DRUGS CONTROL DEPARTMENT
Palace Road, Bengaluru-560001

LIST OF DOCUMENTS TO BE SUBMITTED FOR GRANT OF REGISTRATION CERTIFICATE IN FORM MD-42 TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICE under MDR,2017(Those who don't hold license in Form 20,21, 20B and 21B of Drugs and Cosmetics Rules, 1945)

1. Covering Letter to be addressed to The Drugs Controller and State Licensing Authority (SLA), Drugs Control Department, Palace Road, Bengaluru-01
2. Dully signed application in Form MD-41
3. Copy of the challan for fees of Rs.3000 paid through online/offline to the Drugs Control Department, Head office, Bangalore (Head of Account:0210-04-104-2-01-000) in Khajane-2 portal (https://k2.karnataka.gov.in) as a fee for Registration certificate
4. Self-certification of compliance to Good Distribution Compliance as per Rule 87A of MDR-2017
5. Additional Information Sheet of the applicant or firm including its constitution(proprietorship/partnership/ directors/Trustee) along with identification proof, (such as, Aadhar card or PAN card , photos) and brief description on other activities carried out by applicant.
6. Rent /lease document/ Land Lords Declaration along with latest tax paid receipt and Copy of premises plan in duplicate
7. Details of competent technical staff (CTS):
   (a) Dully filled competent technical staff Proforma
   (b) Competent Technical staff Qualification & experience certificate (any Degree holder or Registered Pharmacist or Intermediate or equivalent 12^{th} passed with one year experience in sale of MD.
   (c) Address proof of CTS (Election ID Card / Aadhar Card /Passport / Ration Card / Driving Licence) and photos
8. An undertaking to the effect that the storage requirements to sell, stock, exhibit or offer for sale or distribute a medical device/ in vitro Medical Devices will be complied Medical Devices Rules, 2017.
9. Proforma of Firm and CTS details for SLA approval
10. Bio Medical Waste and CTS Affidavit with notary (on Rs 20/- stamp paper)

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:

3. Contact details of applicant including telephone number, mobile number, fax number and email id:

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

5. Name, qualification and experience of competent person appointed:

6. Fee paid on _____ Rs_____ receipt/challan/transaction Id_____.

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 of Director/Proprietor/Partner

CHALLAN FOR REFERENCE

Remitter's copy

ಚಲನ್ ಚಾಲ್ತಿ ಅವಧಿ Challan Validity	ಜಿಲ್ಲೆ District	ಇಲಾಖೆ Department	ಡಿಡಿಓ ಕಚೇರಿ DDO Office	
7 Days	BENGALURU URBAN	DRUGS CONTROL DEPARTMENT	DRUGS CONTROL DEPARTMENT HEAD OFFICE, BANGALORE	
ವರ್ಗ Category	ದಿನಾಂಕ Date	ಚಲನ್ ಉಲ್ಲೇಖ ಸಂಖ್ಯೆ Challan Reference Number	ಡಿಡಿಓ ಕೋಡ್ DDO Code	
Government	25/10/2022	CR1022021000559627	19243D	
ಸಂದಾಯದಾರನ ಹೆಸರು Remitter Name	NAME OFTHE FIRM			
ವಿಳಾಸ Address	COMPLETE ADDRESS			
ಉದ್ದೇಶ Purpose	ಲೆಕ್ಕ ಶೀರ್ಷಿಕೆ Head of Account	ಉಪ ಉದ್ದೇಶದ ಹೆಸರು Sub Purpose Name	ಉದ್ದೇಶ ನಿರ್ದಿಷ್ಟ ಐಡಿ Purpose Specific ID	ಮೊತ್ತ Amount
DRUGS AND COSMETICS ACT AND RULES-DRUGS CONTROL DEPARTMENT	0210~04~104~2~01~000	059-OTHER FEES	NA-	3000
ಸಂದಾಯದ ಬ್ಯಾಂಕ್ Remittance Bank	STATE BANK OF INDIA	ಒಟ್ಟು ಮೊತ್ತ Grand Total		3000
ಪಾವತಿ ಹಂತ Payment Status	Payment Yet To Be Made At Agency Bank	ಒಟ್ಟು ಮೊತ್ತ ಅಕ್ಷರಗಳಲ್ಲಿ Total Amount in Words	Three Thousand Only	
ಪಾವತಿ ವಿವರಗಳು\Payment Details				
ಪಾವತಿ ವಿಧ Payment Mode	Cash			

Additional information to be submitted with the Application in form MD-41

1. a) The constitution of the firm
Proprietorship/ partnership/company/ Private limited /public limited/Co-operative Society/Registered /Unregistered Necessary Documentary evidence like partnership deed. Memorandum articles etc., should be submitted.

b) Names of all the partners or directors or Proprietors etc. and full residential Address of each:

(1) ----------
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(2) ----------
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(3) ----------
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2. The educational qualifications of:-

a. the applicant or / and
b. person in charge of the premises for which licence applied for.

3. Has the applicant ever engaged himself or on Behalf of any other person in selling drugs Any time prior to this application? If so the Dates together with necessary documentary Evidence may be supplied.

4. What other business is carried on by the Applicant at present

5. Is the application for fresh Registration of retention?

7. Year in which Registration was first granted

8. Particular of Drug licence/Medical Device granted under drugs Rules Form Licence no. date of issue

MD-42
20
20A
20B

20C
20D
21
21A
21B

9. Was the application ever rejected or licence previously cancelled or suspended of surrendered? If so, for what reason?

10. Was the applicant ever warned for selling goods which were not of standard quality?

11. Was the applicant or any person at present employed by him on these premises ever convicted and sentenced under
a) Drugs & cosmetics Act 1940
b) NDPS Act 1985
c) DMR Act, 1954
e) Any other Act.

12. GST Registration No. licence no. date of issue

13. Shops and Establishment Act

14. Application Fee: Amount Challan No. date of Challan

15. Is the applicant an agent or distributor of any Medical mDevice manufacturing concern? If so, the area of distribution and date of appointment should be stated with full particulars The applicant shall inform the Licencing Authority if the agency is terminated any time during which the licence is in force
Is the firm company a –
a) Restaurant? –
b) Provision stores? –
c) Petty shop? –
d) General Merchant? –
e) Drugs Stores? –
f) Chemist and druggist? –
g) Dispensing chemist? –
h) Distributing Agency? –
i) stockiest? –
k) Importer? – 3

16. The applicant has in all – rooms for storage and sale of Medical Device the floor area square feet of each room must be give with a sketch. Whether the applicant is a legal tenant? or owner of the premises? Necessary Documentary evidences should be enclosed

17. The applicant does/does not stock or sell Medical Device at any other premises nor has office except at the premises for which this application is applied for. OR The address of other premises are 1. 2.

18. The applicant deals in the following class of commodities only besides Medical Devices on these, premises viz. 1. 2. 3. 4

19. Storage facilities –
1) Racks –
2) locked cupboards –
3) Refrigerator –
4) cold Room –

20. Hours of business and working days - Is it working 24 hours –

21. Name of the trade or professional Association of which the applicant is A member and the date of commencement of membership.

22. Names/Categories of Medical Devices/proposed to be/are being sold should be furnished detail in a list in triplicate

I certify that all the above information is true and understand that my application is liable to be rejected summarily of the licence liable to be cancelled for with if the above information is proved to be false in any particular.

Signature of the applicant:

Place:

Name in block letter _ _ _ _ _ _ _ _ _ _

Date:

Designation _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Seal _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

PROFORMA FOR APPOINTMENT OF COMPETENT TECHNICAL STAFF FOR REGISTRATION CERTIFICATE IN FORM MD-42

1. Firm Name & Address:

2. Name and Qualification of Competent Technical Staff to be included in the licence

Name of the CTS	Qualification	Date of Appointment

LETTER OF APPOINTMENT OF COMPETENT TECHNICAL STAFF

In compliance of provisions envisaged under the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017 Sri/Smt ..... is appointed as competent Technical Staff to supervise to the sale, stock and distribute the Medical Devices in our firm.

Place:
Date:

signature*

Name and
designation

* Note: Please note if the person who signed this request shall produce proper authority document if their name is not already in the record.

CONSENT OF COMPETENT TECHNICAL STAFF

I hereby declare that I have consented to work as competent Technical Staff as envisaged under the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017 in M/s .... Situated at ....and supervise to the sale, stock and distribute the Medical Devices throughout the working hours of the firm.

1.

Name of the CTS	Qualification

2. Previous experience of competent person If any, with name and addresses of the firm From _ to :

Signature*

Place:
Date:

Name

(.....)

Residential address:

* Note: Please note if the person who signed this request shall produce proper authority document if their name is not already in the

DECLARATION FOR GOOD DISTRIBUTION COMPLIANCE

I/We,..... S/o/W/o/D/o/C/o .....
..... aged about..... Years and residing at.....
....
.....,
do solemnly affirm and state on oath as follows:

I am the Proprietor/partner/director of the
M/s..... situated at .....
....
....
....
will be responsible for the day to day conduct of the business of the firm as per the provision s laid down under Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017.

I have declared that, I will maintain Good Distribution practice and keep records of all Medical devices and In vitro Diagnostic Medical Devices received. Such as Date, Name of the Medical Device and In vitro Diagnostic Medical Devices, Batch no, manufacturer's name, Quantity received, or supplied and Name & address of the supplier.

I will maintain the dispatch information such as Date of dispatch, complete name & address, description and Quantity of the products and Applicable transport & storage information. Further I will recall Medical Devices and In vitro Diagnostic Medical Devices and maintain all records and produce whenever asked by authority.

I have provided sufficient and suitable storage facilities like racks to stock the Medical Devices and In vitro Diagnostic Medical Devices.

What is stated above is true and correct to the best of my knowledge and belief.

If Any information furnished by me is found to be not true/incorrect, I am liable to surrender the Registration Certificate granted to me by the licensing authority, for cancellation of the same.

Place:

Deponent

Date:

BIOMEDICAL WASTE DECLARATION

(on Rs 20/- stamp paper)

I/We, ... (Name and Address of the Proprietor/partner/director/Authorised Signatory)
Do solemnly affirm and state on oath as follows:

(1) I am the Proprietor/partner/director of the M/s..... (Name and Address of the Firm) will be responsible for the day-to-day conduct and business of the above firm

(2) I, abide to dispose date expiry Medical devices and In vitro Diagnostic Medical Devices /Discarded medical devices and In vitro Diagnostic Medical Devices /un-used medical device and In vitro Diagnostic Medical Devices /Returned medical device and In vitro Diagnostic Medical Devices, As per Biomedical Waste (Management & Handling) Rules, 1998.

(3) I will dispose off date expiry medical device and In vitro Diagnostic Medical Devices / Discarded medical device and In vitro Diagnostic Medical Devices /Un-used medical device and In vitro Diagnostic Medical Devices /Returned medical device and In vitro Diagnostic Medical Devices as per Bio medical waste (Management & Handling) Rule 1998 and we will abide to protect Environmental pollution.

(4) I, declare that I maintain all the necessary records of Date expiry medical device and In vitro Diagnostic Medical Devices etc and produce to the State Licensing Authority on demand.

I am making this affidavit to obtain Registration certification in Form-42 from State licensing Authority.

Whatever is stated above is true and correct to the best of my knowledge and belief.

Place:

Deponent

Date:

COMPETENT TECHNICAL STAFF AFFIDAVIT

(on Rs 20/- stamp paper)

I/We, ..., (Name and Address of the Proprietor/partner/director/Authorised Signatory) do solemnly affirm and state on oath as follows:

I had passed Intermediate/PUC/Degree/ Examination held during the year ..... and having register No.....

I was working in M/s..... (Mention address) from ..... (Date) to..... (Date) and thereby gained satisfactory knowledge in dealing of Medical Devices &In vitro Diagnostic Medical Devices.

I have accepted to work as competent Technical Staff at **M/s..... .....** (Name and Address of the Firm). Except this firm, I am not working elsewhere as competent Technical Staff / neither employee nor I am continuing further studies. I will be present throughout the working hours of the firm and supervise sale, stock, exhibit or offer for sale or distribute a medical device and In vitro Diagnostic Medical Devices. Further, if I were to leave the firm for any reason, I will inform the Drugs Controller and State licensing authority.
I abide to follow Rules as per Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

I declare that the above statement is true and correct.

Place:

Deponent

Date:

PROFORMA OF THE FIRM AND CTS DETAILS

REGISTRATION CERTIFICATION NO.IN FORM MD-42:

NAME & ADDRESS OF THE FIRM:

OWNER PHOTO

NAME OF OWNER/PA :

SIGNATURE OF PROPRIETOR:

NAME OF THE COMPETENT TECHNICAL STAFF

SRI/SMT :

CTS PHOTO

SIGNATURE OF COMPETENT TECHNICAL STAFF

DATE OF ISSUE:

PLACE:

The Drugs Controller &
State Licensing Authority,
Drugs Control Department
Bengaluru