Regulatory guideline of labelling requirements for medical devices, medical and laboratory equipment and In Vitro Diagnostics, components and production inputs

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Content

نسخة مترجمة من اللغة العربية ، و في حالة إختلاف اللغة العربية عن اللغة الإنجليزية، يكون النص المحرر باللغة العربية واجب النفاذ

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1- Introduction:

This guide is concerned with the minimum requirements that must be available on the labels of medical devices, medical and laboratory equipment, *In Vitro* diagnostics for the purpose of circulation within the Arab Republic of Egypt, and production components and inputs for the purpose of production.

2- Definitions:

- ✓ **Medical device:** any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
— Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of *In Vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

- ✓ ***In Vitro* diagnostic medical device:** any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing details

  - Concerning a physiological or pathological state, or
  - Concerning a congenital abnormality, or
  - To determine the safety and compatibility with potential recipients, or
  - To monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. 'Specimen receptacles are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.
Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination.

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- ✓ **Imported Medical devices:** fully manufactured medical devices that are imported from abroad to be circulated within the Arab Republic of Egypt.
- ✓ **Locally manufactured medical devices:** medical devices that are manufactured in factories within the Arab Republic of Egypt.
- ✓ **Non-sterile medical devices:** medical devices that are manufactured without being sterilized and are used in their non-sterile state or require to be sterilized by the user before using them.
- ✓ **Locally manufactured laboratory and diagnostic reagents:** Laboratory and diagnostic reagents that are manufactured in factories within the Arab Republic of Egypt.
- ✓ **Imported laboratory and diagnostic reagents:** fully manufactured laboratory and diagnostic reagents that are imported from abroad.
- ✓ **Importer:** the first establishment in the supply chain within the Arab Republic of Egypt that means any establishment which imports a device from abroad to the Egyptian market.
- ✓ **Manufacturer:** a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

3- Relevant regulatory guides:

- Regulatory guideline for registering imported and local medical devices that have international quality certificates
- Guideline for variants on registered medical devices.
- Guidelines for international barcodes concerning all medical devices.

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4- Labeling details for the medical devices, medical and laboratory equipment, *in vitro* diagnostics fully manufactured (Imported/Locally Manufactured):

- The minimum data written on any medical that may be traded within the Arab Republic of Egypt shall be as follows:

1	Item details	-Trade name (if present) -Product name.(*b,d,e,f,h) -Product code or model or Ref. (*b,d,e.f.h) -Batch number or serial No (if necessary) (e.g.) -Any special handling precautions (if present).(b,d,e,f,g,h) -Any special storage precautions (if present). (b,d,e,f,g,h) -An indication of single use (In the case of single-use medical supplies) - Expiry date in accepted format (if applicable) (b,d,e,f,g,h) **i.e., clear identification of the time limit for using the product (in month/year format at least)** **for example: expires on 12-2025** **Or manufacturing date and shelf-life time** **for example: manufactured on 12-2020, shelf life: 3 years** -UDI on the label of the device or on its packaging (when applied)
2	Factory details	- Factory Name (* b,d,e,f,g,h) -Factory Address (* b,d,e,f,g,h) -Country of Origin. (*b)
3	Details on sterilized items only	The sterilization word or symbol in addition to the sterilization method must be present (* b,d,e,f,g,h) <u>Note</u> It is necessary to specify the sterilization method of any device on the package, except for chemical sterilization, which can be specified on the package or the insert leaflet of the device.
4	Details related to the Egyptian importer or agent	-Full name of the importing company (*b, d, f, g) -Address (as recorded in the importers registry) (*b, d, f, g)

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5- Labeling details for production components and inputs of medical devices, medical and laboratory equipment and *in vitro* diagnostics:

1	Item details	-Trade name (if present) - Product name. (*b,d,e,f,g,h) - Product code or Ref. (if applicable) (*b, d, e, f, h). - batch number or lot no (if necessary) (*e, g) - Any special handling precautions (if present). (*b,d,e,f,g,h) - Any special storage precautions (if present). (*b,d,e,f,g,h) - Expiry date (at least in terms of year and month) in accepted format (if applicable). (*b, d, e, g, f) **i.e., clear identification of the time limit for using the product (in month/year format at least).** **for example: expires on 12-2025** **Or manufacturing date and shelf-life time** **for example: manufactured on 12-2020, shelf life: 3 years** - UDI on the label or on packaging (when applied)
2	Manufacturer details	- legal manufacturer name (* b,d,e,f,g,h) -legal manufacturer address (* b,d,e,f,g,h) -Country of origin. (*b)

6- General Requirements

- The data is to be written either in Arabic or English language at least so that it is easy to be read and understood by all those who deal with the product, whether they are working in the medical field or the ordinary Egyptian citizen. (*a,b,e,g)

- Medical devices are to be imported with at least all the previous data written on them and it is not permissible to process any of the previous data within the customs office except for the country of origin or the data for the Egyptian importer only, and that is after all the required documents have been submitted and the approval to conduct the treatment has been obtained from competent authority. (*c,f)

- These data are written (at least) on the sales unit in a clear and stable manner that is difficult to remove, erase or obliterate throughout the validity period of the medical devices. (*b,g)

- The importing company/local manufacturer has to pledge to abide by the minimum data on all the shipments, emphasizing that he takes full technical and legal responsibility in the event of non-compliance with the data and the copy provided among the import approval documents.

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- It is prohibited to import and trade any item on which any of the following is mentioned:

A) Over - label: presence of an upper label to cover another label with different information.

B) Double - label: presence of two labels with two different incompatible information beside each other.

It shall not be released from the customs offices unless all legal and technical measures are taken in this regard. (*i)

- In case of importing huge equipment consisting of several parts, it is enough to mention the minimum data on the Major unit only, provided that there is a statement, code or serial number that connects all the parts to the basic unit and is easy to match with the documents and invoice attached to the shipment. (*g)

7- References

a) ISO 15223-1:2012 Symbols to be used with medical device.
b) ISO 20417:2020 Medical device - Information to be supplied by the manufacturer.
c) ISO 13485:2016 Medical device - Quality Management System
d) The European Union Medical Device Regulation - MDR
e) Guidance for the Labelling of Medical Devices - Canada
f) WHO TRS No. 902, 2002 Annex 9: Guidelines on packaging for pharmaceutical products
g) Requirements for labelling of medical devices - Ministry of health – Malaysia
h) Medical Device labeling obligations - (TGA)- Australia
i) Quality system regulation labelling requirement – FDA

8- Glossary

abbreviation	term
FDA	**Food & Drug Administration in United States**
TGA	**Therapeutic Goods Administration in Australia**
Ref.	**Reference**
UDI	**Unique device identifier**
WHO	**World health organization**
ISO	**International organization of standardization**

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