REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

REGULATING THE IMPORTATION & USE OF MEDICAL DEVICES

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MoPH – Ansm Cooperation project

- Protocol signed in January 2011
- Cooperation carried out in the framework of this agreement 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.

→ Establishment of a national procedure

MINISTERE DE LA SANTE PUBLIQUE

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1. Decision Overview

Decision no.	• 455/1
Issuance Date:	• 16 April 2013
Effective Date:	• July 1st, 2013
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

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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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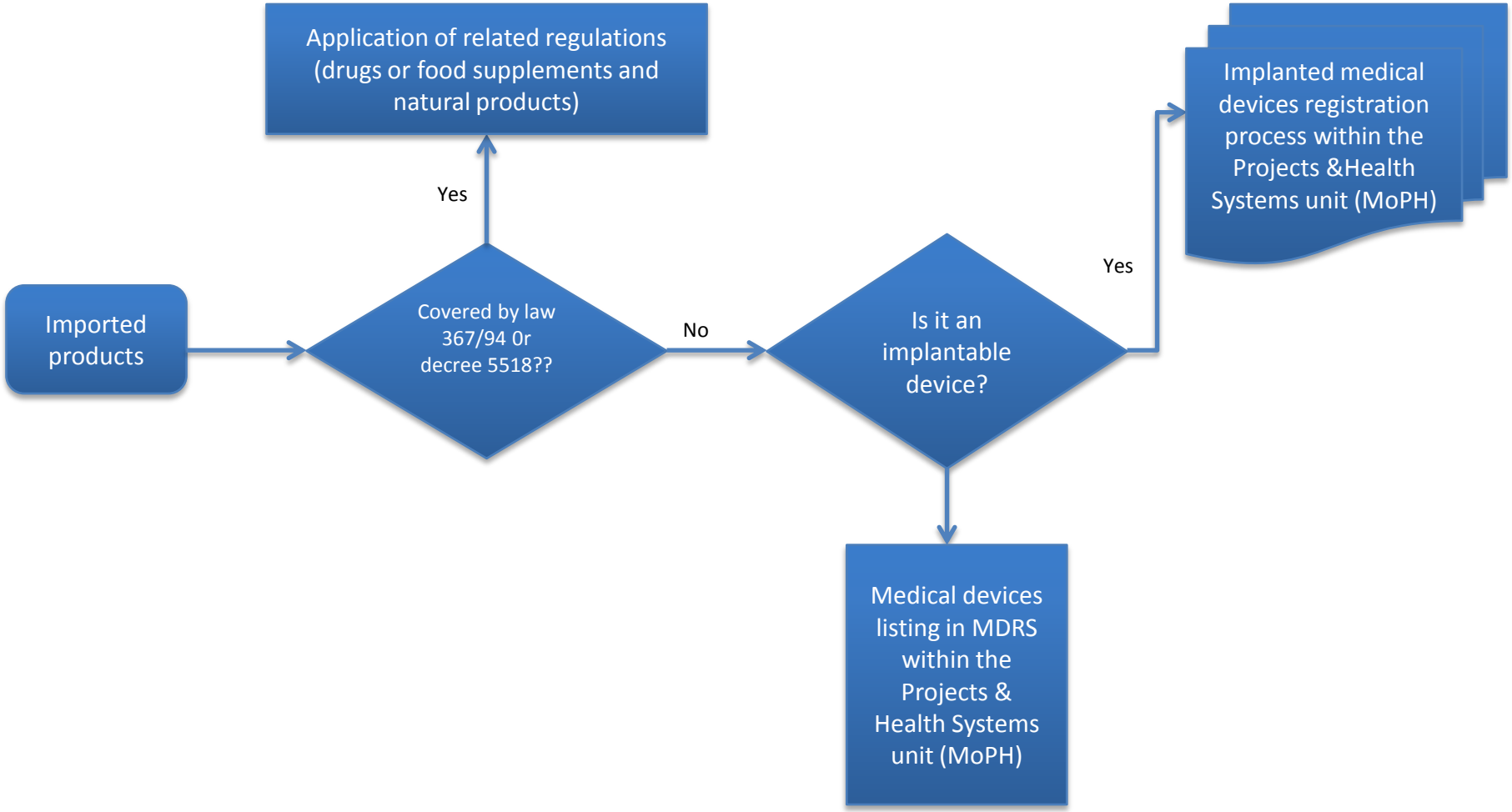
3. General Process



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3.1.a. Non implantable Medical Devices Endorsement Requirements (Article 2):

- Identification Card **(DM-01) (print out of MDRS)**
- Copy of the manufacturer invoice showing the manufacturer name, country of origin, name and address of the importer, commercial name, quantities and dimensions for each product.
- Customs statement
- Copy of a Certificate of Conformity to the international requirements (issued by the FDA, EC or IRI…)??

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3.1.b. Implantable Medical Devices Endorsement Requirements:

- Identification Card **(DMI-01)** **(print out of MDRS)**
- Copy of the manufacturer invoice showing the manufacturer name, country of origin, name and address of the importer, commercial name, quantities and dimensions for each product.
- Customs statement

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3.2. Implantable Medical Devices Registration

- MOH Definition:

  "All medical devices that are dedicated to be implanted totally or partially, by a surgical or medical intervention, in human body or, by a medical intervention in a natural orifice and are destined to be left in place after the intervention."

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3.2. Implanted Medical Devices Registration Requirements (Article 6):

- Identification Card **(DMI-01)** related to the Implanted Medical Device (MDRS printout).
- Instruction for use of the Implanted Medical Device.
- Labels placed on the Implanted Medical Device package.
- Copy of the manufacturer invoice.
- Copy of a Certificate of Conformity to the international requirements (issued by the FDA, EC or IRI…)
- Soft copies of all documents included in the Registration file.

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3.3. Medical devices registration software

Company‘s Administrative Profile

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

Sterilization Method

Certificate of Conformity

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3.3. Suppliers' registration

- Submittal of a form including the following information:
  - Company name
  - Legal representative name
  - Address, phone & fax no., E-mail, website, etc.
  - Establishment date,
  - Registration no. (Commercial register)
  - Type of activity and type of MD
  - Name, addresses and phone/ fax numbers of represented manufacturer(s)
- A copy of Commercial register extract (إذاعة تجارية)

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3.4. Data Uploading

July 1st 2013

Implanted Medical Device

- DMI-01
- Instruction for use
- Labels
- invoice
- Certificate of Conformity
- CD

Non-Implanted Medical Device

- DM-01
- soft copy of the invoice

May 1st 2013

- Get the Username and password from the MOH Projects and Health Systems department to upload data directly on the website.
- Print DMI-01 & DM-01 directly on the MDRS.

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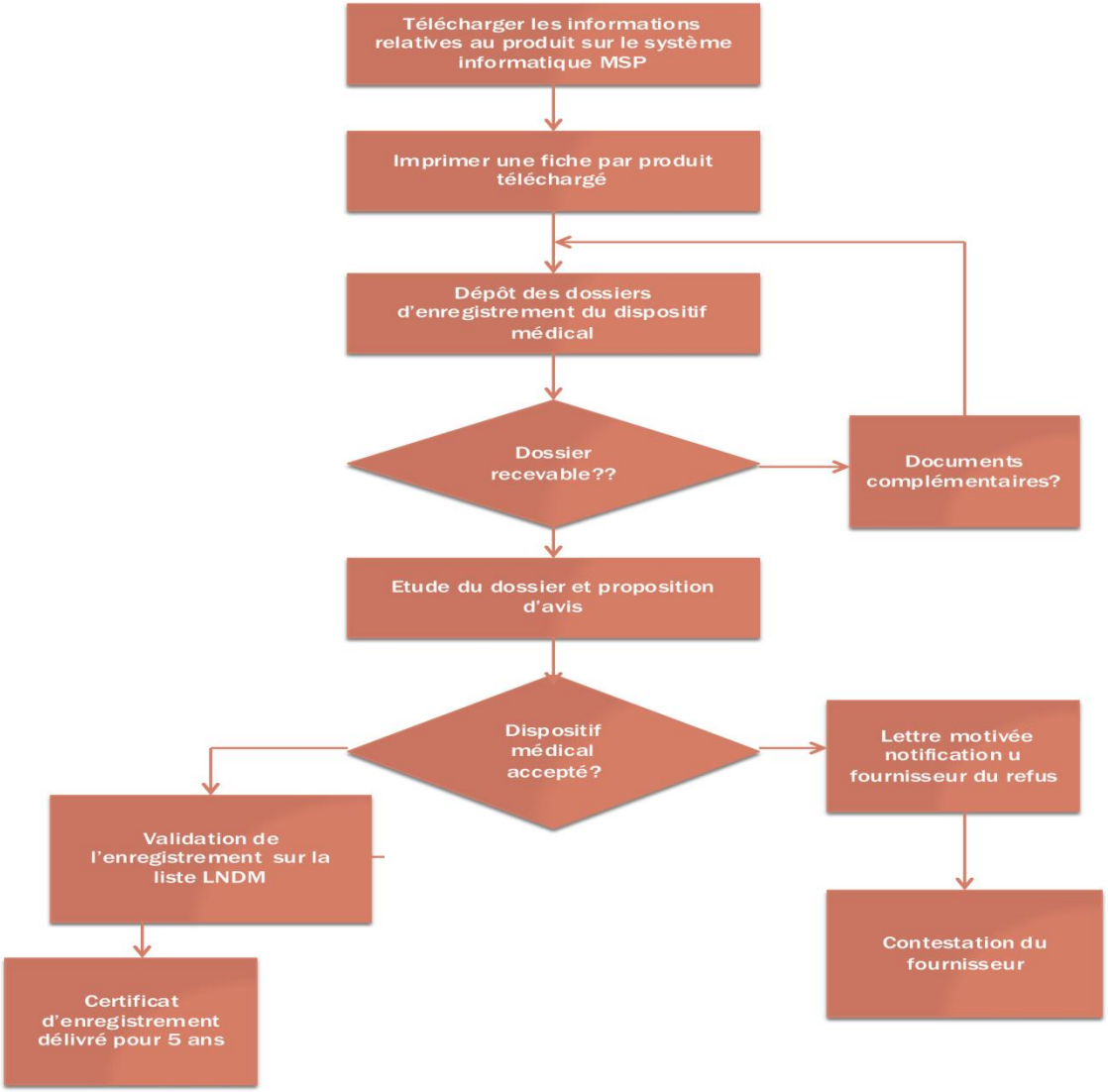
4. Registration Process



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5. Traceability Records (Article 8):

Suppliers' Required Records

Traceability record (Export 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.

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6. Vigilance System :

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

Work in progress on a procedure establishing the vigilance system defining what, when, how to declare..

"Procédure Nationale de réglementation des dispositifs médicaux au Liban

Modallités d'importation, déclaration des fournisseurs, évaluation des dossiers d'enregistrement des DM" published for comments on www.moph.gov.lb

Comments should be sent to projectshealthsystems@gmail.com

before May 31st , 2013

THANK YOU…