CDSCO LICENSE PROFILE

Including Medical Device (MD) Forms List

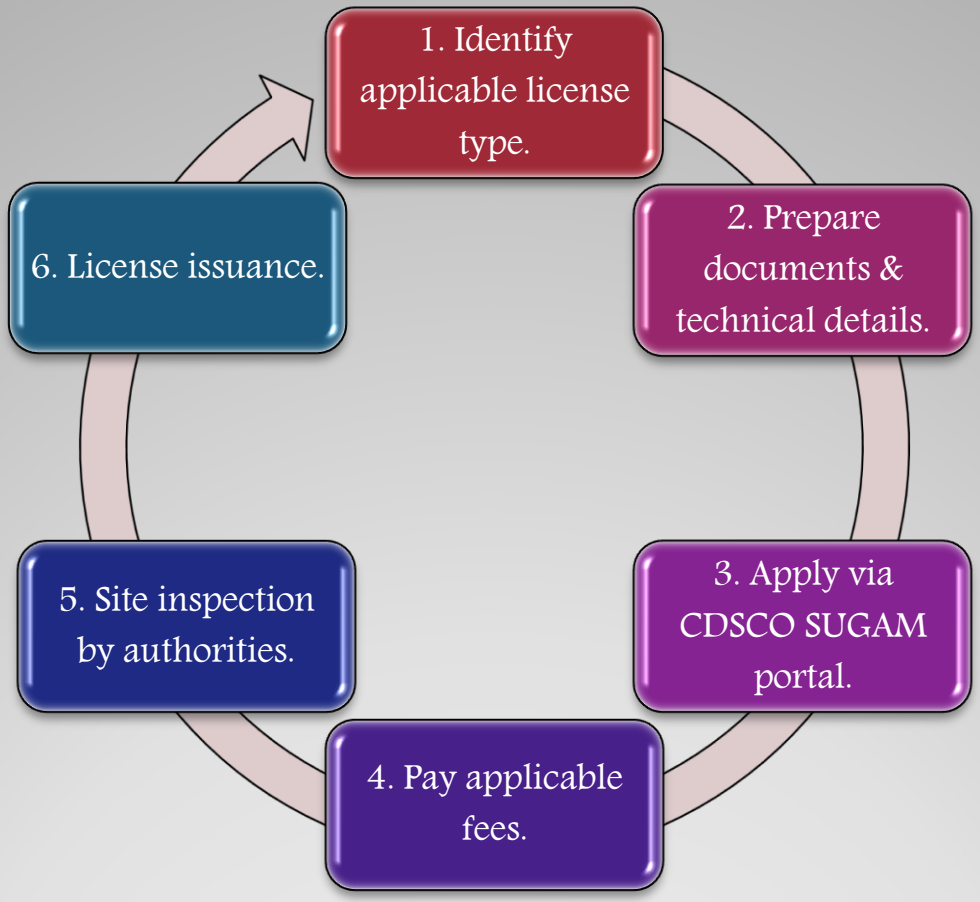
INTRODUCTION TO CDSCO

- Central Drugs Standard Control Organization (CDSCO) is India's National Regulatory Authority (NRA).
- Regulates pharmaceuticals, cosmetics, and medical devices.
- Works under Ministry of Health & Family Welfare.
- Ensures product safety, quality, and efficacy.

IMPORTANCE OF CDSCO LICENSE

MEDICAL DEVICE CLASSIFICATION

- Class A: Low risk
- Class B: Low–moderate risk
- Class C: Moderate–high risk
- Class D: High risk



CDSCO LICENSE PROCESS

Application form (relevant MD form).

ID & address proof.

Site plan & layout.

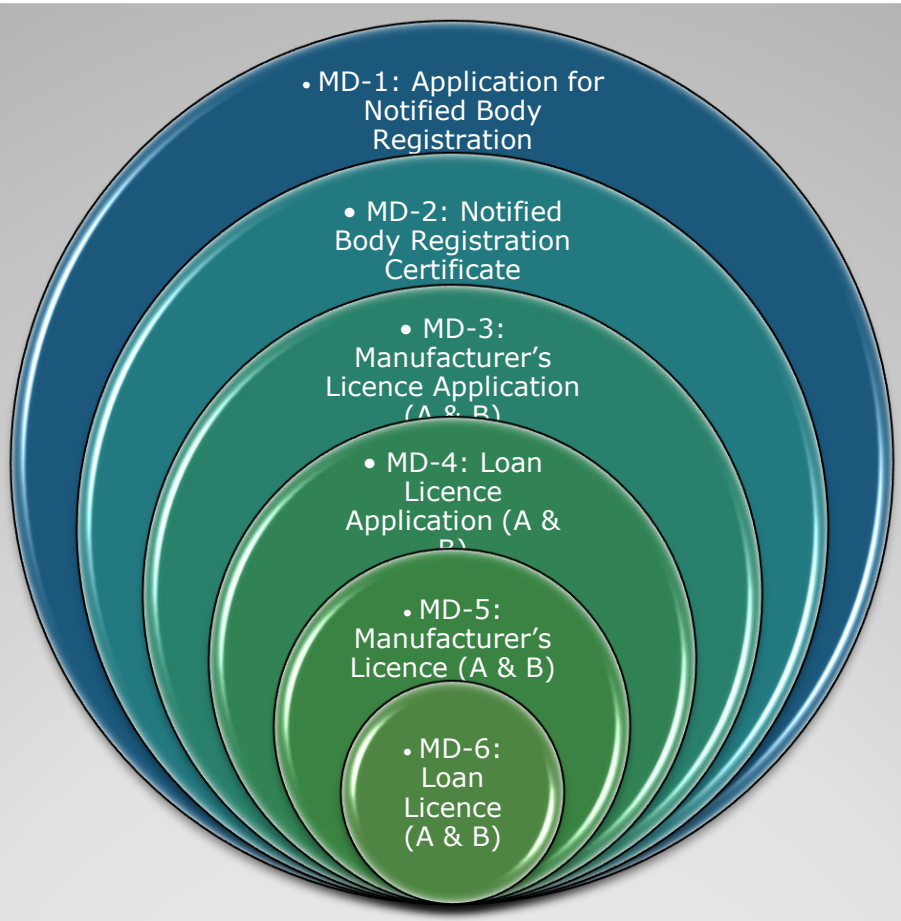
List of equipment & machinery.

Product list.

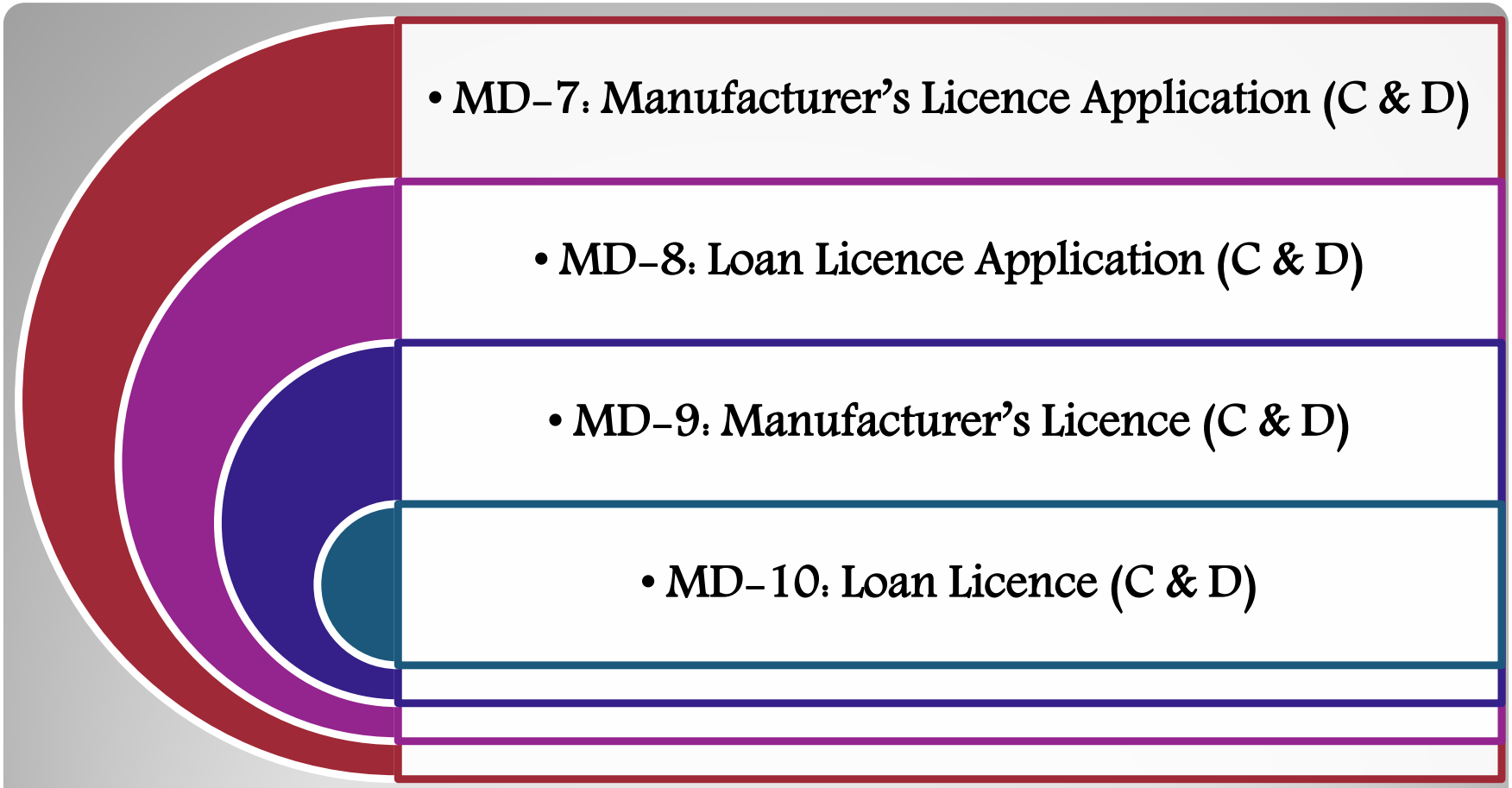
DOCUMENTS REQUIRED

MD FORMS OVERVIEW

- CDSCO has prescribed Medical Device (MD) forms under MDR 2017.
- Forms vary by device class and activity type.
- MD-3: Application for manufacturing Class A & B devices.



FORMS FOR CLASS A & B DEVICES



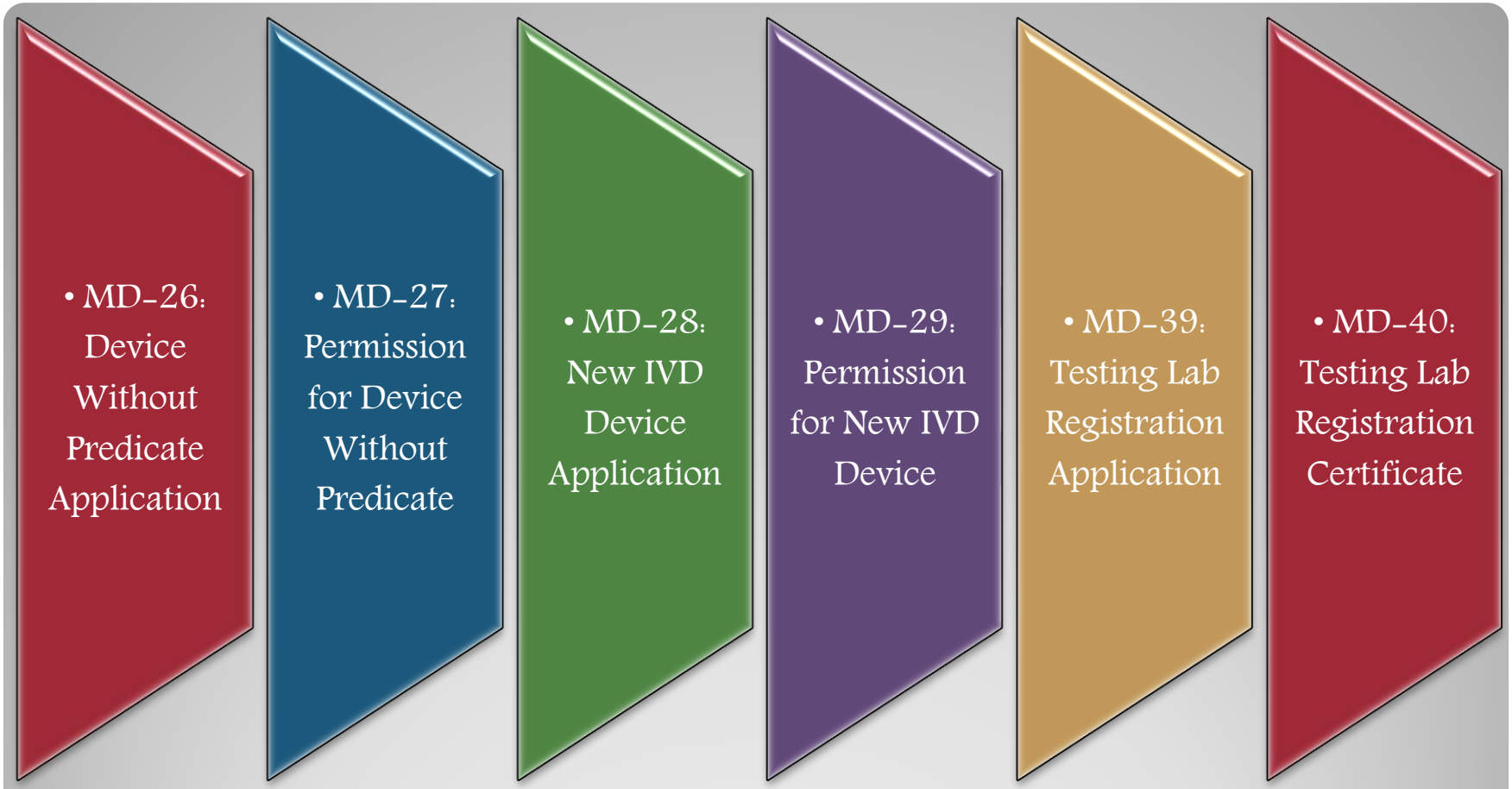
FORMS FOR CLASS C &D DEVICES

IMPORT FORMS

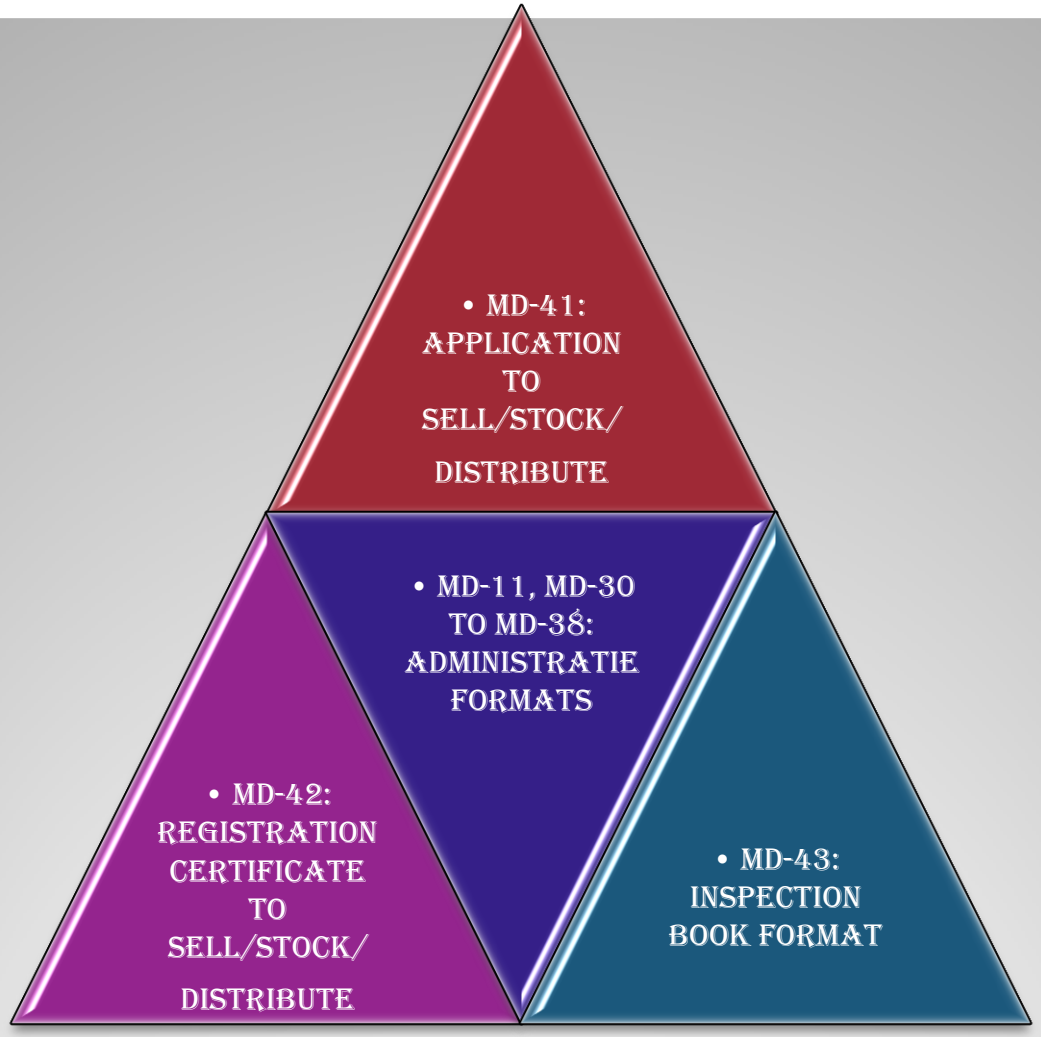
- MD-14: Import Licence Application
- MD-15: Import Licence
- MD-16: Import for Test/Evaluation Application
- MD-17: Test Import Licence
- MD-18: Investigational Device Import Application
- MD-19: Licence for Investigational Device Import

- MD-12: Manufacture for Test/Evaluation Application
- MD-13: Test Licence (Manufacture)
- MD-22: Clinical Investigation Permission Application
- MD-23: Permission for Clinical Investigation
- MD-24: Clinical Performance Evaluation Application (IVD)
- MD-25: Permission for IVD Clinical Performance Evaluation

TESTING & CLINICAL EVALUATION



SPECIAL CASES & LAB REGISTRATION



SALE & DISTRIBUTION FORMS

CONCLUSION

- CDSCO licensing is mandatory for medical device business in India.
- Correct MD form selection is crucial for approval.
- Ensures product safety, quality, and regulatory compliance.

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THANK YOU
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