Medical Devices Company Registration Form

Form B

Kurdistan Medical Control Agency (KMCA),
Erbil, Kurdistan region,
Iraq,
2012

Applicant company	Name: Main Address: Telephone no.: Fax: Email: Website:
Applicant company category	Wholesaler ☐ Distributor ☐ Legal manufacturer representative ☐ Others (specify) ☐

Responsible Pharmacist:

Full name	
Present residency	
Job titles	
Business address	Main Address : Telephone no.: Fax : Website : Email :
Date and number of registration at Kurdistan Pharmacist Syndicate	

1- General information:

1: 1 - Manufacturer name	
1:2 – Names of various working branches inside the country of origin.	Main Address Telephone no. Fax Website Email
1:3 Names of various working branches out side the country of origin.	Main Address Telephone no. Fax Website Email
1:4 - Year of Foundation	{ } year
1:5- Number and Date of Registration in the country of origin.	

2- Affiliates:

- If the company is owned by another company or belong to a group pf companies, describe your position within the structure.

3- Regulatory issues:

3:1- Number and date of the last inspection report by regulatory authority in charge in the country of origin **(attach a legalized copy)**.	
3:2- Regulatory authority at the country of origin.	Name Main Address Telephone no. Fax Website Email
3:3- Does regulatory authority at the country of origin organizes periodic inspection?	Yes ☐ No ☐
3:4- Periodicity of the inspection	[ ] years Others (specify)
3:5- Good manufacturing practice (GMP), indicate the GMP standards (WHO, EU, FDA, ISO or others) with which the company complies.	

4- Manufacturing

4.1- Manufacturing site:

A - Source of Raw materials 4.1.1 Self Manufacturing 4.1.2 Under license 4.1.3 Other sources	 Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐
B - Availability of suitable storage conditions according to Good Storage Practice (GSP) for : 4.1.7 Raw materials 4.1.8 Final Products 4.1.9 Rejected Products	 Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐
E- Availability of system for batches registration .	Yes ☐ No ☐

4:2 Key Personnel

Title	Qualifications and degrees	Background and experience
Marketing manager		
Technical manager		
Production manager		
Quality control manager		
Quality assurance manager		
Others		

Total number of key personnel	

4:3 Quality control laboratories

a- Does manufacturer company contains quality control laboratories?	Yes ☐ No ☐	
b- Number and qualification of key personnel working in these laboratories.	**Qualification**	**Number**

4:4 Tests:

a- Type of tests performed on starting materials (raw materials)	
b- Type of tests performed on intermediate(in process) materials	

c - Type of tests on finished product	

The undersigned here declares that all the information contained herein is correct to the best of my knowledge and belief.

Signature of responsible person
(Of the Manufacturer)

Name of responsible person
(Of the Manufacturer)

Date

Manufacturer stamp

Requirements for distributor, wholesaler and representative agent registration at KMCA:

1- Distributor, wholesaler and representative agent application form:

- **Page 1 to be filled by representative company in Kurdistan Region**
- **Page 2 – 5 to be filled by the person in charge at manufacturer company**
- **Each page contain the life signature of person in charge at the site and the life stamp of the manufacturer**
- **This form legalized by the Health Authority in the country of origin**
- **This form should be legalized by Ministry of Foreign Affaires and Iraqi Embassy in the country of origin.**

2- GMP or/and Quality assurance certificate such as ISO 9001, 9002 or equivalent certificate(s):

- **Document issued by the Health Authority in the country of the origin where the site is located**
- **Document should be legalized by Ministry of Foreign Affaires and Iraqi Embassy in the country of origin**

3- Manufacturer registration certificate in the country of origin officially legalized from Health Authority in the country of the origin where the site is located, Ministry of Foreign Affaires and Iraqi Embassy in the country of origin

4- Authorization letter:

- **Issued from the manufacture company appointing its representative in Kurdistan Region being responsible to submit files for registration and distribute its products**
- **Document legalized by chamber of commerce , Ministry of Foreign Affaires and Iraqi Embassy in the country of origin**

5- List of medical devises produce by the manufacturer (catalogue).

6- Registration Fees should be paid by the company

7- Registration document at Ministry Of Health / Kurdistan Region government (for the applicant company).

8- Responsible pharmacist registration document at Kurdistan Pharmacist Syndicate.

9- Medical Appliances, Disposable products and laboratory diagnostic kits their selves are not required to be registered.

10- The registration committee has the right to ask for any additional information or documents.

11- Files to be submitted should be numerated and have a table of contents.