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MINISTRY OF PUBLIC HEALTH

REGULATION SYSTEM OF MEDICAL DEVICES IN LEBANON

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PLAN

- Medical devices policy at the Ministry of Public Health
- Regulatory framework for MD
- The way forward…

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Context analysis

- Similarity with neighboring markets.
- Low local production capacity => Total dependence on the import from multinational firms.
- Weak regulatory environment leaves seep products not always complying with the minimum security requirements
- Dominance of private providers with excessive and profitable high technology services implemented and offered with almost no controls or evaluation.
- Excess supply of physicians and an imbalance between specialists and general practitioners
- No systematic evaluation of safety and benefits.
- Incapacity to perform testing and premarket evaluation for medical devices

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National policy for MD

Promotion of continuous improvement of quality of care and patient safety.

MoPH adopted a national strategy with an approach that emphasizes:

- Cohesive policies between phases of the medical device life cycle: a harmonized health technology regulation, an appropriate health technology assessment and a global health technology management.
- Transparency, consistency and large participation of all stakeholders.
- Regulatory framework focusing on quality and security through products' compliance with international standards to reduce the risks associated with the use of non-compliant products.
- Post-marketing surveillance in accordance with recent international guidelines, the establishment of a traceability and vigilance system for implantable high-risk products (class IIb and III).

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MoPH – Ansm Cooperation project

- Exploratory mission carried out in April 2010
- Protocol signed in January 2011
- Cooperation is taking place in the following areas:
  - **Exchange of information** on drugs, mostly generic (quality, efficiency and safety) and medical devices
  - Scientific and practical cooperation in the field of quality, effectiveness and safety of drugs and medical devices
  - **Skills' development** (training of MOH staff).

Ecole Supérieure des Affaires in Beirut (ESA) is the implementation operator for this cooperation.

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MoPH – Regulatory framework

Objective

1. To ensure that the imported MDs meet the minimum requirements of quality and safety
2. To be able to retrieve products subject to recalls in case of incident.

Action plan to establish a medical devices (MD) regulatory system:

- Requirements for importation of MD

(Establishment of a national procedure for importation of MD)

- Registration of implantable MD/ implantable MD suppliers
- Follow up on implantable MD importation
- Traceability of MD.

Priority is given to the optimal use of resources for market knowledge and the exercise of a minimum post-marketing surveillance which will follow up any health measures following the recent international orientations.

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International experience in regulation of medical devices

- The Global Harmonization Task Force (**GHTF)** was a voluntary group of representatives from national medical device regulatory authorities and the regulated industry: representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific and North America, each of which actively regulates medical devices using their own unique regulatory framework.
- Purpose : to encourage convergence in regulatory practices related to **ensuring the safety**, **effectiveness/performance and quality** of medical devices, **promoting technological innovation** and **facilitating international trade**.
- Publication and dissemination of harmonized guidance documents on basic regulatory practices adopted/implemented by member national regulatory authorities.
- Served as an information exchange forum through which countries with medical device regulatory systems under development could benefit from the experience of those with existing systems and/or pattern their practices upon those of GHTF founding members.

- IMDRF was born in October 2011, to build on the strong foundational work of the GHTF on Medical Devices and to accelerate international medical device regulatory harmonization and convergence.
- Current members are **Australia**, **Brazil**, **Canada**, **China**, **Europe**, **Japan**, **Russia**, **Singapore**, **South Korea**, and the **USA**.
- The World Health Organization (WHO) and the APEC LSIF Regulatory Harmonization Steering Committee are Official Observers. The Asian Harmonization Working Party (AHWP) and the Pan American Health Organization (PAHO) are IMDRF Affiliate Organizations.

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Nomenclature system of medical devices

- The Global Medical Device Nomenclature (GMDN): list of generic names used to identify all medical devices (used in diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans).
- **Purpose**: to provide a naming system that can be used to exchange medical device information and support patient safety.
- GMDN is used for:
  - Data exchange between manufacturers, regulators and healthcare authorities
  - Exchange of post-market vigilance information
  - Supporting inventory control in hospitals
  - Purchasing and supply chain management
- Recommended by the International Medical Device Regulators Forum (IMDRF) and used by over 70 national medical device regulators.
- Managed by the GMDN Agency which has a Board of Trustees, which represent regulators and industry.
- GMDN Database: Information in the form of a 5 digit numeric GMDN Code is cross-referenced to a precisely defined Term Name and Definition.
- *Example:*
  - *GMDN Term Name: Scalpel, single-use*
  - *GMDN Code: 47569*
  - *GMDN Definition: A sterile, hand-held, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless steel alloy or carbon steel and the handle is often made of plastic. This is a single-use device.*

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1. DECISIONS OVERVIEW

Decisions no.	• 455/1 & 1506/1
Issuance Date:	• 16 April 2013 • 1 September 2014
Effective Date:	• July 1st, 2013 • April 1st, 2015
Objective:	• To guarantee the safety and quality of all medical equipment, supplies and instruments that are sold in the Lebanese market and used in various medical procedures.
Content	• 10 articles detailing the entire process • 7 items detailing implementation of 455/1

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2. Field of application

- "Medical devices **that are not covered** by the Drug Registration Technical Committee (law 367/94) nor by decree 5518" should be listed/ registered.
- Medical devices classified into 16 categories according to GMDN agency classification:
  1. Active implantable devices
  2. Anesthetic 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

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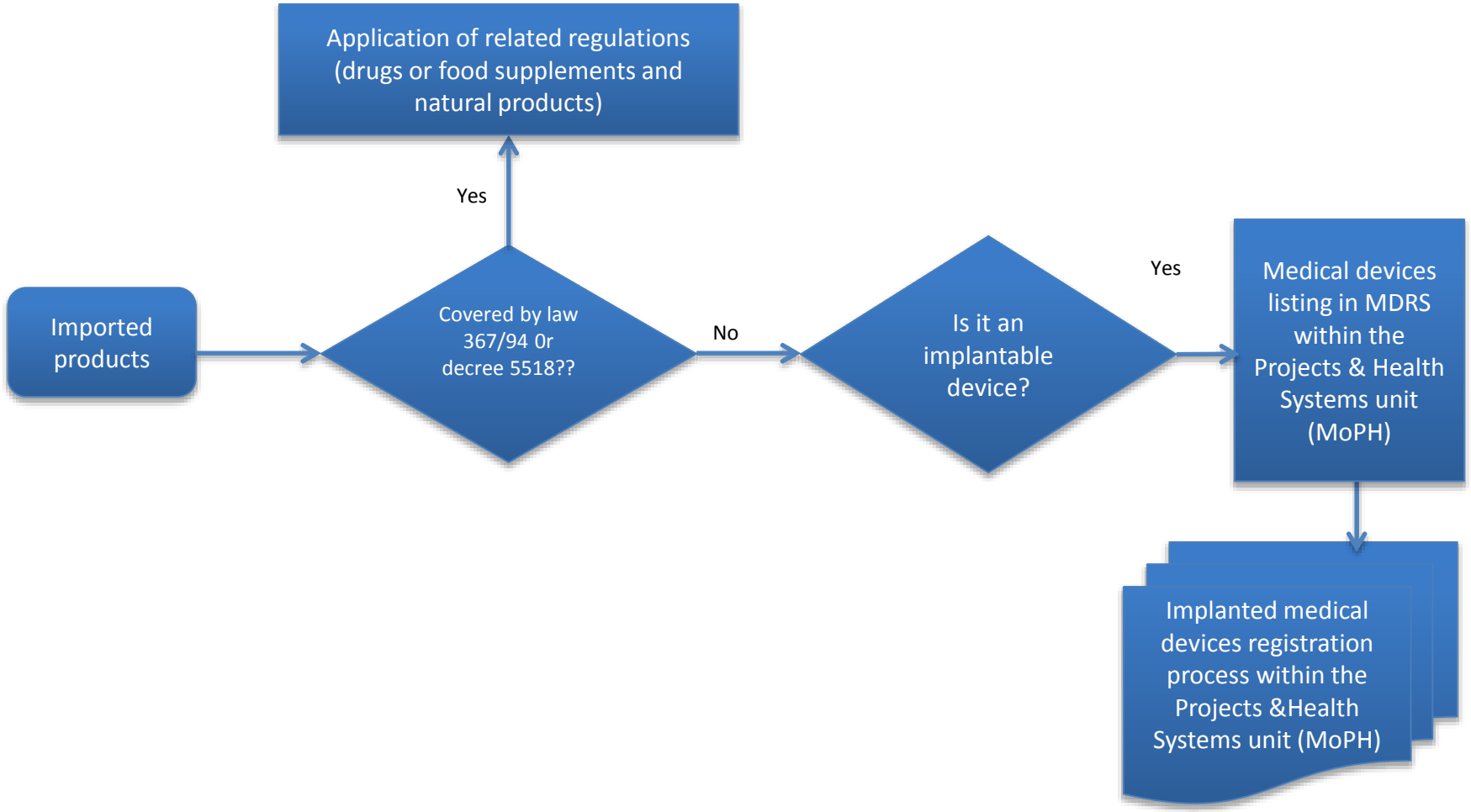
3. General Process



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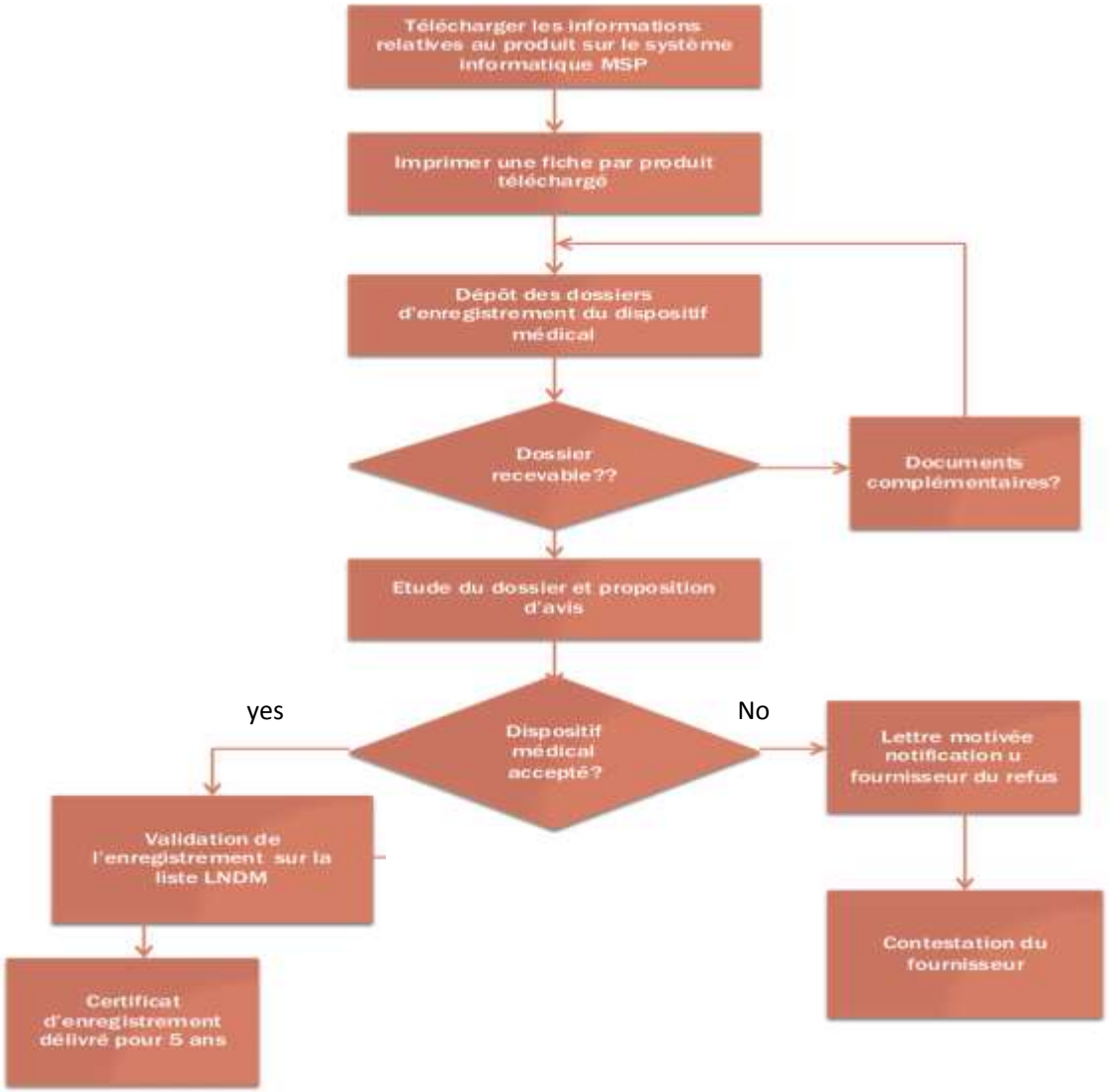
Registration Process as defined in the national procedure



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4. Traceability Records & vigilance system

Article 8: **Traceability Records**

Suppliers' Required Records

Traceability record (Import Date; Quantity; Entities that received the goods)

Healthcares' Facility Required Records

keep records of all patients who received the implanted medical devices, including patient name, address and telephone number.

Article 9: "Notify the MOH of all unexpected adverse events and side effects resulting from the use of these products".

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5. Decision 1506/1

1. Definition of a MD
2. Adoption of GMDN nomenclature system
3. Classification of MD
4. Additional compliance certificates
5. Amendment of DMI identification form
6. Deadline

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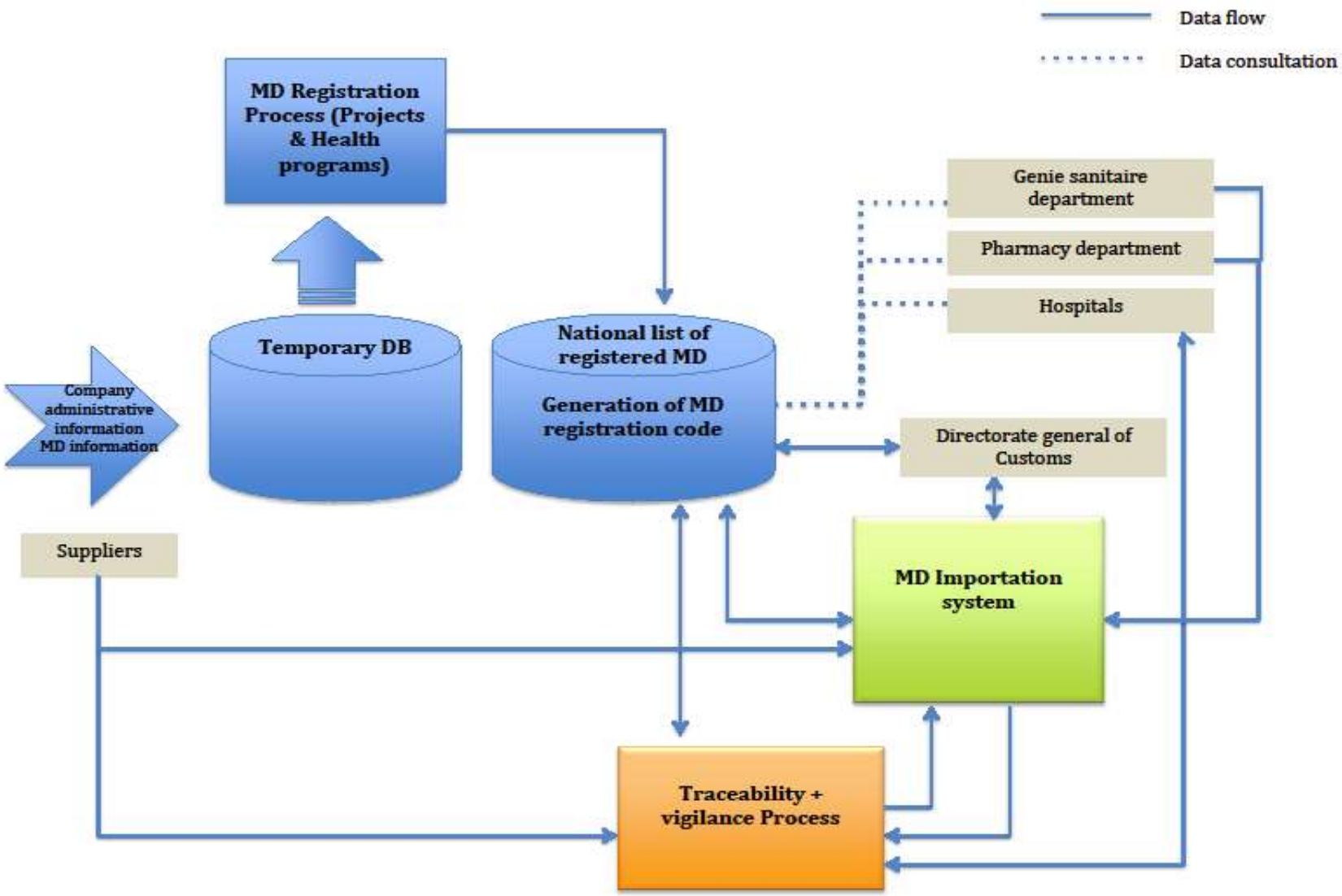
MoPH MD regulatory scheme



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Medical devices registration software (MEDReg)

Company‘s Administrative Profile

Device Specification (Components, Functions, Scope of use…)

Sterilization Method

Certificate of Conformity

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Medical devices registration software (MEDReg)

شهادات المطابقة

الشهادة	شرح	الرمز	التاريخ	تاريخ انتهاء الصلاحية
EC-full quality assurance		D1024900045	27/06/2014	27/05/2018
CE Marking of Conformity		CE 002/V15	27/06/2014	27/05/2018
Free Sale Certification		93/42/EEC	17/12/2015	27/05/2018

ربط جدول بالأجهزة المتشابهة لنفس مواصفات الجهاز المعروض مع مقاساتها المختلفة — يوجد

جدول الأجهزة

رقم النموذج	شرح النموذج
LS 01 025	Implant testiculaire lisse 25
LS 01 034	Implant testiculaire lisse 34
LS 01 040	Implant testiculaire lisse 40
LS 01 050	Implant testiculaire lisse 50
LS 01 053	Implant testiculaire lisse 53

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سعر الجهاز ,

العملة: Euro

مرفقات الإستمارة

دليل المستخدم: True

البطاقة الملصقة: True

الاسم والتوقيع

الاسم	الوظيفة	التاريخ
Jean-Pierre Asmar	General Manager	04/08/2016

عودة الى لائحة الأجهزة

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تفاصيل الجهاز

عودة الى لائحة الأجهزة

رقم الجهاز	7628
Commercial Name/الاسم التجاري	Testicular Implants Lisse
Category / الفئة	Implantable devices
Generic Name/التسمية العامة	Testicle prosthesis
Code of Customs /الرمز الجمركي	مفاصل اصطناعية
NSSF Code/رمز الضمان	
Device's Code /رمز الجهاز	
Country of Origin/ بلد المنشأ	France
تصنيف الجهاز حسب مستوى الخطر /Class of the product	IIb
Manufacturer name/اسم الشركة المصنعة	SEBBIN
أجزاؤه (إذا توفرت) /(Its Components (If Available:	
Technical Description/ وصفه الفني	a flexible silicone elastomer envelope obtained by successive dips of a mould that defines the shape, the profile and the volume - a silicone elastomer occlusion patch whose thickness and diameter are defined), - a high cohesive biocompatible, medical grade, Naturgel™ cohesive gel, complying with the ISO 14607 standard.
يتضمن مشتقات من أصل: /It Contains Derivatives from	None
غير محدد	
Function /طبيعته	Non-Active Implanted Medical Device
Scope of Use / نطاق استعماله	For Treatment

Specialty / اختصاصه:			
Cardio-Vascular /قلب – شرايين	False	Orthopedic/عظم	False
ENT/أنف، أذن، حنجرة	False	Plastic Surgery/تجميل	True
Dental /أسنان	False		
Gastroenterology/جهاز هضمي	False	Uro-Gynecology/مسالك بولية – تناسلية	False
Neurology/أعصاب	False	Face Reconstruction/ترميم وجه	False
Others / مختلف	True	cancer patients	

Sterilization Mode/ طريقة تعقيم الجهاز	Ethylene oxyde
غير محدد	
هل الطريقة مطابقة لمعايير التعقيم العالمية؟	نعم
حدد المعايير	ISO 14607 standard

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MoPH – Follow up on Importation of MD

- **Goal** : to ensure that only implantable MD compliant with minimum quality and safety requirements are imported to the Lebanese market
- Implemented within the departments in charge of invoice endorsement (pharmacy for sterile items and health engineering departments for non sterile)
- Invoices uploaded by suppliers
- Linked to MEDReg
- Training sessions are provided to the suppliers in order to ensure satisfactory implementation.

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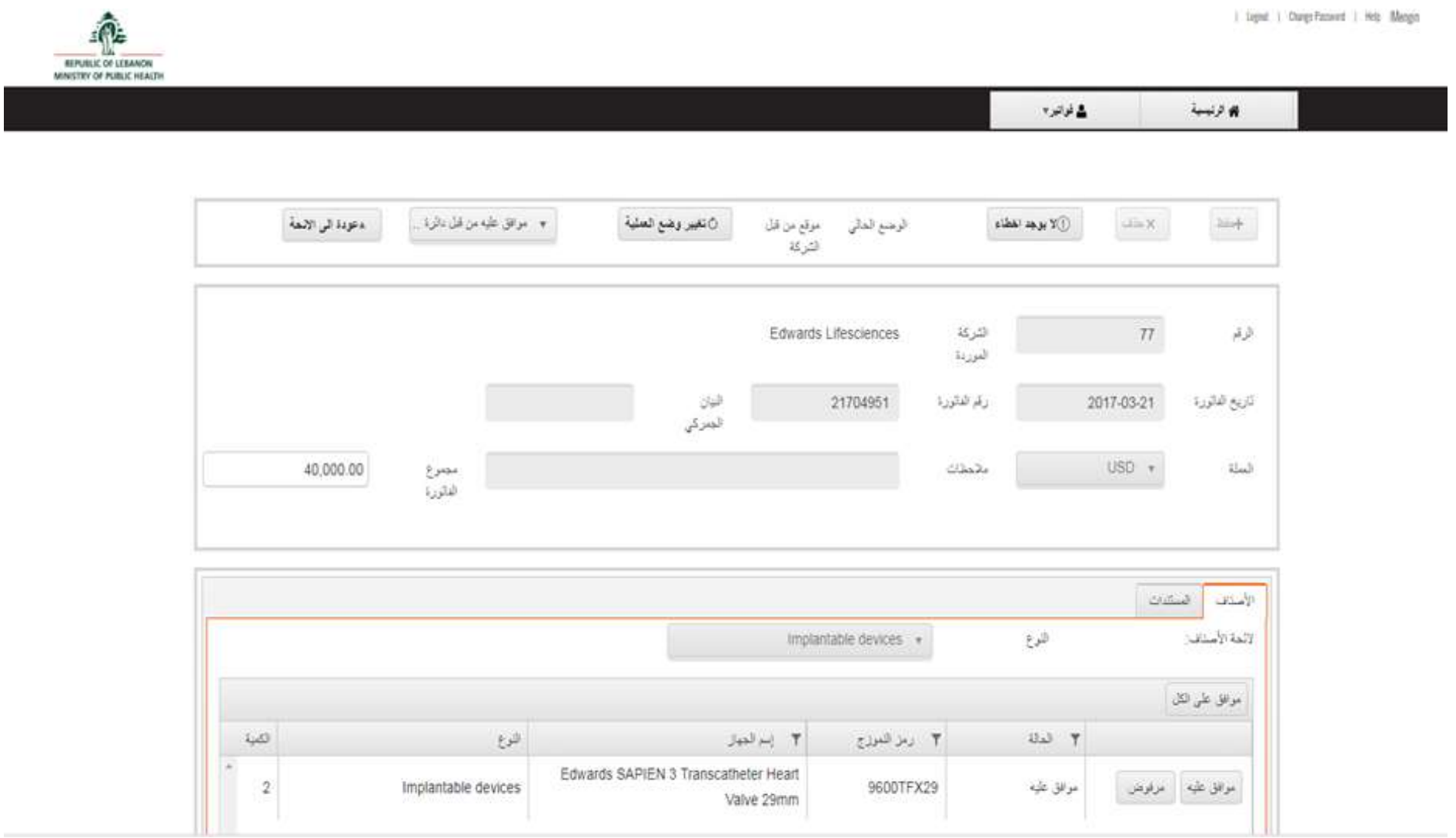
MoPH – Follow up on Importation of MD



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MoPH – Traceability of MD Module (MEDTrac)

- **Goal :** to track the use of the medical devices by hospitals.
- Allow all hospitals to register the medical devices implanted for each case.
- Hospitals will access this module online.
- MEDTrac will be linked to MedReg and MedImport in order to validate registered data.

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MoPH – Traceability of MD Module (MEDTrac)
Uploaded data

Supplier data 1. Supplier ID (from MedREG.) 2. Supplier Name 3. Supplier Focal person name 4. Supplier Phone Number	**Medical Device Data** **1. Device Label Data** (Reference number, Device Name, UDI, Lot Number, Expiry date, Serial Number) **2. Manufacturer name** (retrieved from MedReg or registered by the user if not found) **3. Quantity** **4. Device registration code**: if the supplier and the reference number are registered in MedReg, the system will retrieve the code of the device automatically.	**Patient Identification** National ID if available First name Middle name Last name Maiden name Mother name Date of birth Place of birth Sex Register number Place of register Phone number Address
Hospitalization data Hospital ID Hospital name Date of admission Diagnosis on discharge (ICD10 code)		**Guarantor** Name Approval number (if not private) Doctor's Syndicate number Doctor's Name.

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Achievements

- ✓ **National procedure for the importation of medical devices** (November 2013)

  Defining the minimum safety and quality requirements for the importation of medical devices into the Lebanese market and objective criteria for the validation of submitted documents
- ✓ **Standard Operation Procedure for MD registration** (september 2014)
- ✓ **Standard Operation Procedure for importation of medical devices** (october 2015)
- ✓ **Procedure for traceability and declaration of adverse events** (April 2017)

  To identify patients holding a MD if a corrective action is needed and to identify the MD in case of incident.
- ✓ **Establishment of:**
  - ✓ **MD Registration System (MEDReg) –** developed and implemented in application of decision 455/1 (for implantable MD)
  - ✓ **MD Importation System (MED'Import) –** developed, tested, implementation in progress
  - ✓ **MD Tracking System (MEDTrac) –** developed, testing in progress

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The Way forward…

- Coordination with the customs and IRI
- Institutionalization of the established MD Regulatory System
- Pre-marketing phase: Dissemination and follow-up of procedures and rules for the evaluation and import of DMI and extension to other categories of MD.
- Post-marketing phase: Implementation of the IMD traceability and establishment of the materiovigilance system

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The Way forward…

Etablissement et mise en place du système d'évaluation et de surveillance des dispositifs médicaux DM sur le marché Libanais						
Plan d'action 2018 - 2021						
Objectif		**Actions**	**Acteurs**	**Intervention Experts Ansm**	**Date d'envoi du MSP**	**Delai de réponse de l'Ansm**
1. Organisation administrative: Institutionaliser le système de réglementation des DM établi						
	1.1	Assurer le suivi avec les instances concernés sur la création de l'unité des technologies de la santé au MSP et recrutement des cadres	MSP	Assurer la formation du personnel (modalités à fixer ultérieurement).	2018-2019	
	1.2	Institutionaliser le cadre réglementaire à travers les décrets et arrêtés nécessaires pour la création et la formation des comités d'évaluation des DM et la surveillance post commercialisation.	MSP		2019	
	1.3	Intégration des aspects réglementaires établis dans les processus régulateurs du MSP (programme accréditation, contrats avec les hôpitaux, …)	MSP		2018-2019	
2. Phase pré-commercialisation: Diffusion et suivi des procédures et des règles pour l'évaluation et l'importation des DMI et extension à d'autres catégories de DM.						
	2.0	Suivi et maintenance des systèmes MEDReg et MEDImport	MSP			
	2.1	Extension du système établi pour les dispositifs médicaux implantables DMI aux autres catégories des dispositifs médicaux: Etablissement des priorités à adresser, Rédaction des procédures opérationnelles et des lignes directrices pour détailler les différentes étapes du processus (Recevabilité et évaluation des dossiers de déclaration des fournisseurs et des dispositifs médicaux, évaluation et traitement des dossiers d'enregistrement, de renouvellement, modification ou retrait, évaluation des dispositifs médicaux qui n'ont pas d'approbation obtenue de l'une des autorités réglementaires des pays de l'IMDRF	MSP - Ansm	Lecture et commentaires des documents	2019-2021	
	2.2	Formation du personnel des départements concernés au MSP	MSP - Expert		2018-2019	
	2.3	Définir les mécanismes de coordination avec les parties prenantes (douanes, IRI) pour la diffusion du système réglementaire établi.	MSP	Modalités à fixer ultérieurement.	2019-2021	
	2.4	Déclaration on-line des produits importés (faite par les importateurs)	MSP		2018-2019	
	2.5	Organisation d'un séminaire pour la présentation du système de réglementation des DM.	MSP	Participation au séminaire de publication	2018	
	2.6	Modification des procédures opérationnelles pour le suivi des importations des DMI pour inclure les modalités pour les non implantables et établissement d'un code de bonne conduite à signer par les fournisseurs			2018	
	2.7	Organiser des séances de formation des importateurs (des DM non implantables concernés) à la procédure et au système de télé-déclaration MEDReg.	MSP - Expert		2018-2019	
	2.8	Connexion du systeme MEDReg/ MEDImport avec le système informatisé des douanes (najm)			2019-2021	
	2.9	Etablissement d'un lien pour échange de données avec la base européenne des DM (EUDAMED) via l'Ansm		Exploration de la possibilite d'établir cette connexion et les modalités de l'établissement.	2021	
3. Phase post-commercialisation: Mise en place de la traçabilité des DMI et établissement du système de matériovigilance						
Mise en application du système de traçabilité des DMI sur le territoire libanais	3.1	Poursuivre la mise en place du système de traçabilité des DMI: Publication de la procédure, schéma organisationnel national de la traçabilité, suivi de l'application de MEDTrac dans les hôpitaux, Formations sur l'identifiant unique des DMI, etc.	MSP		2018-2019	
Etablissement du système de matériovigilance au MSP	3.2	Etablissement des modalités de suivi des déclarations des évènements indésirables et schéma national d'organisation, définition des responsabilités des acteurs			2019	
	3.3	Nomination des experts en charge du suivi du système			2019	
	3.4	Etablissement du cahier des charges pour l'établissement et le développement du système de matériovigilance			2019	
	3.5	Analyse et conception du module de suivi de la matériovigilance MEDVig			2020-2021	
	3.6	Développement du module MEDVig			2020-2021	
	3.7	Testing, formation et déploiement de la matériovigilance			2021	