Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of
Medical Devices

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للمستلزمات الطبية

Free sale certificate

For presentation to the competent authorities / bodies of the (---country -)

Certificate No: **Date:**

*It is certified that the following invitro diagnostic medical devices bearing the CE marking in accordance with regulation (**2017/746 or 98/79/EC**) may be marketed without restriction within **Arab Republic of Egypt.***

Product/Products:

See attached product list

Manufacturer 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 confirms that the invitro diagnostic medical devices comply with:

(The essential requirements of the Directive 98/79/EC of the European Parliament and of Council of 27 October 1998 on in vitro diagnostic medical devices

OR

The general safety and performance requirements of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical device)

In the valid current version and that the required conformity assessment procedure 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 of Medical Device

Dr. Miriam Boles

Tel.: +202 – 25354100 Ext.:1513 Fax: +202 - 23684194
Website: HYPERLINK "http://www.edaegypt.gov.eg" www.edaegypt.gov.eg Email md.ivd.list@edaegypt.gov.eg

:Certificate No

	Device name	License No/ initial approval No.	license Date/ Initial approval date
1			

Tel.: +202 – 25354100 Ext.:1513 Fax: +202 - 23684194
Website: HYPERLINK "http://www.edaegypt.gov.eg" www.edaegypt.gov.eg Email md.ivd.list@edaegypt.gov.eg