات الطول	Address العنوان	authorised Contact Person اسم الشخص المخول	Telephone Numbers ارقام الهواتف	Email البريد الالكتروني
Salalah	Al Nahda	17.018600	54.086700	Ghala , arbat Building store number 6	A.abraham-General manager	991122334 245678910	

Commercial activity name as in CR



صناعة أجهزة وأدوات ومعدات للطب والجراحة والطب البيطري وطب الأسنان والعيون	331101	Manufacture of instruments and appliances used in medical, surgical, dental, veterinary practice and opthalmic instruments
صناعة أجهزة ومعدات أنواع الأشعة و أجهزة التعقيم	331102	Manufacture of instruments based on the use of X-rays or alpha, beta or gama radiations and sterlizers
صناعة أجهزة التدليك الطبي والعلاج النفسي وأجهزة التنفس	331103	Manufacture of mechano-therapy appliances, massage apparatus, psychologivcal tesing apparatus and artificial respiration or other therapeutic respiratory apparatus.
صناعة أجهزة تقويم الأعضاء بما فيها العكازات الطبية	331104	Manufacture of orthopeadic appliances including crutches.
صناعة الأحنية والأحزمة الطبية وأجهزة السمع ومنظمات ضربات القلب	331105	Manufacture of surgical belts and trussues, orthopaedic corsets and shoes, appliances warn, carried or implanted (hearing aids and pace makers).
صناعة الأسنان والأطراف الصناعية	331106	Manufacture of artificial teeth, artificial timbs and other artificial parts of the body.
صناعة الأثاث الطبي للمستشفيات والعيادات الطبية والبيطرية مثل الأسرة ومناضد العمليات ومقاعد طب الأسنان والحلاقين	331107	Manufacture of medical, surgical, dental or veterinary furniture such as operating tables, hospital beds with mechanical fittings, dentists chair with the same movement capability.
أنشطة أخرى لصناعة المعدات الطبية والجراحية وأجهزة تقويم الأعضاء(تشمل الصيانة والإصلاح)	331199	Other activities related to manufacture of medical and surgical equipment and orthopaedic appliances.
صناعة عدسات العيون بما في ذلك العدسات اللاصقة، أطر نظارات، أطر مجهزة بعدسات مثل النظارات الطبية أو الشمسية أو الواقية ... الخ	332003	Manufacture of opthalmic lenses, including contact lenses, spectacle frames and frames fitted with lenses wheter or not the lenses are optically worked, sunglasses, protective glasses and corrective glasses.
تجارة السلع الصيدلانية والطبية والأدوات والأجهزة الجراحية وأجهزة تقويم الأعضاء	513904	Wholesale of pharmaceutical and medical goods, surgical and orthopaedic instruments and devices.
تجارة التجزئة في الأدوات والأجهزة الطبية وأجهزة تقويم الأعضاء	523103	Retail of medicla goods and orthopaedic apparatus
صيانة المعدات والاجهزة الطبية	523107	Maintenance of medical equipment and instruments
صنع الاجهزة الطبية وأدوات القياس والساعات	33	Manufacture of medical, precision and optical instruments, watches and colcks
صنع الأجهزة الطبية والادوات والاجهزة المستخدمة لاغراض القياس والتحقق والاختبار والملاحة	331	Manufacture of medical appliances and instruments and appliances for measuring, checking, tesing, navigating a
صنع المعدات الطبية و الجراحية و اجهزة تقو يم الاعضاء	3311	Manufacture of medical and surgical equipment and orthopaedic appliances

manfacturing تصنيع	
بيع بالجملة Wholesale	
بيع بالتجزئة Retail	
صيانة وتصليح Maintenance and Repair	

Product listing

Product Name اسم المنتج	Description وصف المنتج	manufacturer المصنع	manufacturer Address عنوان المصنع	country of Origin بلد المنشأ	Model number رقم الموديل	Serial Number/Batch Number رقم التسلسل/ا لتشغيلة	Expiry Date تاريخ الانتهاء
HVAD® Pump Implant Kit	Ventricular Assist System	Heart Ware	14400 NW 6oth Ave , Miami Lakes, Florida		11044		21/01/2014

Product listing

Category الفئة choose from list) (	Device Classification التصنيف choose from list) (	MDMA Listing Number (Medical Device Marketing Authorisation Number) رقم الاذن بالتسويق بهيئة الغذاء والدواء السعودية ان وجد if any) (MM00057SFDAA0001	MDMA certificate attachment مرفق لشهادة الاذن بالتسويق بهيئة الغذاء والدواء السعودية
complimentary therapy devices	Self test		to be sent as attachment

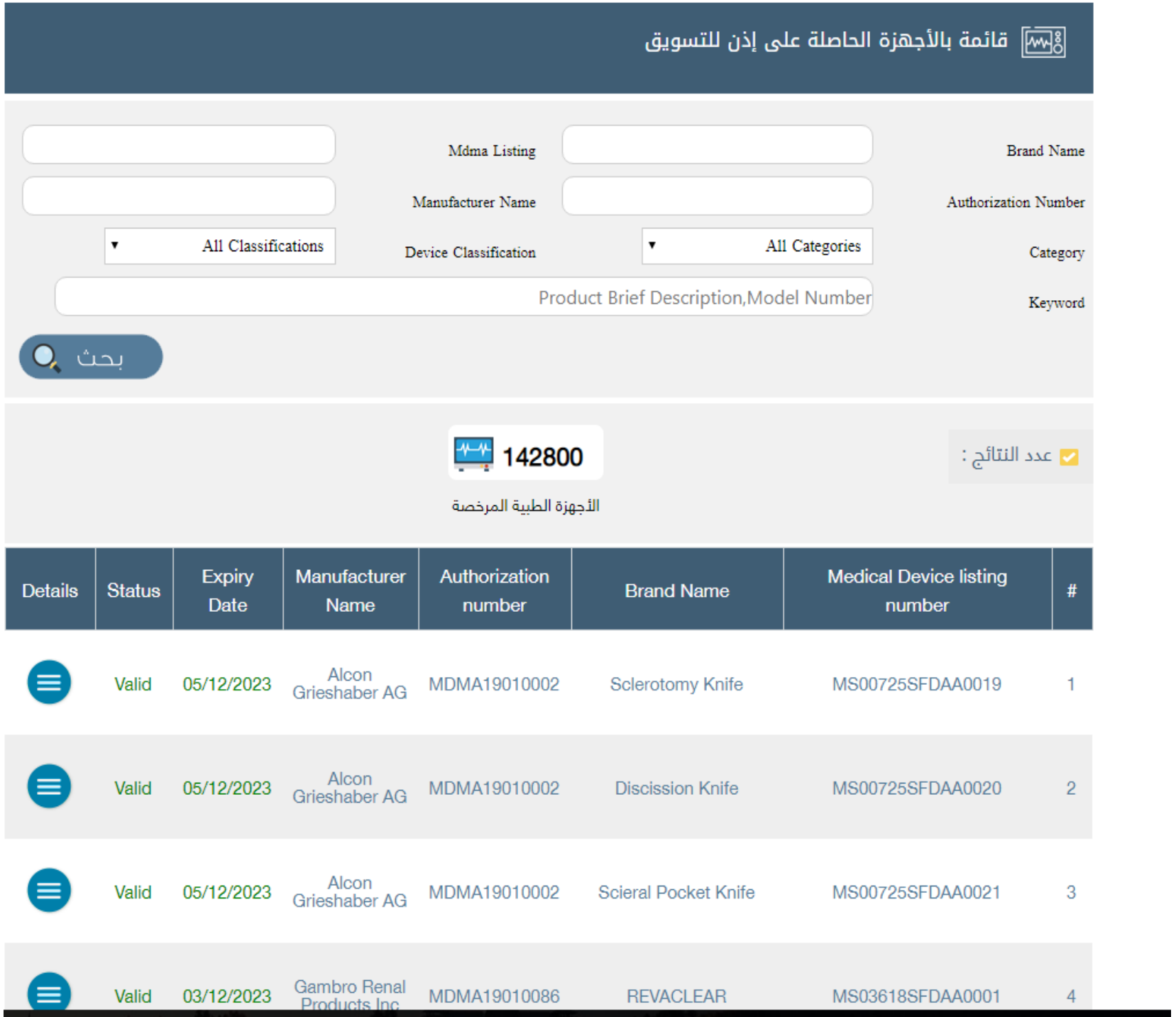
Product listing Category (see separate guidance)

1. Active implantable devices
2. Anaesthetic and respiratory devices
3. Dental devices
4. Electro mechanical medical devices
5. Hospital hardware
6. In vitro diagnostic devices
7. Non-active implantable devices
8. Ophthalmic and optical devices
9. Reusable devices
10. Single-use devices
11. Assistive products for persons with disability
12. Diagnostic and therapeutic radiation devices
13. Complementary therapy devices
14. Biologically-derived devices
15. Healthcare facility products and adaptations
16. Laboratory equipment

Product listing Classification (refer separate guidance)

Jurisdiction	Type	Class	Process
EU & Australia	MD	I non measure & non sterile	Administrative fees
		Is & Im	Reduced fees
		IIa	
		IIb	
		III	
		AIMD	
	IVD	GIVD	Administrative fees
		Self Test	Reduced fees
		List B	
		List A	
USA	MD	Unclassified	Administrative fees *
		Class I Exempt	
		Class II Exempt	
		I	
		II	
		III	
	IVD	Class I Exempt	Administrative fees *
		Class II Exempt	
		I	
		II	
		III	
CANADA	MD & IVD	I	Administrative fees
		II	
		III	
		IV	
JAPAN	MD& IVD	I	Reduced Fees
		II	
		III	
		IV	

MDMA Medical Device Market Authorization for Saudi Food & Drug Authority



Details	Status	Expiry Date	Manufacturer Name	Authorization number	Brand Name	Medical Device listing number	#
	Valid	05/12/2023	Alcon Grieshaber AG	MDMA19010002	Sclerotomy Knife	MS00725SFDAA0019	1
	Valid	05/12/2023	Alcon Grieshaber AG	MDMA19010002	Discission Knife	MS00725SFDAA0020	2
	Valid	05/12/2023	Alcon Grieshaber AG	MDMA19010002	Scieral Pocket Knife	MS00725SFDAA0021	3
	Valid	03/12/2023	Gambro Renal Products Inc	MDMA19010086	REVACLEAR	MS03618SFDAA0001	4

Web site access

- https://www.sfda.gov.sa/ar/medicaldevices/Authorized/Pages/Authorized-Medical.aspx

References for further reading

- صيغة قرار "تعزيز نظم تنظيم المنتجات الطبية" بالاجتماع 67 للجمعية العمومية لمنظمة الصحة العالمية http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-ar.pdf?ua=1
- بناء نظام رقابي للأجهزة والمنتجات الطبية خطوة بخطوة من منظمة الصحة العالمية http://applications.emro.who.int/dsaf/EMROPUB_2016_EN_18962.pdf?ua=1
- كتاب التشغيل لبناء منظومة رقابية متجانسة للأجهزة والمنتجات الطبية لتجمع دول التجانس الآسيوي AHWP http://www.ahwp.info/sites/default/files/ahwp-files/4_Technical_Committee/AHWP%20Playbook%20for%20Implementation%20of%20MD%20Reg%20Framework.pdf
- تعريف الجهاز أو المنتج الطبي بحسب المنظمة الدولية للأجهزة الطبية IMDRF http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n29r16-2005-definition-medical-device-050520.pdf
- أساسيات تصنيف مستوى خطورة الجهاز أو المنتج الطبي IMDRF http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n15-2006-guidance-classification-060627.pdf
- أساسيات تصنيف مستوى خطورة الجهاز أو المنتج الطبي للاتحاد الأوروبي http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_4_1_rev_9_classification_en.pdf
- المتطلبات الأساسية لسلامة وكفاءة الأجهزة والمنتجات الطبية IMDRF http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n68-2012-safety-performance-medical-devices-121102.pdf
- مواصفة آيزو 16142 (قائمة المواصفات الخاصة بضمان سلامة ومأمونية الأجهزة والمنتجات الطبية) https://www.iso.org/standard/63939.html
- نظام إدارة الجودة للأجهزة الطبية بهيئة الغذاء والدواء الأمريكية https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070897.htm
- الدليل الإرشادي لنظام إدارة جودة الأجهزة الطبية للموزعين من تجمع التجانس الآسيوي للهيئات الرقابية http://www.ahwp.info/sites/default/files/ahwp-files/7_Documents/3_Guidance_Documents/19th_ahwp/Guidance%20on%20Medical%20Device%20Quality%20Management%20System_Requirements%20for%20Distributors_FINAL%20document.pdf
- متطلبات الرقابة لما بعد التسويق (تجمع التجانس الآسيوي للجهات الرقابية AHWP) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n79r11-medical-devices-post-market-surveillance-090217.pdf

Thank you

Any questions