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DEVICE REGULATION AND CERTIFICATION

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REGULATION AND CERTIFICATION IN INDIA

CONTENTS

- Medical Device Regulation in India
- Device Classification
- Registration Process, Requirement and Timeline
- Import and Export Registration in India
- IVD Classification, Regulation
- Summary
- Q &A

No	Description	Name
1	Jonas Pollard	Malaria diagnostic
2	Nicee Srivastava	3D model of coronary arteries to predict plaque progression
3	Lukas von Tobel	Modular prosthetic hands for Children and Adults
4	Gaurasundar Conley	Embryo MRI
5	Alexander Nitsch	Neonatal brain oxygen monitoring
6	Sandal Kotawala	Portable visual field perimeter for diagnosis of glaucoma
7	Mayur Sanas	Device for immobilisation of fractured limb
8	Saiprasad Sanjay Poyarekar	Skin spray device for wound healing
9	Deepika Sharma	Point-of-care testing for early disease detection using biomarkers
10	Aishwarya Lakshmi	Hygiene meter-Give a rapid readout of the contamination presence
11	Dr Vaishnavi Mohan Kulkarni	Point of care Preenclapsia screening test

INDIAN REGULATORY

- **Central Drug Standards Control Organization (CDSCO)** is India's main regulatory body for pharmaceuticals and medical devices
- **The Drug Controller General of India (DCGI**) is the key official within the CDSCO.
- Product needs to be registered according to Medical Device Regulation 2017

DEFINITIONS

- Central Licensing Authority means the Drugs Controller General of India appointed by the Central Government;
- Authorised agent means a person including any firm or organisation who has been appointed by an overseas manufacturer through a power of attorney to undertake import of medical device in India;
- Post Marketing Surveillance means systematic process to collect and analyse information gained from medical device that have been placed in the market;

LICENSING AUTHORITY IN INDIA

- Central Licensing Authority
  - Import of all classes of IVD
  - Manufacture of classes of IVD
  - Clinical Performance and Approval of New IVD
  - Registration of Laboratories to carry out evaluation
  - Test license for import of all classes
- State Licensing Authority
  - Manufacture and Sale of Class A and Class B IVD
  - Sale, stock and Distribution of IVD

BASIC PRINCIPLES FOR CLASSIFICATION

- Based on the intended purpose of the device
- Software, which drives a device or influences the use of a device, falls automatically in the same class.
- If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.
- If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.
- Accessories are classified in their own right separately from the device with which they are used.

CLASSIFICATION - IVD

- IVD classification is into
  - Class A : Low risk
  - Class B : Moderate
  - Class C: Moderate High risk
  - Class D : High Risk

Malaria screening reagents /kits	Class D	Malaria test reagents/kits is a medical device intended for the screening of Malaria in blood/body fluids

FEES

- fees required to be paid along with the application for grant of licence to manufacture of IVDs

Category	Product Fees (INR)	Manufacturing site (INR)
Class-A	500	5000
Class-B	500	5000
Class-C	1000	50000
Class-D	1000	50000

- fees required to be paid along with the application for grant of import licence for IVDs

Category	Product Fees (USD)	manufacturing site (USD)
Class-A	10	1000
Class-B	10	1000
Class-C	500	3000
Class-D	500	3000

FEES

- fees for the "**Test License**" to import for IVD kits/reagents in India

Classification	Fee (USD)
Class-A, class B, Class C & Class D	100

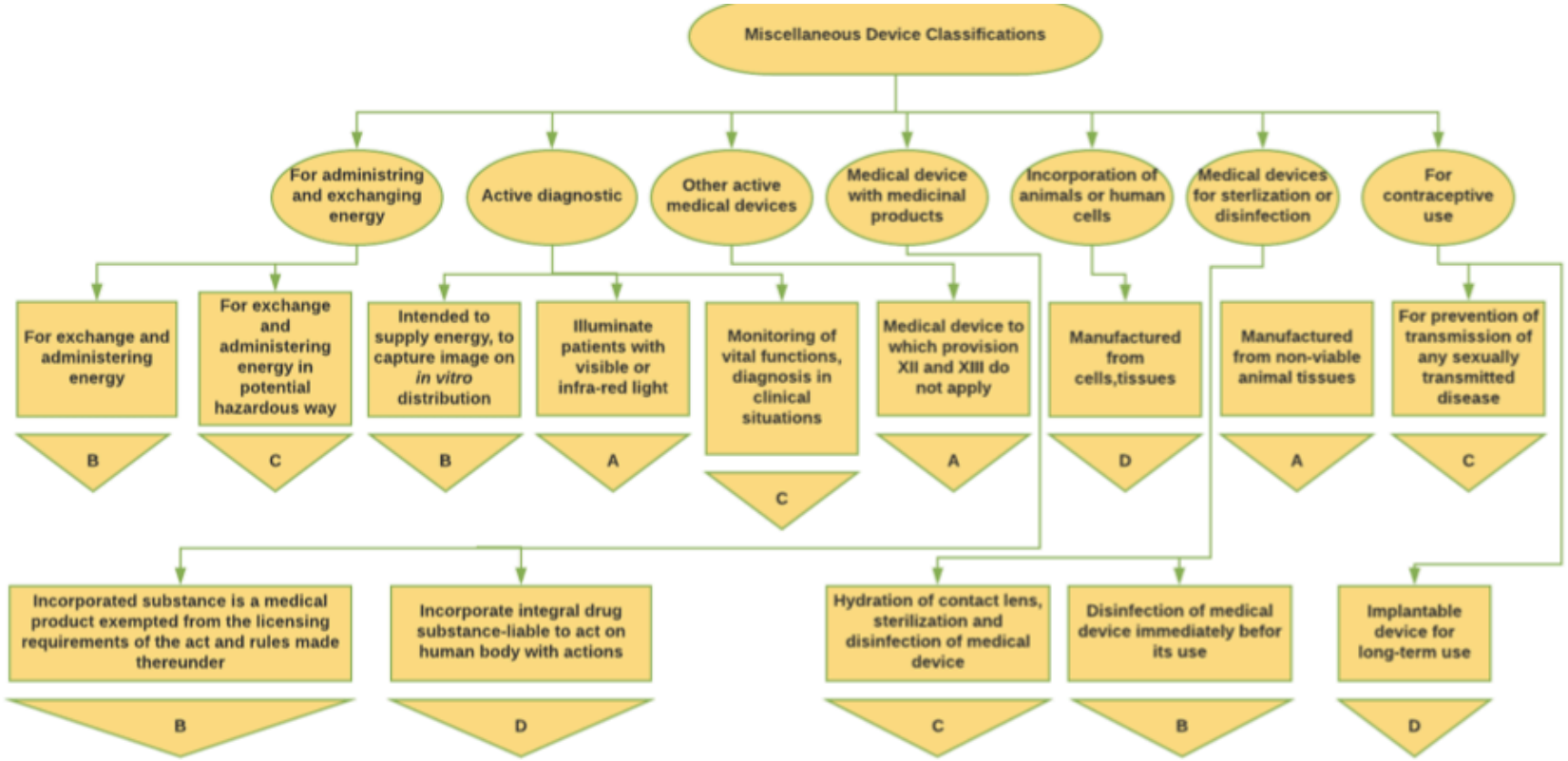
CLASSIFICATION OF DEVICE

Earlier Classification

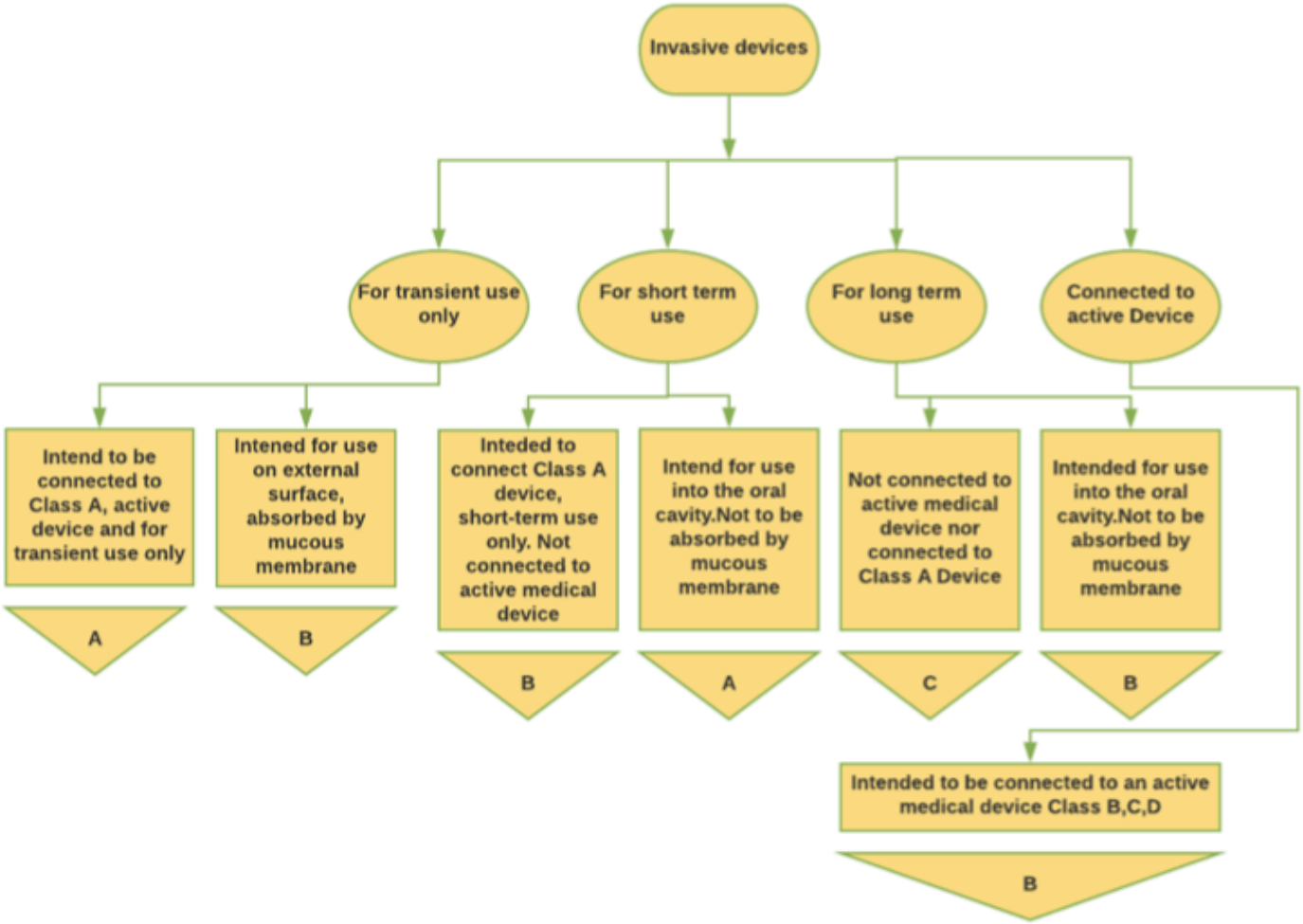
Proposed classification

- Draft regulations for the device classification is outlined as the following:
  - **Class A** - Low Risk (example: thermometers, tongue depressors)
  - **Class B** - Low-moderate Risk (example: hypodermic needles, suction equipment)
  - **Class C** - Moderate-high risk (example: lung ventilator, bone fixation)
  - **Class D** - High Risk (example: heart valves, implantable devices)

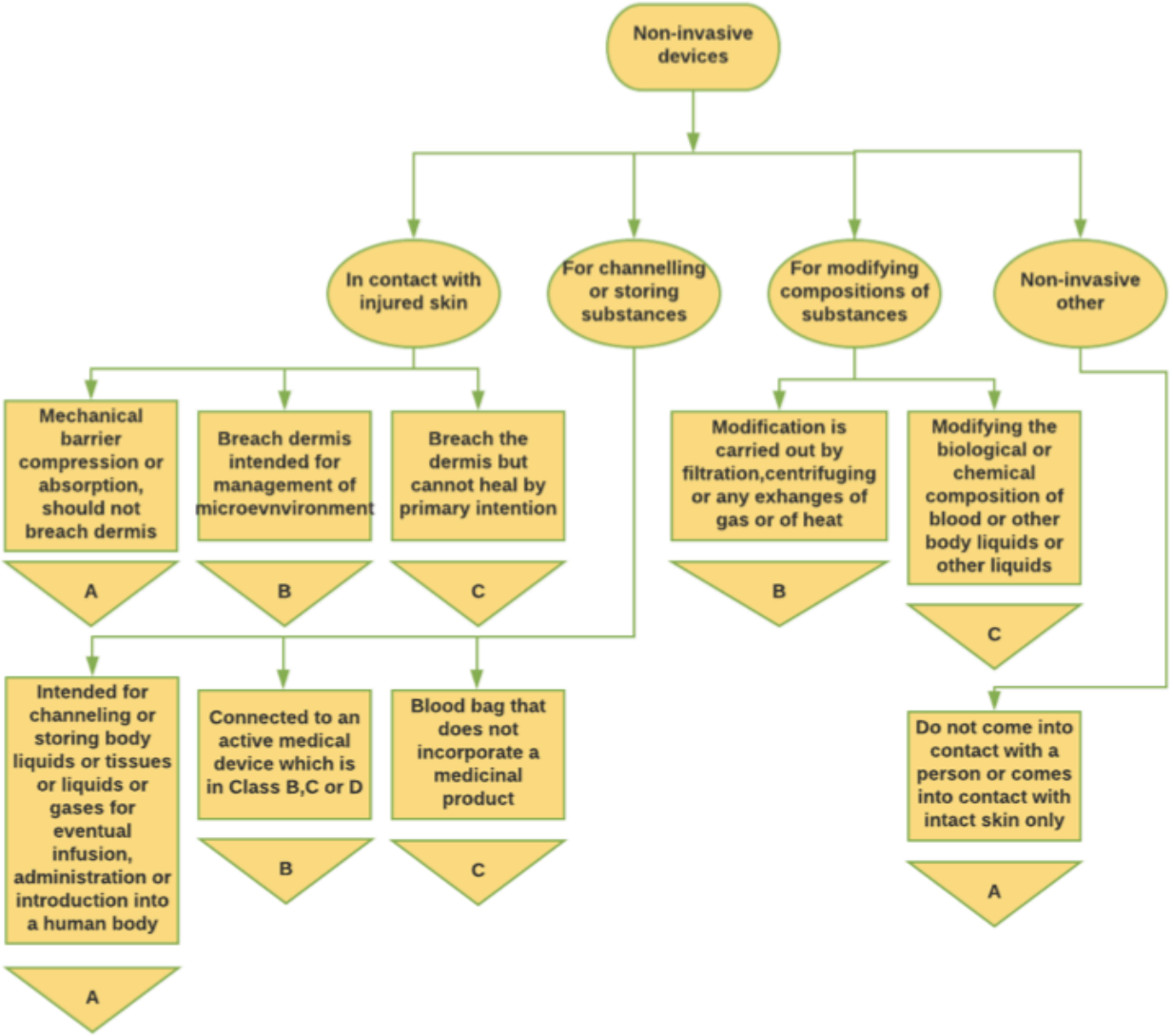
DEVICE CLASSIFICATION



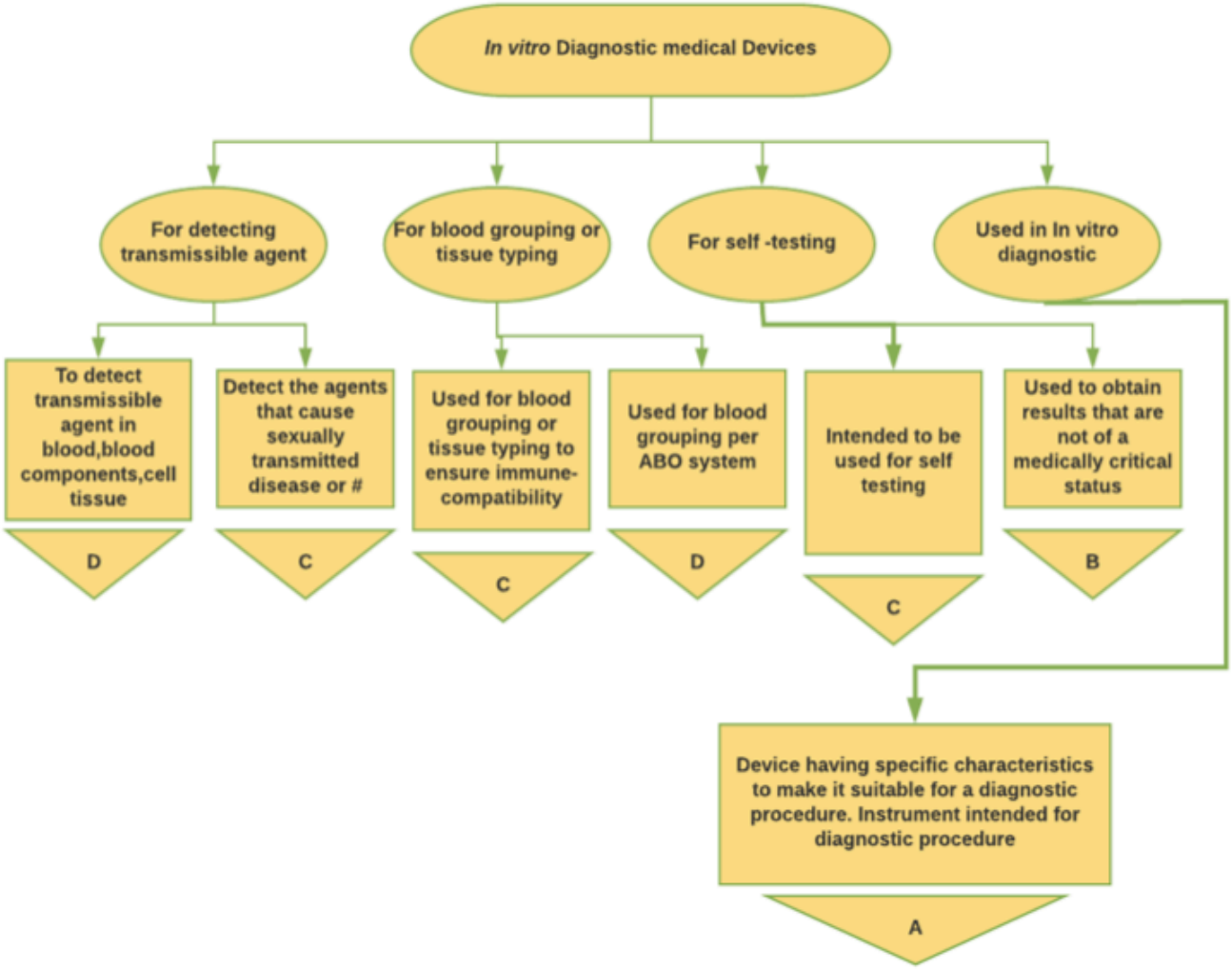
INVASIVE DEVICE CLASSIFICATION



NONINVASIVE DEVICE CLASSIFICATION



IVD CLASSIFICATION



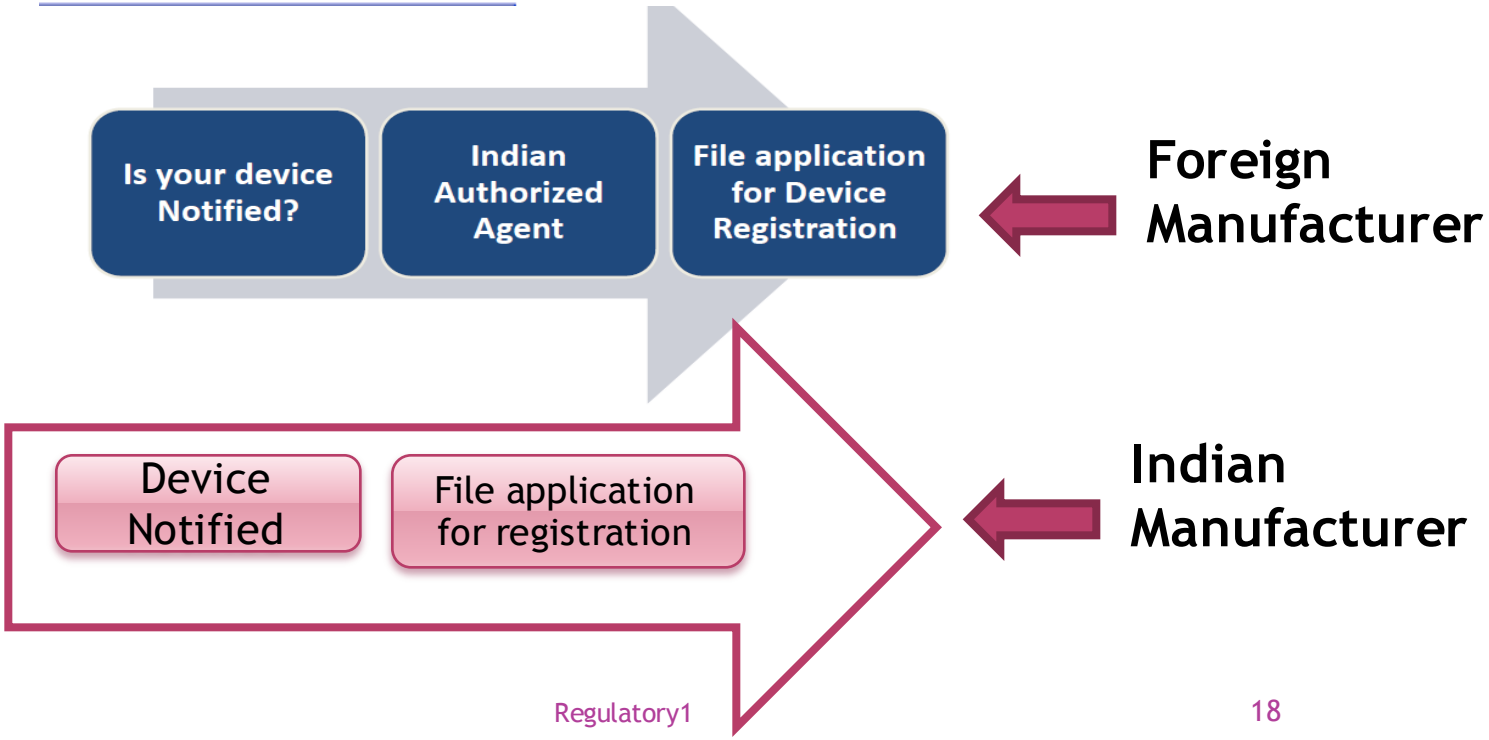
REGISTRATION PROCESS

- Notified /Regulated device require **Registration/Approval**
- Non-Notified Medical Devices does not require registration however manufacturer should obtain a **No Objection Certificate (NOC)** from the DCGI.
  - NOC is a letter from the DCGI stating that the product does not require registration and can be imported freely into India

REGULATORY PROCESS - INDIA

- Submit the application to DCGI
- Application will be prescreened as per checklist http://cdsco.nic.in/Medical_div/medical_device_division.htm

Rules 21 to 30	⇨	Rules related to grant of Registration Certificate and Import License
Schedule DI & DII	⇨	Information required for registration of Mfg site and Product



REGULATORY PROCESS - FOR FOREIGN MANUFACTURER

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Foreign Manufacturer

Appoint a local agent in India to be the applicant and license holder

Prepare Device Master File (DMF)
Prepare Plant Master File (PMF)

Prepare application Form w/supporting documents
Registration Certificate in Form-41 and Import License in Form-10

Submit above documents to DCGI with fees

DCGI reviews and sends back an inquiry letter

Applicant responds and addresses inquiries made by the DCGI

DCGI may request technical presentation

Approval

REGULATORY PROCESS FOR INDIAN MANUFACTURER

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1. Apply for Manufacturing License in Form 27

Indian Manufacturer

Documents required

1. Site master File
2. Device master

Submit above documents to DCGI with fees
(License fees of Rs.6000/-and an Inspection fees of Rs. 1500)

DCGI reviews and sends back an inquiry letter

Applicant responds and addresses inquiries made by the DCGI

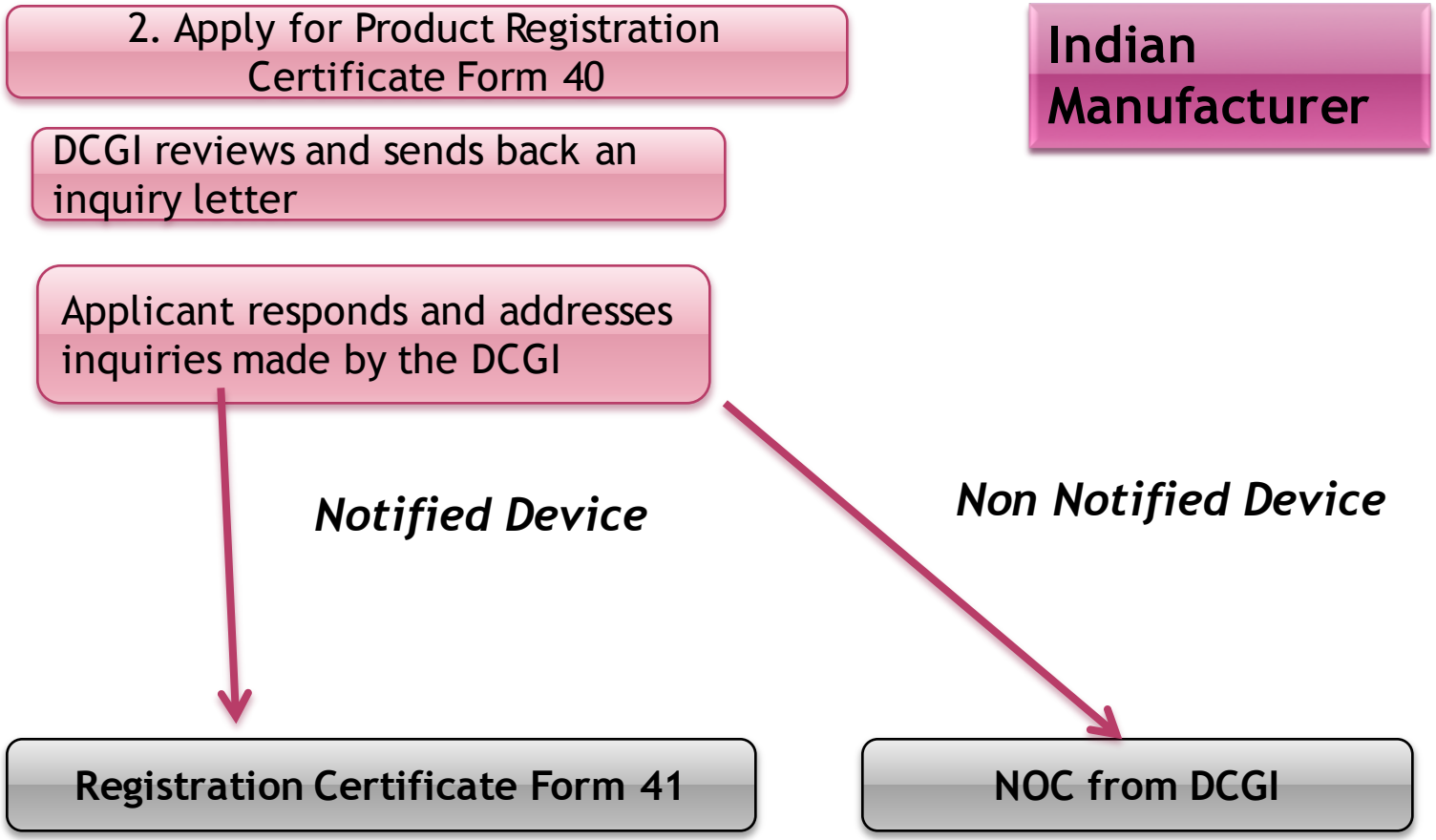
DCGI may request technical presentation or site inspection

Joint Inspection Report to CLAA

CLAA: central licensing approval authority

Manufacturing License Form 28 received

REGULATORY PROCESS FOR INDIAN MANUFACTURER



DOSSIER CONTENT

- Documents required
  1. Covering Letter
  2. Authorization Letter
  3. Form 27
  4. Fees receipt
  5. Documents relating to constitution
  6. Approved Manufacturing Premises Plan/Layout
  7. Details of technical staff
  8. Site master file
  9. Specific Environmental Requirements
  10. Device master file
  11. List of Medical Devices

1. Details of Standards
2. Promotional literature, package insert, device labels
3. ISO 13485 certificate
4. DoC
5. Any other approvals

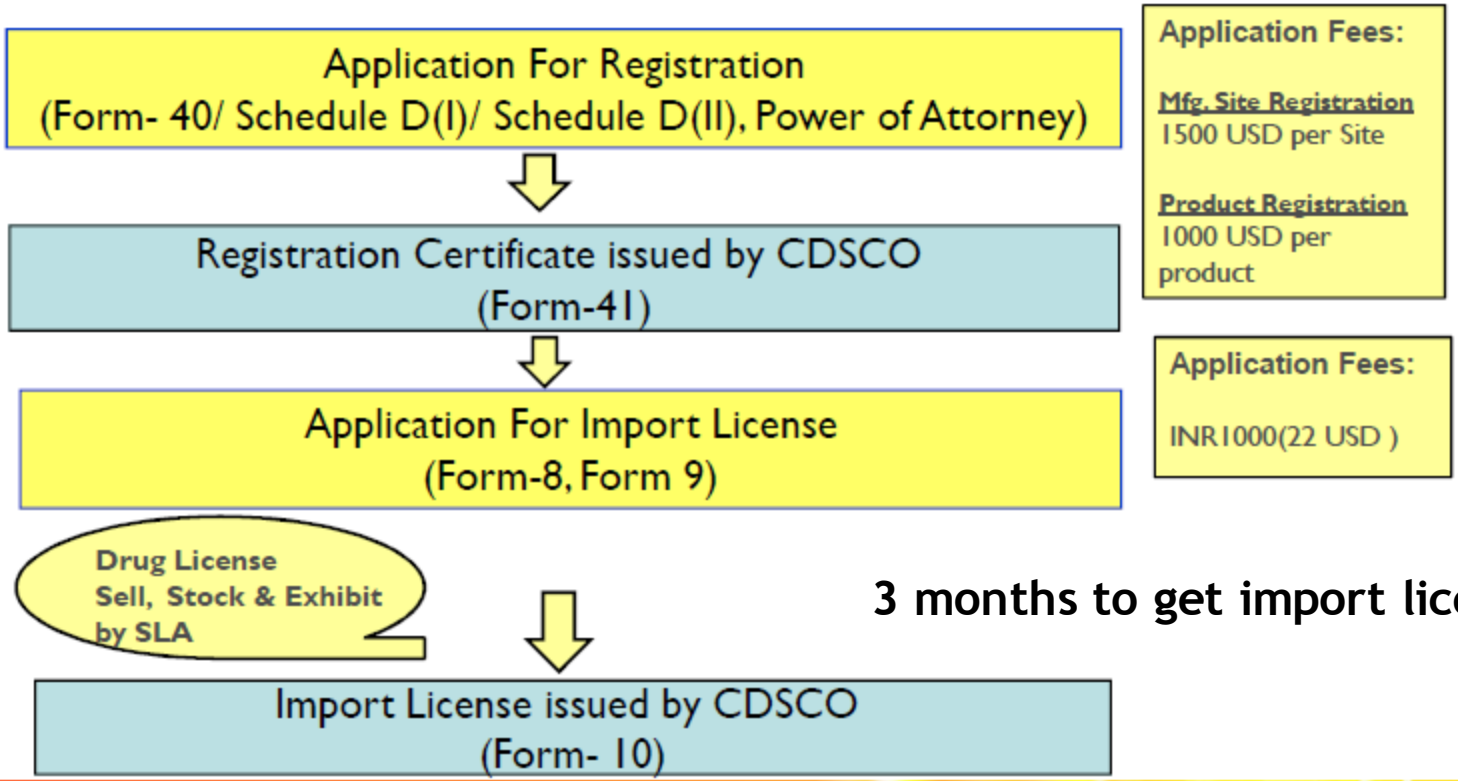
TIMELINE

- The registration of medical devices in India can take between 9 and 18 months if there are no clinical trials.

Requisite fees prescribed by the Drugs & Cosmetics Act for medical device registration include :

- •Rs . 75000 for registration of your manufacturing premises
- • Rs. 50000 for your device, plus Rs .50000 per additional device to be imported to India

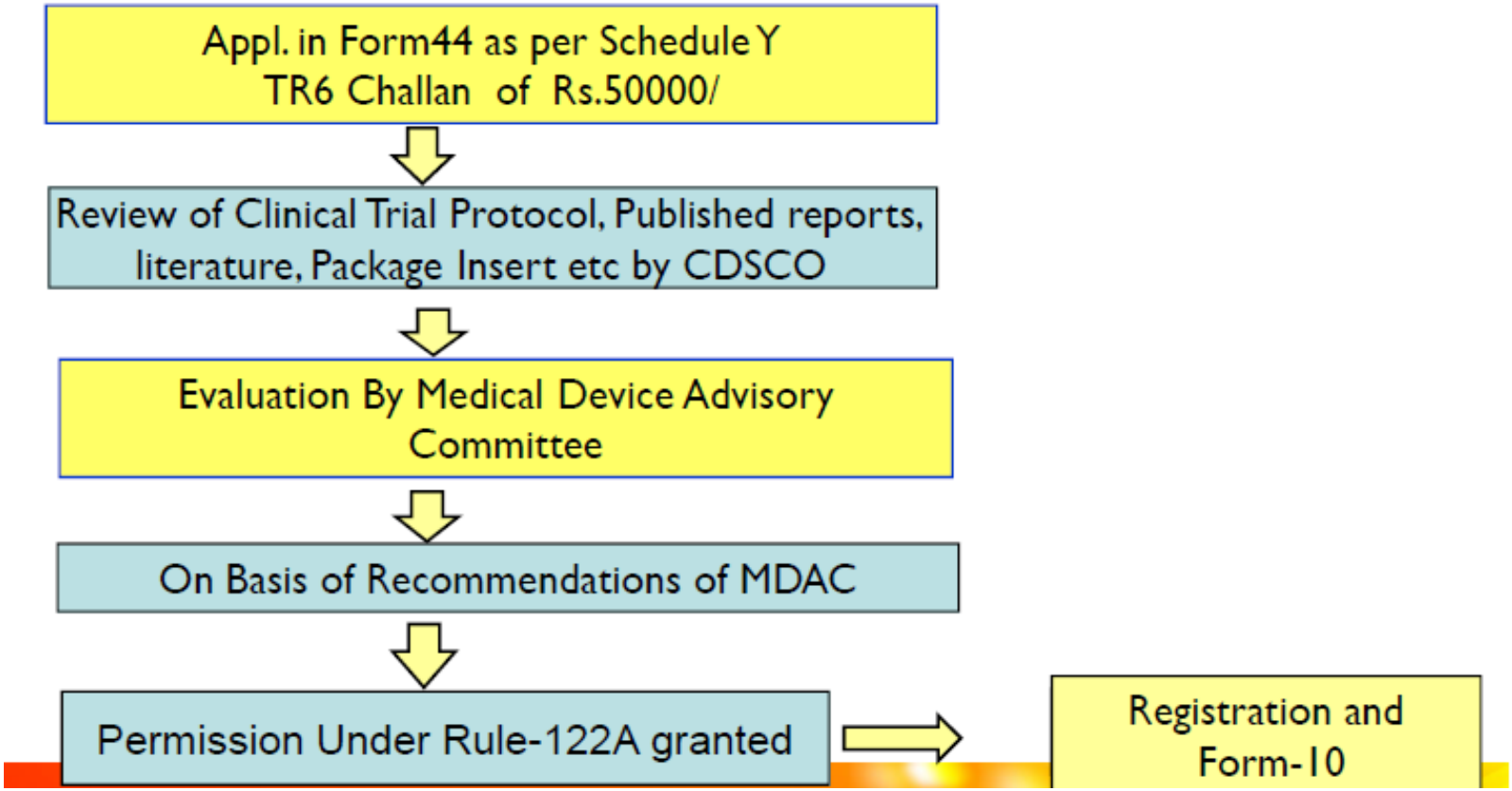
Import Procedure



3 months to get import license

After getting the registration certificate from CDSCO, the Indian agent can import the products from the manufacturer with receipt of Import License

Approval of New Medical Devices



- Medical Device without Predicate Device will be considered as New MD
- Require local clinical for 200 patients / PMS for bigger group

IN-VITRO DIAGNOSTIC PRODUCT

What is an In-Vitro Diagnostic Product (IVD)

- In-Vitro Diagnostic Products are those substances that are intended to be used for or in the use in diagnosis of disease or disorders in human being or animals.

CLASSIFICATION OF DIAGNOSTIC KITS

Current

IVD

Notified Diagnostic Kits

Non- Notified Diagnostic Kits

Examples

In-Vitro Diagnostic Devices for HIV
In-Vitro Diagnostic Devices for HBV
In-Vitro Diagnostic Devices for HCV
In-Vitro Blood grouping sera

All In-Vitro Diagnostic kits and Reagents excluding those listed under Notified category

Import Requirement

Registration Certificate in Form 41 and Import License in Form 10

Import License in Form 10

REGISTRATION PROCESS OF DIAGNOSTIC KITS

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Notified Diagnostic Kits

1. Pay USD1000 Registration fee with application in Form 40
2. Compilation of Registration dossier
3. Submit Product Registration application

9 months- Registration Certificate Form 41

1. Apply for import license Form 10
2. Fees 1000 INR
3. Compilation of Registration dossier

3 months-Import License Form 11

Labeling should comply with requirements of the Rule 96

Additional Documents:

- Performance Evaluation Report from the National Institute of Biologicals.
- Detailed evaluation report conducted by the National Control Authority of the country of origin
- Product Insert (English version or authenticated translated copy)
- Published articles, if any, of each diagnostic kit/reagent proposed to be registered

STANDARDS

- Process standards:
  - ***IS/ISO 13485:2016***
    Medical Devices-Quality Management System-Requirements for Regulatory Purposes
  - ***ISO 14971:2007***
    Medical Device-Application of risk management to medical device
  - ***ISO 14155:2011***
    Clinical Investigation of Medical devices for human subjects
  - ***ISO 15223-1:2016***
    Medical devices-symbols to be used with medical device labels, labelling and information to be supplied-part 1: General requirement
  - ***ISO 18113-1:2009***
  - In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 1: Terms, definitions and general requirements

STANDARDS

- Product standards:
  - which cover safety and performance aspects of specific products or processes,
  - IEC 60601-2-24 Infusion Pumps
  - IEC 60601-2-54 X Ray machine
  - ISO: 15197 Blood Glucosemeter
  - IEC 60601-2-24:2012 applies to the basic safety and essential performance of infusion pumps and volumetric infusion controllers.
  - ISO 15197:2013 specifies requirements for in vitro glucose monitoring systems
  -

SUMMARY

- Regulatory authority is the Central Drug Standards Control Organization (CDSCO)
- Devices are classified as notified and non-notified similarly IVD
- Registration is not required for import of non-notified medical devices in India whereas for notified device it is mandatory.
- Most of the devices are regulated as “Drugs” under Drugs and Cosmetics Act and Rules, hence registration and import license is required for import in to India.

THANK YOU FOR KIND ATTENTION

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