NO.B.17011/24 (B)/17-DHS/DRUGS/105
GOVERNMENT OF MIZORAM
DIRECTORATE OF HEALTH SERVICES
(FOOD & DRUGS ADMINISTRATION)
MIZORAM: AIZAWL
***

Dated Aizawl,the 10th July, 2024

To,

The Asst. Director (F&D)/Drugs Inspector/Asst. Drugs Inspector
_____District

Subj: ***Checklist for Application in Form MD-41 – reg.***

Sir/Madam,

The department has received of late application in Form MD-41, *Registration Certificate to sell, stock, exhibit for sale or distribute a medical device including in vitro diagnostic medical device.* For approval of the application, certain line of action needs to be executed by the applicant as per Medical Device (Fifth Amendment) Rules, 2022 and that, compliance should be checked by competent authority for consideration of their application. In line with this, ***Checklist for Application in Form MD-41*** is prepared for Drug Control Officers and attached herewith alongwith ***Procedures for obtaining Registration Certificate for Medical Device*** for perusal and future reference.

Furthermore, Copy of Checklist for Application in Form MD-41 should be attached alongwith application in future.

This is for favour of your kind information and necessary action.

Enclo*: As above.*

(LALSAWMA)
Joint Director (F&D),
Controlling & Licensing Authority
Directorate of Health Services
Mizoram: Aizawl

Memo No.B.17011/24 (B)/17-DHS/DRUGS/105 ***Dated Aizawl, the 10th July, 2024***
Copy to:
1. Guard File (Circular)

10/7/24

Joint Director (F&D),
Controlling & Licensing Authority
Directorate of Health Services
Mizoram: Aizawl

CHECK LIST FOR APPLICATION IN FORM MD-41

Name of applicant : _____
Address : _____
Proposed location :_____

Sl. No.	Particulars	Compliance
1	Duly filled-in application form in MD-41	
2.	Fee paid receipt	
3	Self certificate of compliance with respect to GDP	
4	Constitution of the firm & identification proof	
5	Documentary evidence in respect of ownership or occupancy on rental of the premises	
6	Appointment of competent technical staff	
7	Brief description on other activities carried out by applicant, or any other activities carried out by the applicant in the said premises	
8	An undertaking to the effect that the storage requirements to sell, stock, exhibit or offer for sale or distribute a medical device will be complied with.	
Remarks :		

MEDICAL DEVICE REGISTRATION CERTIFICATE

Medical Device (Fifth Amendment) Rules, 2022
(G.S.R.754(E) : Date 30th September, 2022)

Rules 87A : ***Registration Certificate to sell, stock, exhibit for sale or distribute a medical device including*** *in vitro* ***diagnostic medical device***

Procedures for obtaining **Registration Certificate for Medical Device** including *in vitro* diagnostic medical device :-

1. An application form in **Form MD-41** is to be submitted to the State Licensing Authority
2. Form MD-41 shall be accompanied by –
   1) A fee of Rs.3,000/- (as specified in Second Schedule) and will be deposited only after granting consent is obtained from LA)
   2) Self certificate of compliance with respect to Good Distribution Compliance
   3) Details of applicant or firm including its constitution, along with identification proof such as, Aadhar card or PAN card
   4) Documentary evidence in respect of ownership or occupancy on rental of the premises
   5) Details of competent technical staff, under whose direction and supervision the sales activity of medical device shall be undertaken, who shall possess the following educational qualification and experience, namely :-
      (a) he is a registered pharmacist; or
      (b) hold a degree from a recognized University/Institution; or
      (c) has passed intermediate examination or its equivalent examination from a recognised Board with one year experience in ***dealing with sale of medical device***
   6) Brief description on other activities carried out by applicant, namely, storage of drugs, medical items, food products, stationeries, etc., or any other activities carried out by the applicant in the said premises
   7) An undertaking to the effect that the storage requirements to sell, stock, exhibit or offer for sale or distribute a medical device will be complied with.
   8) A printed copy of the inspection book in Form MD-43 may be obtained from LA on payment of fee.

"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 i.d

   _____
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