Saudi Arabia
Country Updates - SFDA

Eng . Essam M. Al-Mohandis
Executive Director of Surveillance and Biometrics
5th Dec 2013, KL –Malaysia

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Agenda

- Introduction
- Vision
- Mission
- Regulation
- Electronic Systems
- Organization Structure
- International outreach
- Statistics
- Future Progress

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Introduction

- Saudi Food & Drug Authority was established under the council of ministers resolution no (1) dated March 10, 2003.
- A royal decree was issued on Feb. 13, 2007 to establish SFDA law
- A council of ministers resolution no (18) was issued on June 18, 2007 giving the SFDA a full authority to regulate the MD in KSA
- SFDA reports directly to the premier of the council of ministers
- SFDA is an independent body with an independent budget.

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Introduction (cont)

SFDA board of director consisting of 18 member headed by /

HRH Prince

Salman bin Abdulaziz,

Crown Prince, Second Deputy Premier, Minister of Defense, SFDA Board Director

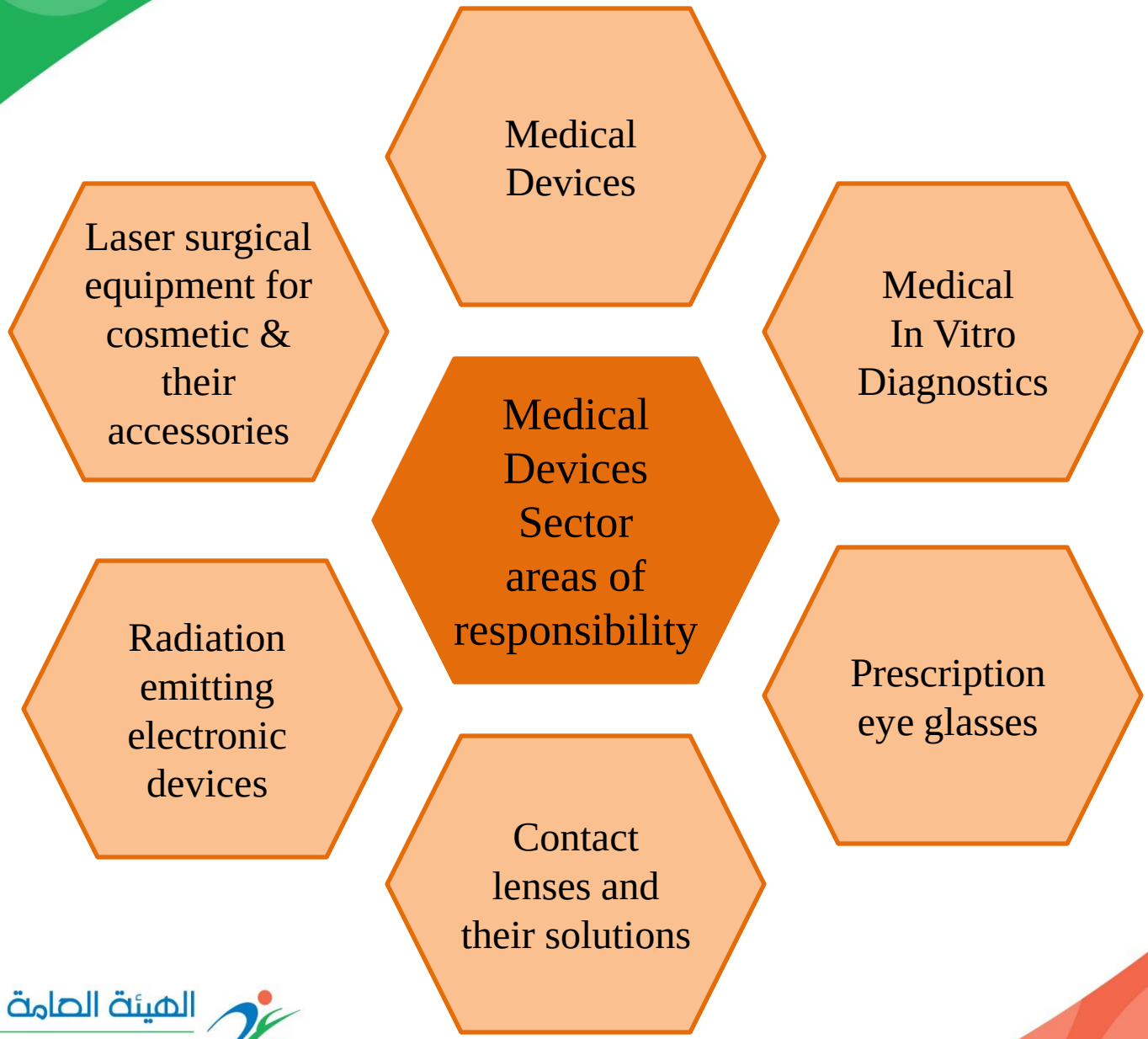
Vision

To be a regionally distinguished regulatory authority for medical devices and related electronic products, working toward safeguarding the public health in Saudi Arabia

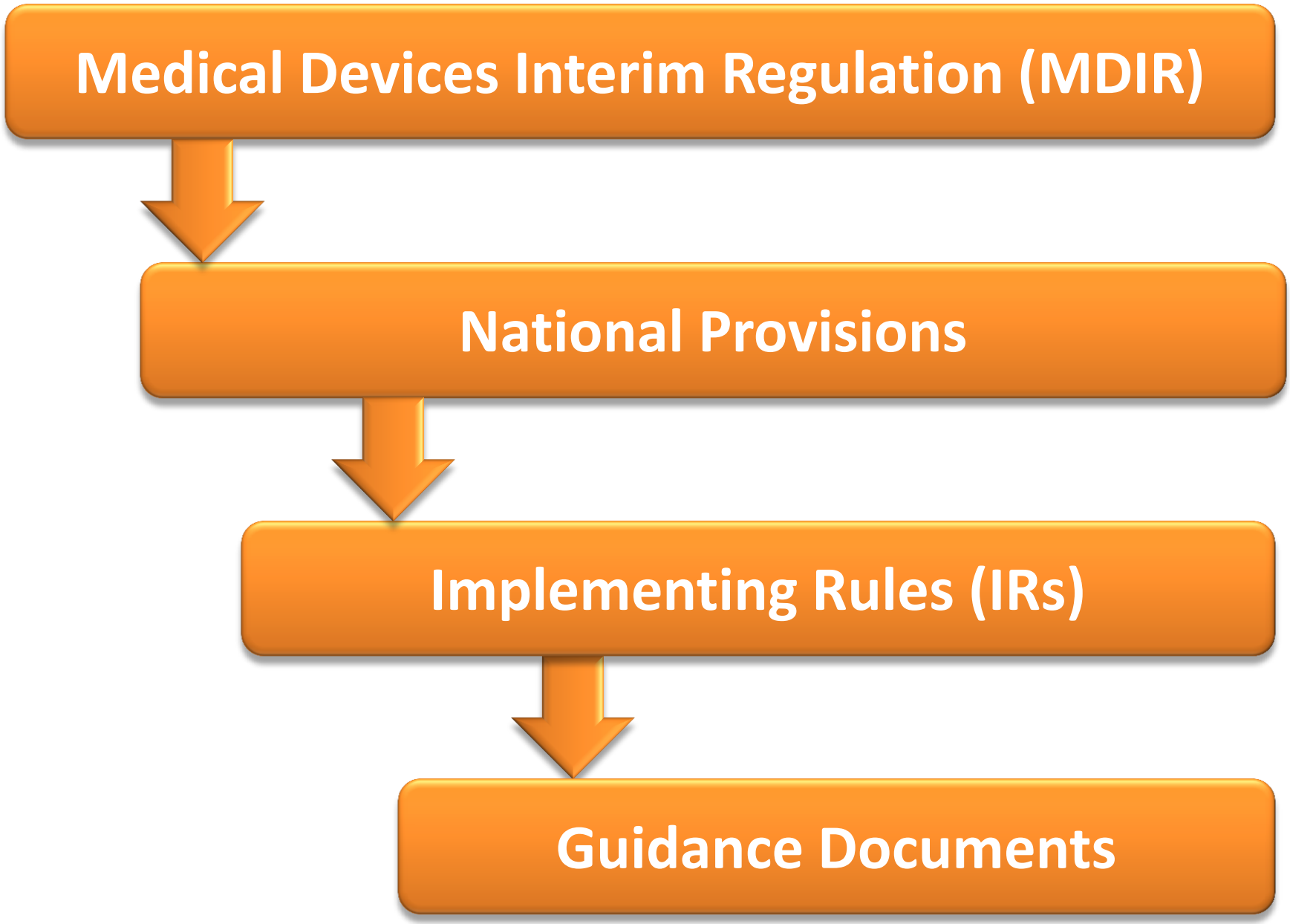
الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

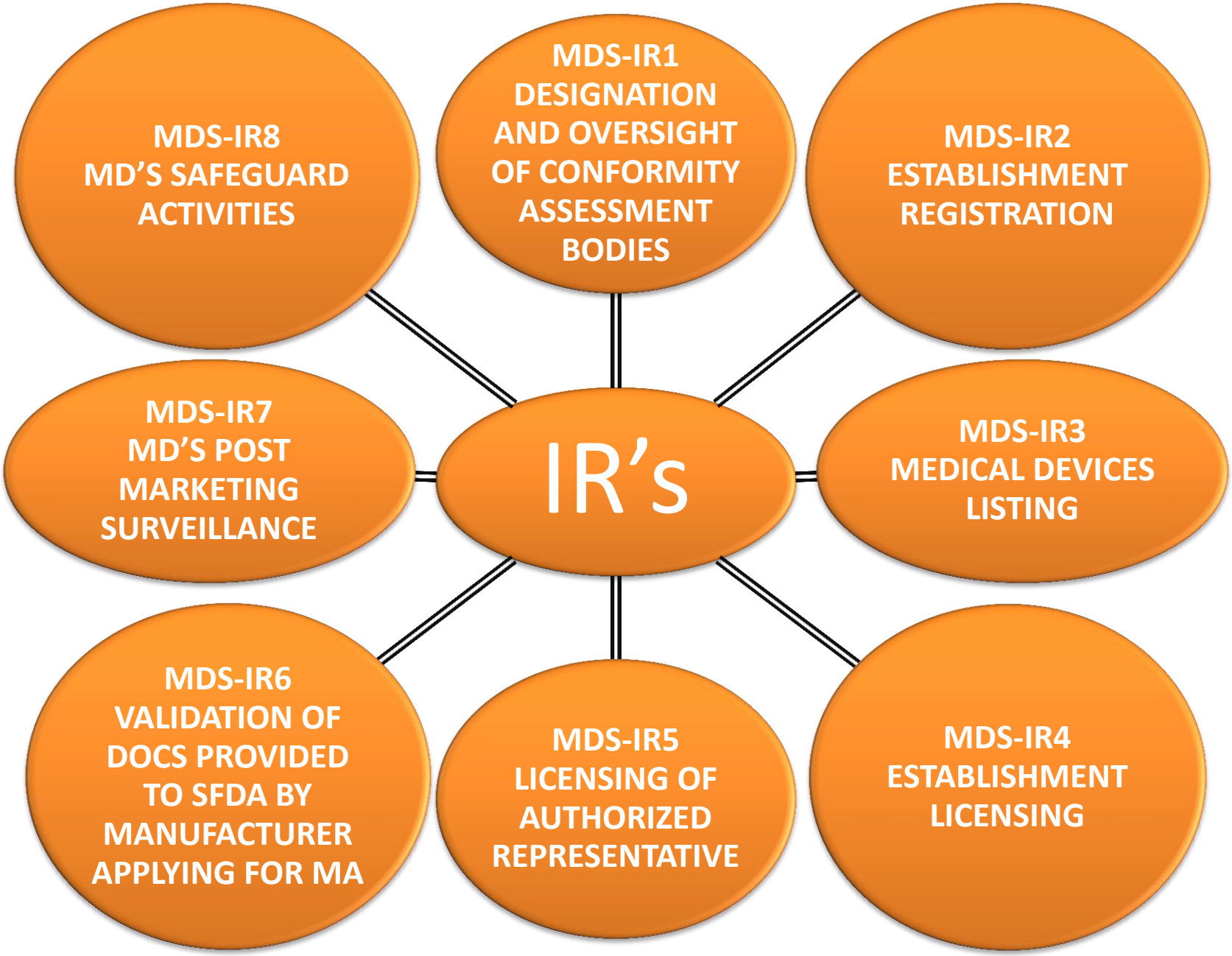
Mission

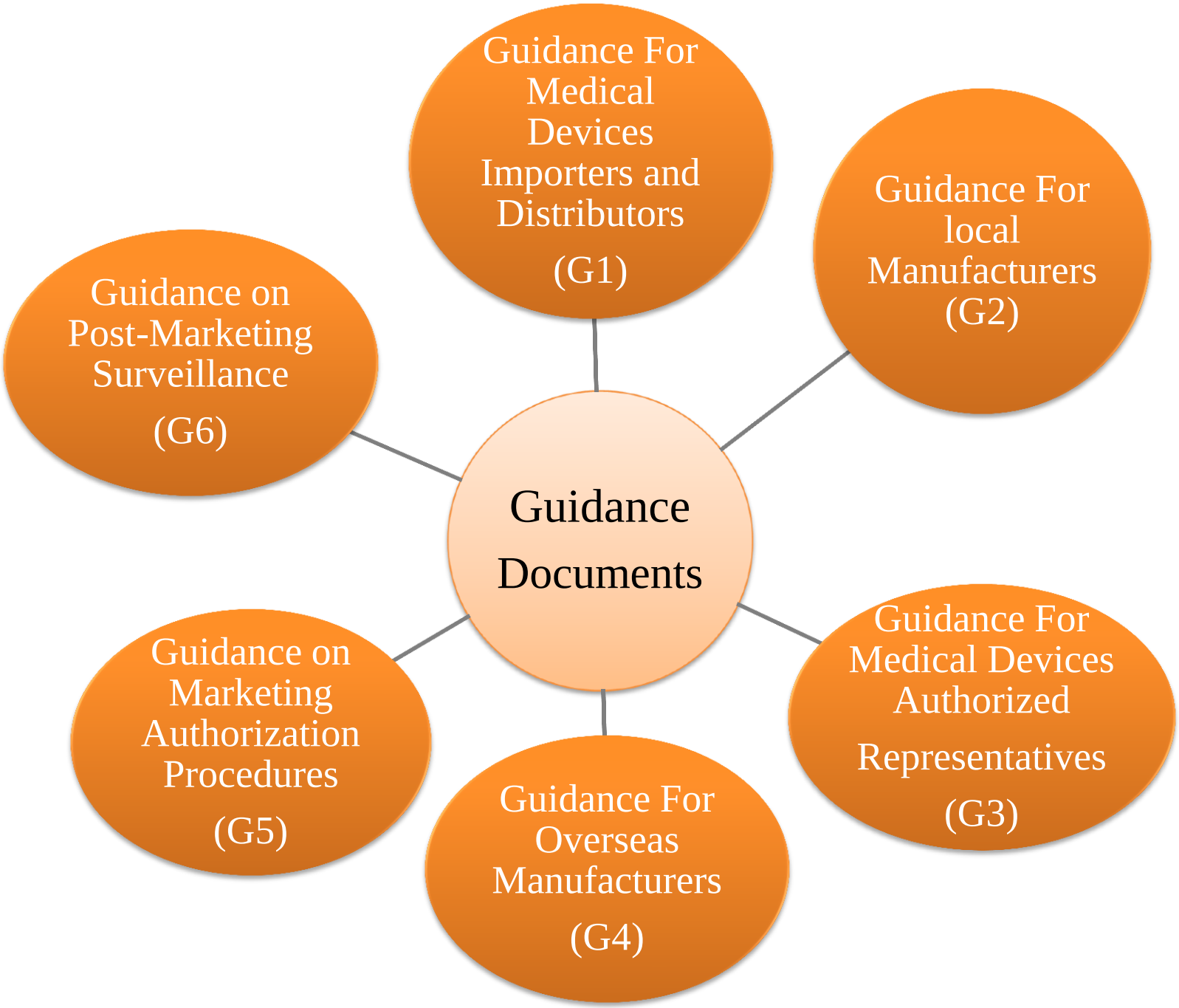
To ensure safety, effectiveness, and quality of medical devices and their performance according to their intended purpose, and to ensure the safety of related electronic products

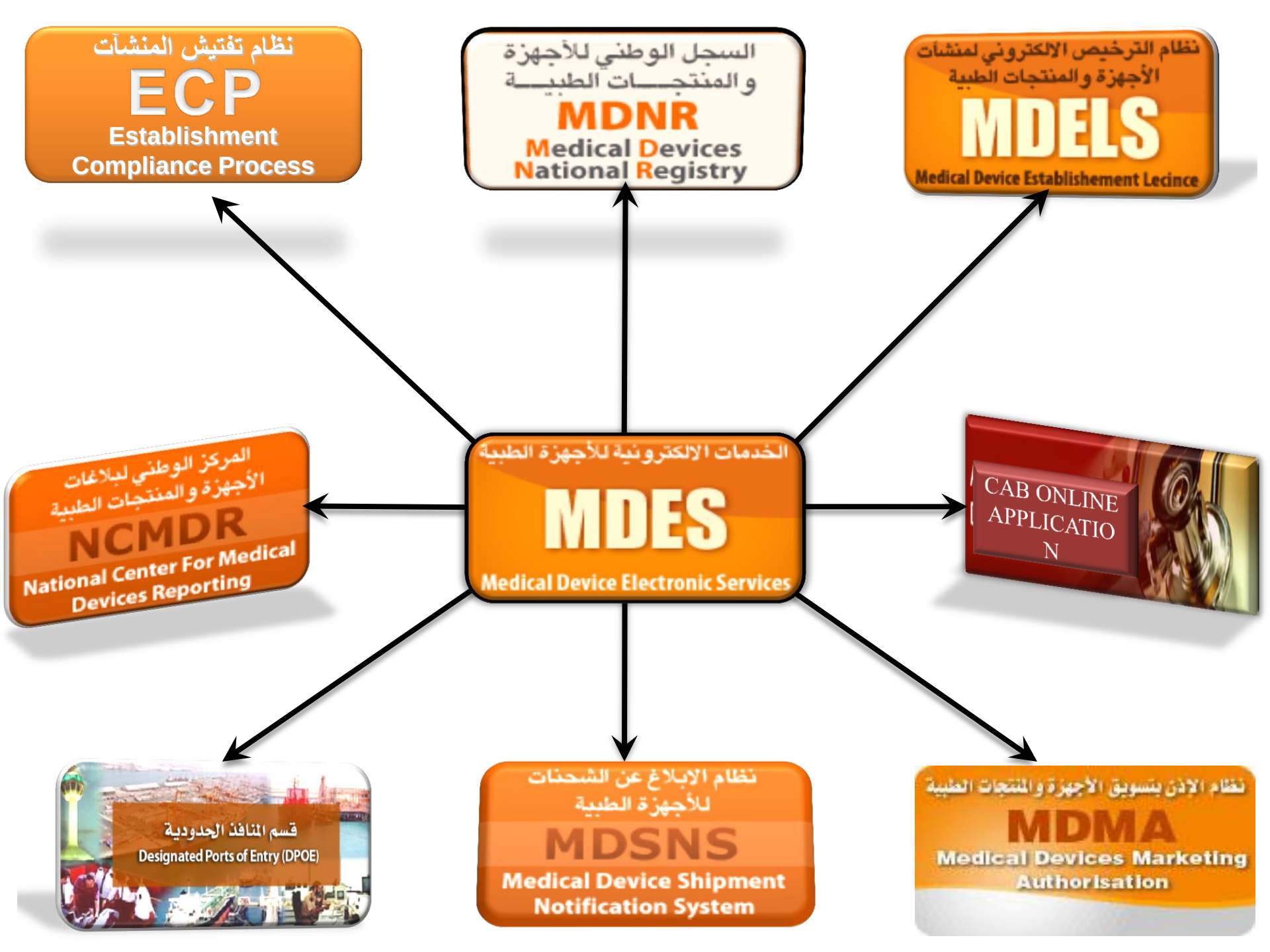


الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

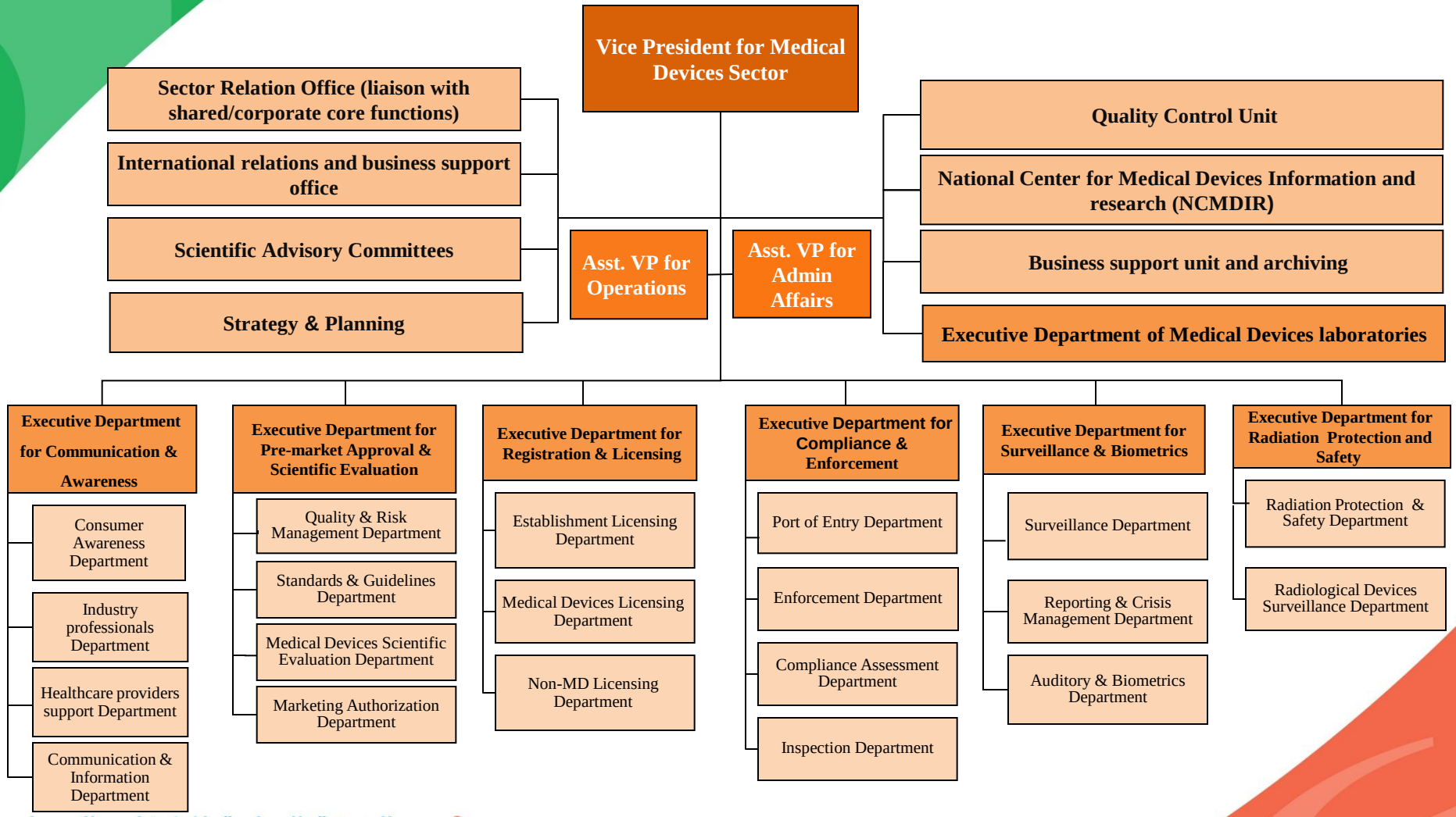

Medical Devices Interim Regulation (MDIR)
National Provisions
Implementing Rules (IRs)
Guidance Documents


MDS-IR8
MD'S SAFEGUARD ACTIVITIES
MDS-IR1
DESIGNATION AND OVERSIGHT OF CONFORMITY ASSESSMENT BODIES
MDS-IR2
ESTABLISHMENT REGISTRATION
MDS-IR7
MD'S POST MARKETING SURVEILLANCE
IR's
MDS-IR3
MEDICAL DEVICES LISTING
MDS-IR6
VALIDATION OF DOCS PROVIDED TO SFDA BY MANUFACTURER APPLYING FOR MA
MDS-IR5
LICENSING OF AUTHORIZED REPRESENTATIVE
MDS-IR4
ESTABLISHMENT LICENSING


Guidance For Medical Devices Importers and Distributors (G1)
Guidance For local Manufacturers (G2)
Guidance on Post-Marketing Surveillance (G6)
Guidance Documents
Guidance on Marketing Authorization Procedures (G5)
Guidance For Medical Devices Authorized Representatives (G3)
Guidance For Overseas Manufacturers (G4)


نظام تفتيش المنشآت
ECP
Establishment Compliance Process
السجل الوطني للأجهزة والمنتجات الطبية
MDNR
Medical Devices National Registry
نظام الترخيص الالكتروني لمنشآت الأجهزة والمنتجات الطبية
MDELS
Medical Device Establishement Lecince
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting
الخدمات الالكترونية للأجهزة الطبية
MDES
Medical Device Electronic Services
CAB ONLINE APPLICATIO N
قسم المنافذ الحدودية
Designated Ports of Entry (DPOE)
نظام الابلاغ عن الشحنات للأجهزة الطبية
MDSNS
Medical Device Shipment Notification System
نظام الاذن بتسويق الأجهزة والمنتجات الطبية
MDMA
Medical Devices Marketing Authorisation

Organization Structure for Medical Devices Sector



الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

International Relations

1) The International Medical Devices Regulatory Forum (IMDRF)

Board member of the International Medical Device Regulators Forum (IMDRF) , via AHWP

MDS participates in the following Working groups (2008-2013) :

- Member WG Quality System

A member of a single audit system for medical devices (MDSAP)

- Member National Competent Authority Report (NCAR) review

International Relations

Cont.

2) Asian Harmonization Working Party (AHWP):

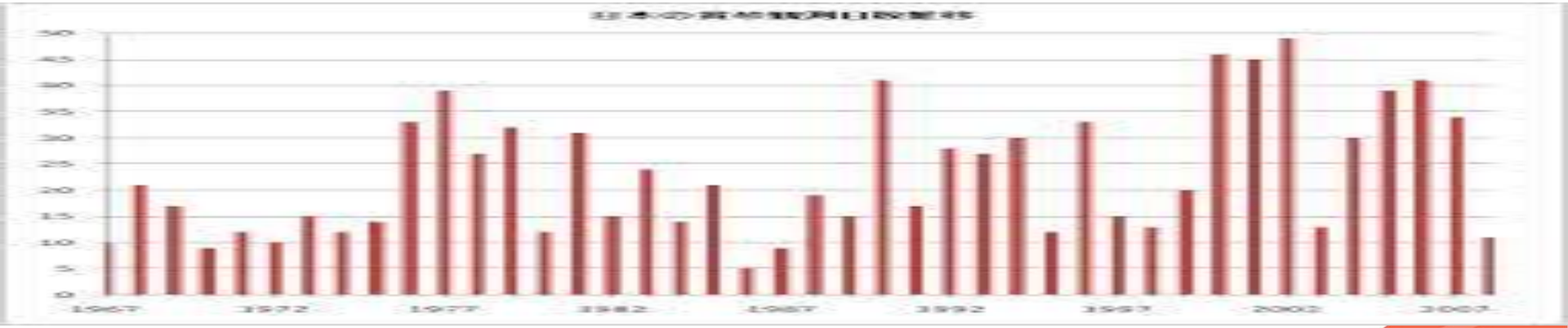
- AHWP Chair
- Vice chair of AHWP Technical Groups

MDS participates in the following study groups:

- Chair Quality Management System (WG3)
- Chair Quality System Audit (WG4)
- Member Post-Market (WG2)
- Member safety and clinical performance (WG5)
- Member Medical device Nomenclature (STG)

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Statistics



الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices National Registry -MDNR

MDNR Medical Devices National Registry

Status	Establishments	Devices
Accepted	**1823**	**135701**

Authorized Representative -AR

MDEL Medical Devices Establishment License

	Licensed	Rejected	Understudy	Total
Manufacturer	2439	438	86	**2963**
AR	557	240	63	**860**

Medical Devices Establishments Status

MDEL Medical Devices Establishment License

Establishment Class	Licensed	Under Review	Total
Class A	70	3	**73**
Class B	217	7	**223**
Class C	286	12	**398**
Class D	35	2	**37**
Total	**608**	**24**	

Medical Devices Marketing Authorization

MDMA Medical Devices Marketing Authorization

MDMA	Number of Applications
Issued	**1139**
Under Process	**310**
Waiting for Payment	**233**
Returned, waiting Re-Submission	**1282**
Draft, waiting Submission	**2322**
Total	**5286**

National Center for Medical Devices Reporting

NCMDR

National Center for Medical Devices Reporting

No. of Field Safety Notice by source:			2008	2009	2010	2011	2012	2013	Total
Emergency Care Research Institute	ECRI	New	7	492	653	387	500	282	2321
		Update	-	-	-	-	1033	743	-
Food and Drug Administration	USFDA	New	1080	1195	515	1238	1199	820	6047
		Update	-	-	-	-	1343	704	-
Medicine &Healthcare products Regulations Agency	MHRA	New	0	149	479	471	440	302	1841
		Update	-	-	-	-	340	348	-
National Competent Authority Report	NCAR	New	59	70	61	85	124	98	497
		Update	-	-	-	-	223	170	-
National Center for Medical Devices Reporting	NCMDR	New	8	52	164	115	109	50	498
		Update	-	-	-	-	78	92	-
The Federal Institute for Drug and Medical Devices, Germany	BfARM	New	0	0	0	35	101	210	346
		Update	-	-	-	-	359	799	-
Swiss Agency for Therapeutic Products, Swaziland	Swiss Medic	New	0	0	0	10	10	92	112
		Update	-	-	-	-	135	251	-
The Medical Device Control Office, Hong Kong	MDCO	New	0	0	0	0	5	0	5
		Update	-	-	-	-	21	0	-
Therapeutic Goods Administration	TGA	New	-	-	-	-	0	99	99
		Update	-	-	-	-	0	225	-
Total	New		1154	1958	1872	2341	2488	1953	11766
	Update		-	-	-	-	3532	3332	-
	Total		-	-	-	-	6020	5285	-

Cleared shipments

	MD	IVDD	Non-Medical IVDD	Total
Cleared Shipments	30,026	16,699	234	46,959
Cleared Items	75,816	24,497	348	100,661
Quantity of cleared items	2,504,816,963	205,309,635	307,819	2,710,434,417

Rejected shipments

	MD	DIVD	Non-Medical IVDD	Total
Rejected Shipments	968	1,271	11	2,250
Rejected Items	5,834	10,007	74	15,915
Quantity of rejected items	40,509,575	4,535,774	280,454	45,325,803

Rejection subjected to Issues related to :

Packing , Transporting ,labeling, Storing and Product Quality

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء
قطاع الأجهزة والمنتجات الطبية

MDPOE 004 V 1

نموذج تقرير رفض شحنة

معلومات عامة:

اسم المنفذ	مطار الملك خالد الدولي	تاريخ ورود المعاملة	1432/05 /01
اسم المستورد	شركة الجيل الطبية والتجارية	إذن الاستيراد	1101383-1100680
رقم بيان الاستيراد	68268	تاريخه	1432/04/30
رقم الفاتورة	9101504586-9101504595-9101505273-9101505827-9101504587-9101504612-9101504610-9101504613-9101504593-9101504690-3159610-9101484939-9101484914-9101484914-9101484229-9101484936-9101484941-9101484921-9101484917-9101483279-9101484916-9101485528-9101483287-9101484938-9101484937-9101484908	رقم البوليصة	85343370
عدد الأصناف	66	الكميات	149

نوع الشحنة:

○ كواشف	✓ أجهزة طبية	○ أخرى:.....

ملاحظات المعاينة :

الشحنة قادمة بتاريخ 1432/04/29 ووجدت أنها تحتوي على عده أصناف منها كواشف وأخرى مستلزمات لكن عند معاينه المؤشر تبين أنها وصلت لدرجه حرارة (60) درجه مئوية لذا تم رفض جميع الكواشف ولم يتم إلا فسح المستلزمات الطبية فقط.

النتيجة:

○ رفض كامل للشحنة

	✓ فسح جزئي للشحنة
عدد الأصناف المرفوضة	142
إجمالي الكميات المرفوضة	369
القيمة بالريال	161205

التوصيات:

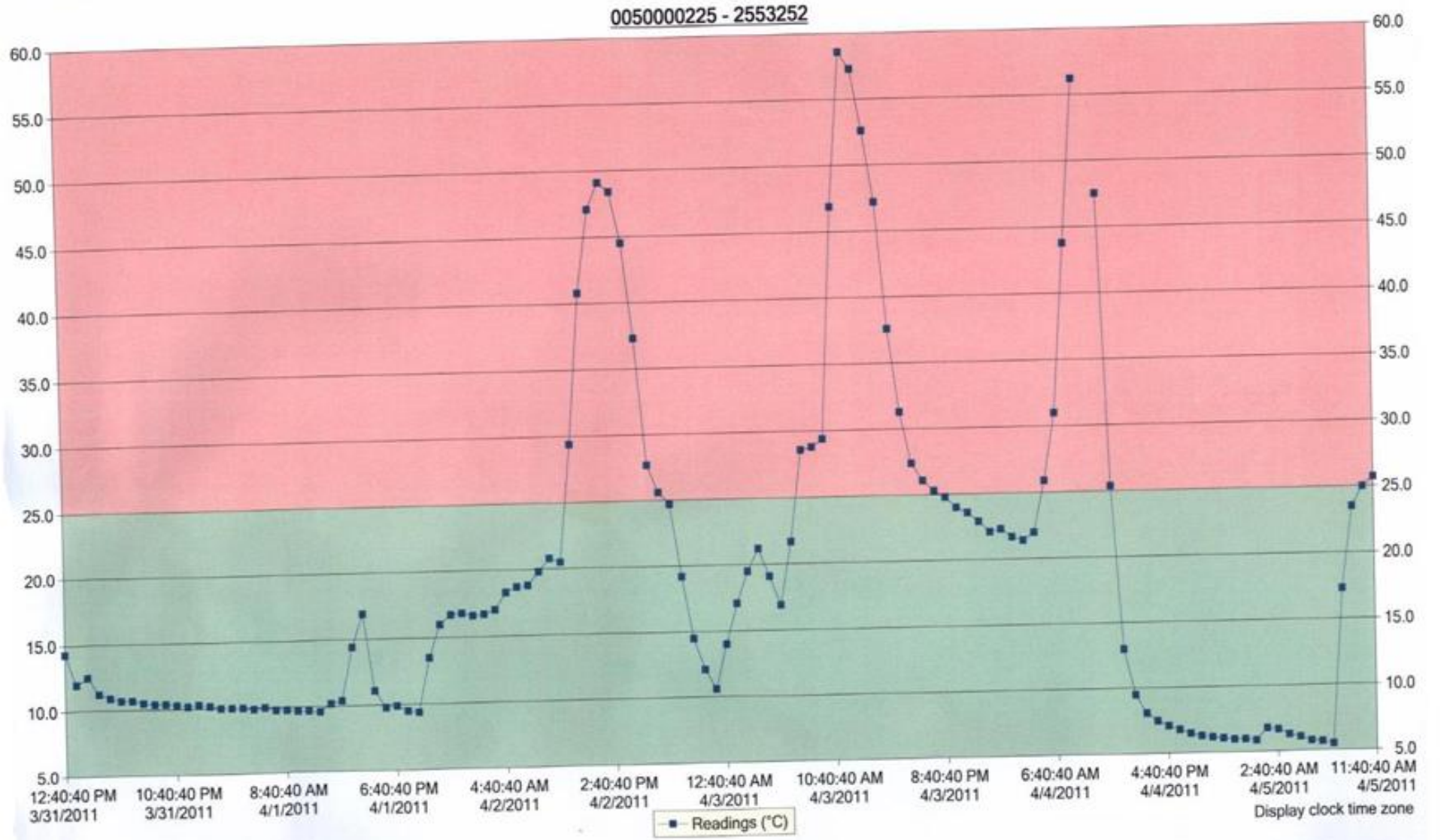
✓ إتلاف	○ إعادة تصدير	○ حجز

اسم الموظف:وليد الحربي
التوقيع:

مشرف المنفذ:مشعل العنزي
التوقيع:

*ملاحظة: يجب إرفاقا لتالي مع هذا التقرير: 1/الفاتورة 2/ بيان الاستيراد 3/ الفسح الجزئي للشحنة.

LogTag ID	0050000225
User ID	2553252
First reading	3/31/2011 12:40:40 PM
Last reading	4/5/2011 11:40:40 AM
Name of file	0050000225 Started 3-31-2011, Finished 4-5-2011.ltd
File location	D:\Documents and Settings\user\My Documents\My LogTag Data\



4/5/2011 1:56:08 PM

Products were exposed to Sun light and rain

Products were exposed to Sun light and rain

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority
SFDA

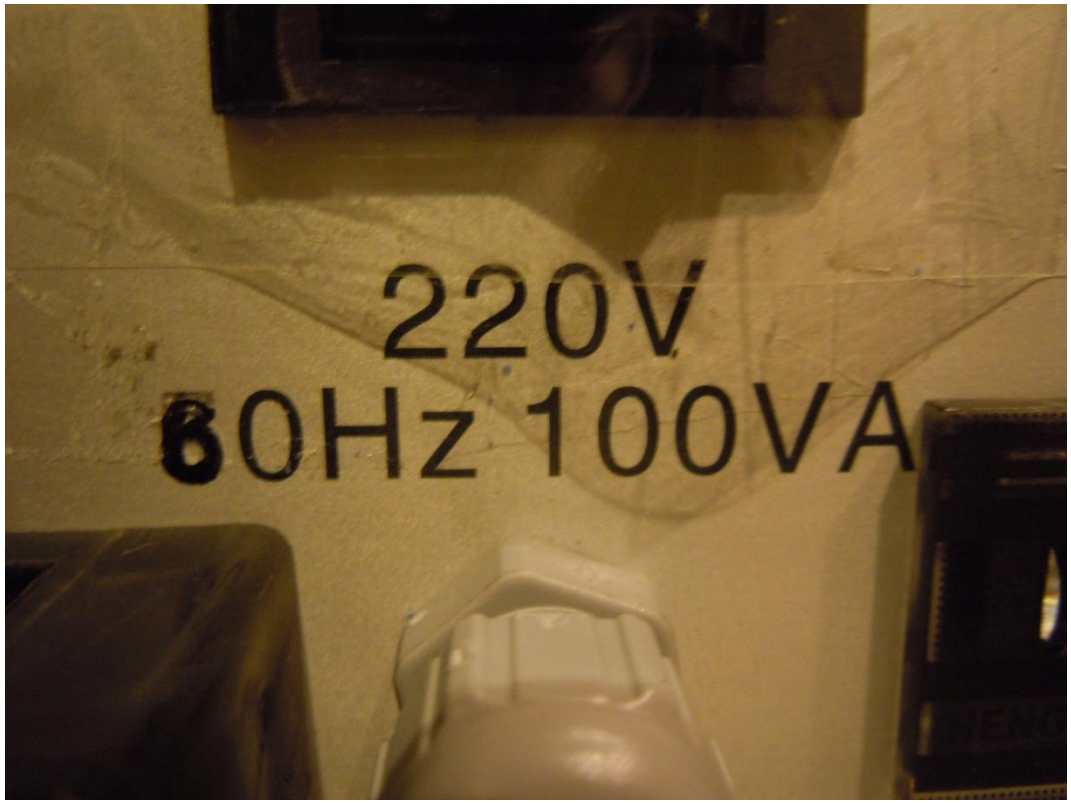
Unsuitable Storage Area (Toilet)

Damaged Medical Products

Damaged Medical Devices Due to Improper Storage

Lack of ID card on the Product

Replaced Identification Card



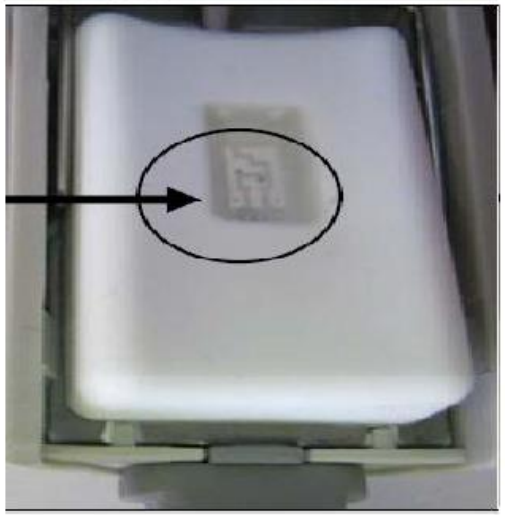
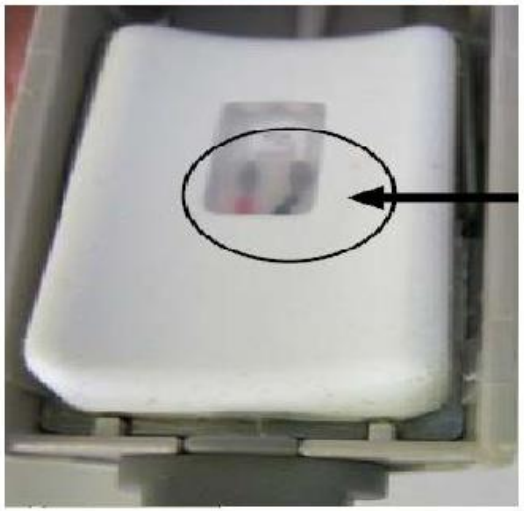
مقلد Counterfeit	أصلي Genuine
لم يتم تحديد الفئة العمرية 	تم تحديد الفئة العمرية للاستخدام لأقل من ثمانية عشر شهر 
لم يتم تحديد الفئة العمرية 	تم تحديد الفئة العمرية للاستخدام من سنة إلى خمس سنوات 

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

1- اختلاف طبقة لون العلبة بين المنتجين .
2- رداءة الطباعة في الجهاز المقلد مقارنة بالأصلي .

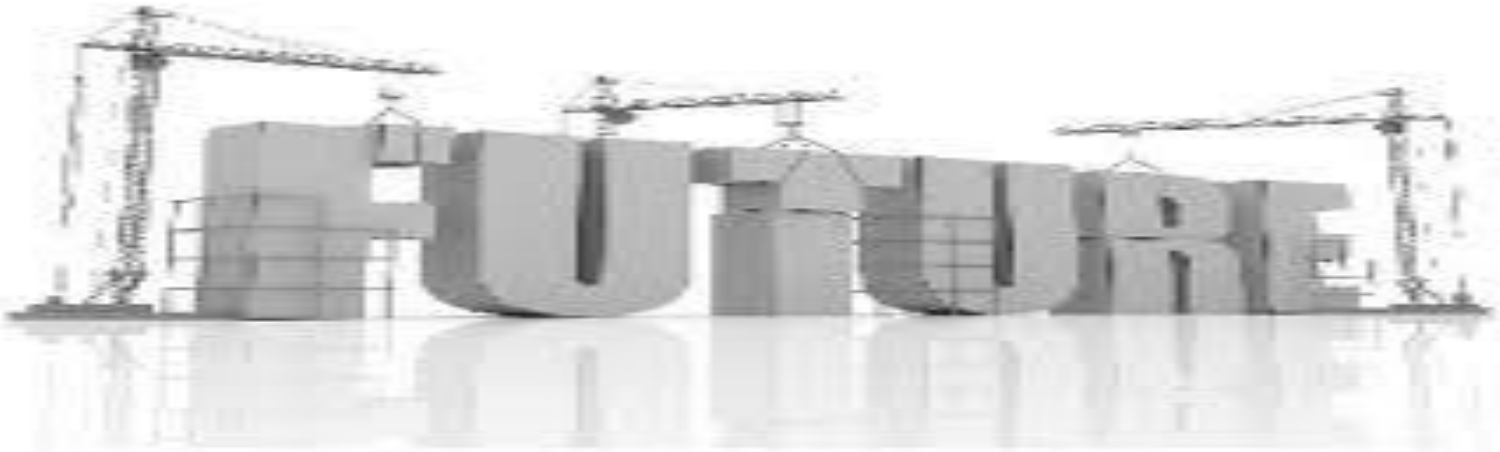
الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

مقلد Counterfeit	أصلي Genuine
	
	

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Future Progresses



Medical Devices Main Frame Reg. (Q.1, 2015)

NCMD Information and Research (Q.1 ,2014)

NCMD Reporting (Q.1, 2015)

National Technical Committee , Standard

National Medical Devices Implant (Q.3, 2013)

Thank You

www.sfda.gov.sa