

## **Formalities for Registration of Medical Devices for sale/distribution**

- Application on Form 41
- Registration Fee of Rs 3000/- to be deposited in the JK Bank No. 0110010200000915, IFSC code J&K bank Moving Secretariat JAKA0MOVING in the name of Controller, Drugs and Food Control organization, J&K
- Undertaking in form of affidavit duly sworn before Notary.
- Documentary evidence in respect of ownership or occupancy on rental of the premises.
- Details of the constitution of the firm and Competent Person.
- Identity Proof copy (self attested AADHAR Card/Driving License/PAN Card) of Applicant / Competent Person and qualification documents
- Brief description of the other activities carried out by the applicant in the premises.
- Self certification of compliance with respect to Good Distribution Practices.
- List of Medical Devices intended to be sold / distribute.
- 2 Recent Colour Photograph of Applicant / Competent Person.
- Photographs of the Premises.

**Form MD-41**

*[See sub-rule (2) of rule 87A]*

APPLICATION FOR GRANT OF REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICE

1. Name of applicant:

2. Address of the premises to be registered: -

2. Contact details of applicant:- Phone /Mobile No:-  
Email id:-

3. Nature and constitution of applicant: (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified) :-

4. competent person appointed:

- Name:
- Qualification
- Experience (if any)

6. Fee paid on \_\_\_\_\_ Rs \_\_\_\_\_ receipt/challan/transaction id \_\_\_\_\_ in JK Bank Account of DFCO A/c No:-0110010200000915

7. I have enclosed the documents as specified in the sub-rule (3) of rule 87A of the Medical Devices Rules, 2017.

Place: \_\_\_\_\_

Date: \_\_\_\_\_

Name:-  
Designation:-

Signature:-.....  
(Director/Proprietor/Partner)

**UNDERTAKING BY WAY OF AN AFFIDAVIT ON TEN  
RUPEES NON JUDICIAL STAMP PAPER**

I.....S/o.....R/o.....  
.....do hereby solemnly affirm and state as under that:-

1. I shall be the Sole Proprietor / partner / Director / Authorized Signatory / Attorney Holder cum Competent Person of the firm\_\_\_\_\_ situated at \_\_\_\_\_.
2. The I am not serving in any Govt / Semi Govt / Private Establishment.
3. That the proposed space is personal property or rented property.
4. That I have passed\_\_\_\_\_ from \_\_\_\_\_ university / Board under Roll No\_\_\_\_\_ Year\_\_\_\_\_.
5. That sales activity of medical devices shall by undertaken under the direction and supervision of the competent person namely\_\_\_\_\_.
6. That adequate space and storage arrangement is provided for storage of medical devices.
7. That proper requisite temperature and lightening shall be maintained as per the requirement of the storage of medical devices for sale or stock.
8. That the Good distribution practice (GDP) with respect to the sale and distribution of the medical devices shall be followed in letter and spirit.
9. That I shall inform to the registering Authority, in case there is any change in the constitution of the firm.
10. That I am not holding any sale licenses under Drugs and cosmetics Rules, 1945 on Form 20/21/20B/21B at the proposed premises where Registration Certificate on Form MD 42 is intended to be obtained.
11. That I shall abide by the conditions of the Registration as mandated under Rule 87B of the Medical Devices Rules 2017.
- 12 I legally undertake to state that the documents enclosed with the application Form on MD-41 are true, correct and nothing contained in it is wrong and false.

DEPONENT

**VERIFICATION**

Verified on this day of (Month), (Year) that the contents of my above Legal Undertaking are true and correct and that no part of it is false and nothing material concealed there from.

DEPONENT

## DETAILS OF CONSTITUTION OF THE FIRM

Name of the firm:

Address of firm

Type of Constitution of firm: Proprietary/ Partnership/ Pvt Ltd/ LLP/Public Ltd  
(Tick whichever is applicable)

Name(s) of Proprietor/ Partners/ Managing Director (s) / Authorized Signatory  
/ Attorney Holder along with their residential address as the case may be:-

PAN /ADHAR No.:-

Mobile No & email id:-

Details of Competent Person:-  
Name with Address:-

Qualification:

Experience (if any)

PAN /ADHAR No.:-

Mobile No & email id:-

Account details (if any):-

GST No (if any):-

Recent Self attested colour photograph of the applicant(s)	Recent Self attested colour photograph of the applicant(s)	Recent Self attested colour photograph of the Competent Person(s)

**Signature of applicant**

**Signature of Competent Person**