

Free sale certificate of medical devices
For presentation to the competent authorities/bodies of (---country -)

Certificate No.:

Date: day-month-year

It is certified that the following medical devices bearing the CE marking in accordance with regulation (93/42/EEC or 2017/745) may be marketed without restriction with in Arab Republic of Egypt.

Product/Products:

See attached product list

Manufacturer or those responsible for first placing the product in the Arab Republic of Egypt:

(Name of manufacturer ----)

(Address of the manufacturer ----)

has its registered place of business in Egypt. It is also certified that the manufacturer with the CE –mark confirms that the medical devices comply with:

the essential requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Or

the general safety and performance requirements of medical device regulations (EU) 2017/745 of 05 April 2017 on medical devices.

In the current version and that the required conformity assessment has been completed.

This Certificate is issued upon the interested party's request for exportation and valid until (.....).

Revised By:

Checked By:

**Head of Central Administration
For Medical Devices
Dr. Miriam Boles**

Annex to Certificate No:
Product List:

Device name	Reg. No.	Reg. Date