Regulations for registration of Medical Device and Lab Equipment manufacturing sites

1) Copy of the legalized Authorization Letter to the Scientific Drug Bureau or to the authorized person in case of direct representation

2) Medical Device Registration form (Appendix 4), stamped by the company and signed by the responsible person in the company on each page (Live stamp & signature)

3) Copy of ISO certificate, valid and duly legalized

4) Copy of the Manufacturing License issued from the country of origin, valid and duly legalized

5) Copy of the Establishment certificate, valid and duly legalized

6) Copy of the Site Master File stamped by the site with a live stamp on each page

7) Copy of a Free Sale Certificate (FSC) for at least two products from the country of origin, stamped by the company with a live stamp

8) Original catalogues for the site's products

9) Positive statement (specifying the countries of origin of the raw materials used in the site) to be original, signed and stamped

10) Copies of the shipping documents (or selling invoice) to at least two countries where the products are sold, to be stamped by the site with a live stamp

11) Copies of valid & duly legalized ISO certificates for the company's branches that cooperate in the production or for the other companies that cooperate in the production

12) A registration file should be submitted for the company's branches or the companies that cooperate in production, in case their products will be exported to Iraq

13) Provide an invitation to the MOH for an inspection visit to the manufacturing site, according to the recommendations of the General Inspector Office, and as applied in the neighboring countries

14) Pay the registration fees after completing the registration requirement

15) The site will be granted a Registration certificate valid for 5 years.
During the 5 years, the site should inform the MOH with any administrative or technical variations happening to the site within one year of the variations. (It is the full responsibility of the site if any variations were not communicated to the MOH)

16) The registration of a manufacturing site for any company will be cancelled, by a decision from the company registration committee, after submission of evidence for the following cases:

1. If existence of fraud or manipulation in the provided documents is proved
2. Incorrect information provided by the company is proven
3. In case of non-conformity or failure or complaints from health institutions for 3 products, in case of foreign companies
4. A decision or recommendation released to suspend the company's activity

NOTE: The canceled companies are allowed to apply again for registration after one year of the cancellation and after correcting the reasons for the cancellation

Re-Registration of a manufacturing site:

Re-Registration of the medical device and Lab Equipment manufacturing sites is required after 5 years from the date if its registration (Retroactively), submission of a full registration file is required for re-registration.

Duly legalized: Legalization from the Ministry of Foreign Affairs and the Iraqi Embassy in the country origin in addition to the legalization of the Iraqi Ministry of Foreign Affairs in Baghdad, and in the absence of an Iraqi Embassy or consulate, the legalization is done in the Iraqi Embassy in one of the country of origin neighboring countries