Required documents for each type of manufacturer

A- Required Documents for Registering A (Conventional medicines/ Biological medicines/GSL Products /Natural Source Medicines) Manufacturer:

A.1. A legalized letter issued by the company on its original letterhead, signed and stamped by the responsible person in the company, authorizing a person or a local establishment to submit the registration file on its behalf, to the Drug Control Department. Attested true by UAE Embassy. This person / the local establishment will be responsible to receive the registration certificate from the Drug Department.

A.2. Legalized Current GMP Certificate Issued By The Competent Authority In Country Of origin. (Attested True by the UAE

Embassy In country of origin).

A.3. Legalized Valid Manufacturing License Issued By The Competent Authority In Country Of Origin. (Attested True By the UAE

Embassy In country of origin).

A.4. List of medicines manufactured at the manufacturing site.

A.5. Site Master File.

A.6. Certified copies of certificates of registration/ certificates of good manufacturing practice of the manufacturing site in other countries.

B- Required Documents for Registering A medical device manufacturing site:

B.1. A Notarized letter issued by the company on its original letterhead, signed and stamped by the responsible person in the company, authorizing a person or a local establishment to submit the registration files on their behalf, to the Drug Department of ministry of health and prevention.

B.2. Valid legalized ISO 13485 certificate issued by the competent authority in country of origin.

B.3. Require Legalized valid Business licenses / Manufacturing License issued by the competent authority in country of origin (Attested true by the UAE Embassy In country of origin).

B.4. List of the products manufactured and/or assembled by the site.

B.5. Detailed Company profile

B.6.A Copy of Previous Site Registration Certificate Issued by UAE MOHAP.