# CLINICAL TRIALS GUIDELINES

**This document has been prepared as a toolkit to guide Contract Research Organisations on the process to apply for a clinical trial license.**

The Clinical Trials Act provides the legal framework for:

(i) Registration of Contract Research Organisations (CROs)

(ii) The conduct of clinical trials for the purpose of discovering or verifying the effects of investigational medicinal products and medical devices.

The Act also provides for the setting up of the:

- Clinical Research Regulatory Council (CRRC) responsible for registration of CROs the regulation and control of trial licenses being issued.
- Ethics Committee (EC) to advise the CRRC regarding welfare, safety, health and protection of human subjects participating in clinical trials.
- Pharmacovigilance Committee (PC) to monitor all clinical trials being performed and ensure Good Clinical Practice (GCP).

# Registration of CROs

- No CRO shall conduct, or assist in, a clinical trial in Mauritius unless it is registered with the Council.

- A CRO seeking registration with the Council shall make an application at least 2 months before beginning of operations

- Application form and supporting documents should be submitted as per the First Schedule of the Clinical Trials (Registration of Contract Research Organisations) Regulations 2021

- The CRO shall ensure that trials are adequately monitored, and the trial related responsibilities transferred to it, partially or fully, by the sponsor are discharged effectively and efficiently.

- The CRO shall implement quality assurance and quality control as per standard operating procedures designed for the purpose.

## REGISTRATION OF CROS - DOCUMENTS TO BE SUBMITTED FOR APPLICANT

- ✓ Certified copy of the Certificate of Incorporation
- ✓ Certificate of Current Standing
- ✓ Corporate Profile, Latest Annual Return and Audited Financial Statements
- ✓ Organogram
- ✓ Floor Plan of Research Offices (demonstrate adequate equipment and infrastructure)
- ✓ Fire Certificate
- ✓ Evidence of compliance to Good Clinical Practice and other relevant trainings
- ✓ Certificates of Insurance (public liability, professional indemnity, cyber protection)
- ✓ ISO Certification
- ✓ Procedures for dealing with non-compliances
- ✓ Adequate Standard Operating Procedures and associated documents (templates and forms)
- ✓ Relevant policies as per the law
- ✓ Quality Management Plan
- ✓ Business Continuity Plan
- ✓ Adequate IT systems
- ✓ Good Data Handling policies (including compliance with Data Protection Act 2017)
- ✓ Confidentiality Procedures in place
- ✓ Provision for Pharmacovigilance (system in place for safe reporting)

***Kindly consult Regulations for detailed information and list of documents required for personnel**

## Applicable Fees for Registration of Contract Research Organisations

| Category | Applicable Fees (Rs) |
|---|---|
| **Registration of CRO** | 50,000 |
| **Application for extension of certificate of CRO** | 25,000 |
| **Inspection fee** | 5,000 |

# APPLICATION FOR A CLINICAL TRIAL LICENSE

- Application for a Trial License with the CRRC accompanied by the prescribed application fee and the required documents**
- Initial Evaluation by the CRRC (As per CTA, Council meets at least once every month)
- Submission of the application and documents to the Ethics Committee for approval
- Further assessment by pharmacovigilance if required
- Payment of the prescribed license fee
- Application granted by the CRRC

**** An application form shall be accompanied by 12 hard copies and 12 soft copies of:**

- Protocol
- An investigator’s brochure
- Brief CV and proof of registration with the medical council for each investigator
- Proof of registration with other regulatory bodies if applicable
- A GMP certificate and a Certificate of Pharmaceutical Product (COPP) in relation to every investigational product or device from the country of origin
- Bilingual forms to be used for the purpose of patient/subject information, informed consent, recruitment of subjects, adverse event reports and adverse reaction reports
- Proof of local insurance coverage

The Sponsor shall also provide :

- Information as to the quantity of every investigational medicinal product to be used in the clinical trial;
- Information relating to the measures to be taken for the health, welfare, safety and protection of subjects;
- Information relating to the financial aspects of the clinical trial, in particular:

(i) Sources of funding for the clinical trial and information on he financial or other interests of the sponsor relevant to the clinical trial;

(ii) The arrangements for the reimbursement of expenses incurred by the subjects;

(iii) Any provision for compensation in the event of injury or death resulting from the clinical trial, including details of any insurance cover to be contracted for the protection of subjects;

(iv) Details of any insurance or indemnity to cover the liability of the sponsor and investigator;

(v) Summary details of any financial arrangements between

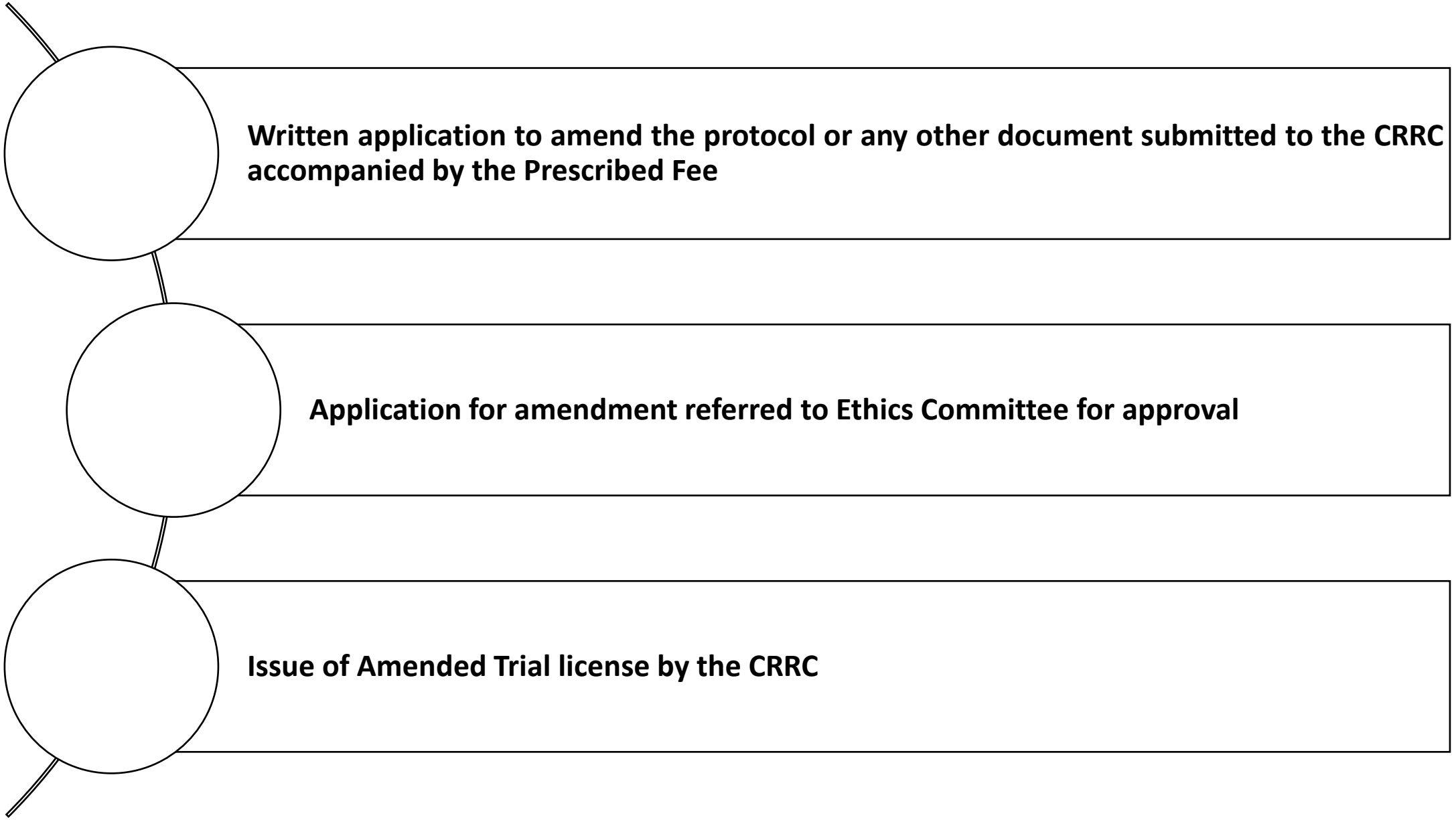
(A) the sponsor and the investigator; and

(B) the sponsor and the owner or occupier of the site;

- Information relating to the anticipated benefits and risks of the clinical trial;
- Information relating to the location, structure and amenities of any site where the clinical trial is to be conducted; and
- Such other information as the Council may require

**If all relevant documents/information are provided, a trial license is deliverable within 60 days**

# AMENDMENT TO TRIAL LICENSE



# GOOD CLINICAL PRACTICE

- Clinical trials shall be conducted in accordance with the conditions and principles of good clinical practice.
- The rights, safety and well-being of a subject shall prevail over the interests of science and society.
- Every sponsor shall ensure that any person involved in conducting a clinical trial is qualified by education, training and experience to perform his tasks.
- Every sponsor and investigator shall comply with guidelines prepared or approved by the Council

***The Clinical Research REGULATORY Council and Ethics Committee are strictly following the ICH European Guidelines to permit the conduct of Clinical Research in Mauritius:***

- ***ICH E6: Good Clinical Practice: Consolidated guidelines***
- ***ICH Harmonised Tripartite Guidelines E8: General Considerations for Clinical Trials***
- ***ICH Harmonised Tripartite Guidelines E10: Choice of Control Group and related issues in Clinical Trials***

# TRIAL MASTER FILE & ARCHIVING

Every sponsor shall keep a trial master file for a clinical trial in respect of which he holds a trial license

A sponsor shall make the trial master file readily available at all reasonable times for inspection by the Council or any person appointed by the sponsor to audit the arrangements for the clinical trial.

The trial master file shall at all times comprise of documents which:

- Enable both the conduct of the clinical trial and the quality of the data produced to be evaluated;
- Show whether the clinical trial has been conducted in compliance with –
  (i) the Clinical Trials Act and regulations made under it; and
  (ii) the guidelines referred to in section 4(f); and
- Contain information specific to each phase of the clinical trial

A sponsor shall keep, for not less than 15 years after the completion of a clinical trial, the trial master file which shall be:

- Readily available at all reasonable times to the Council; and
- Complete and legible

## PROGRESS & COMPLETION OF CLINICAL TRIAL REPORTS

Every sponsor shall furnish to the Council a written report on the progress of a clinical trial, containing such particulars as the Council deems necessary, not later than 6 months after:

- the date on which the trial license is issued;
- the end of every subsequent period of 6 months; and
- the completion of the clinical trial

## COMPLETION & DISCONTINUANCE OF CLINICAL TRIALS

A sponsor shall, not later than 90 days after a clinical trial is completed, notify the Council of the completion.

Where a clinical trial is discontinued, its sponsor shall forthwith notify the Council in writing of the discontinuance and the reasons thereof.

**Applicable Fees for Clinical Trial License (Medicinal Products)**

| **Category** | **Applicable Fees (Rs)** |
|---|---|
| Application fee | 10 000 |
| Fee payable for the issue of an amended trial license | 20 000 |
| **License** | |
| Clinical trial (Phase I) license | 100 000 |
| Clinical trial (Phase II with a known product) license | 150 000 |
| Clinical trial (Phase II with an unknown product) license | 200 000 |
| Clinical trial (Phase III with a known product) license | 150 000 |
| Clinical trial (Phase III with an unknown product) license | 200 000 |
| Clinical trial (Phase IV) license | 20 000 |
| Annual service fee | 20 000 |

# CLINICAL TRIALS ON MEDICAL DEVICES

**In line with the Clinical Trials (Medical Devices Trials) Regulations 2021**

- No person shall conduct a clinical trial in respect of a medical device unless he is registered with the Council for this purpose.

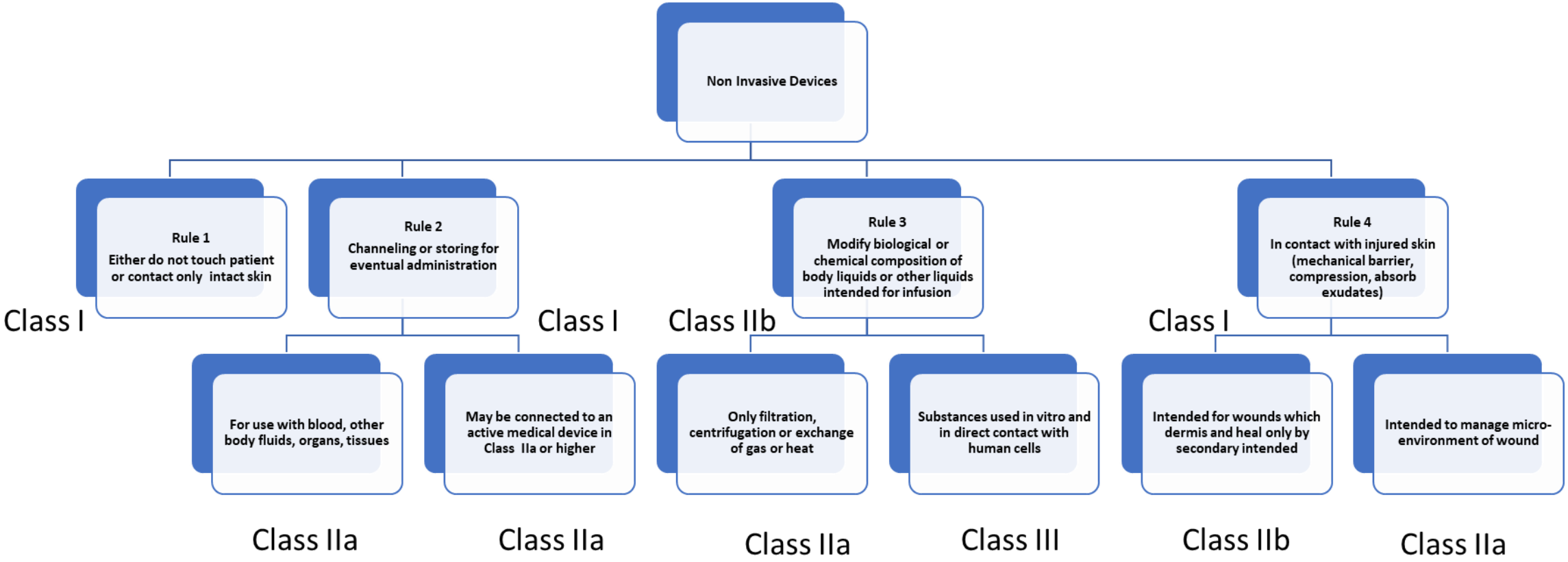
- Any person who intends to conduct clinical trials in respect of a medical device shall make an application for a trial license to the Council.

- Application form and documents to be submitted as per requirements of the Council

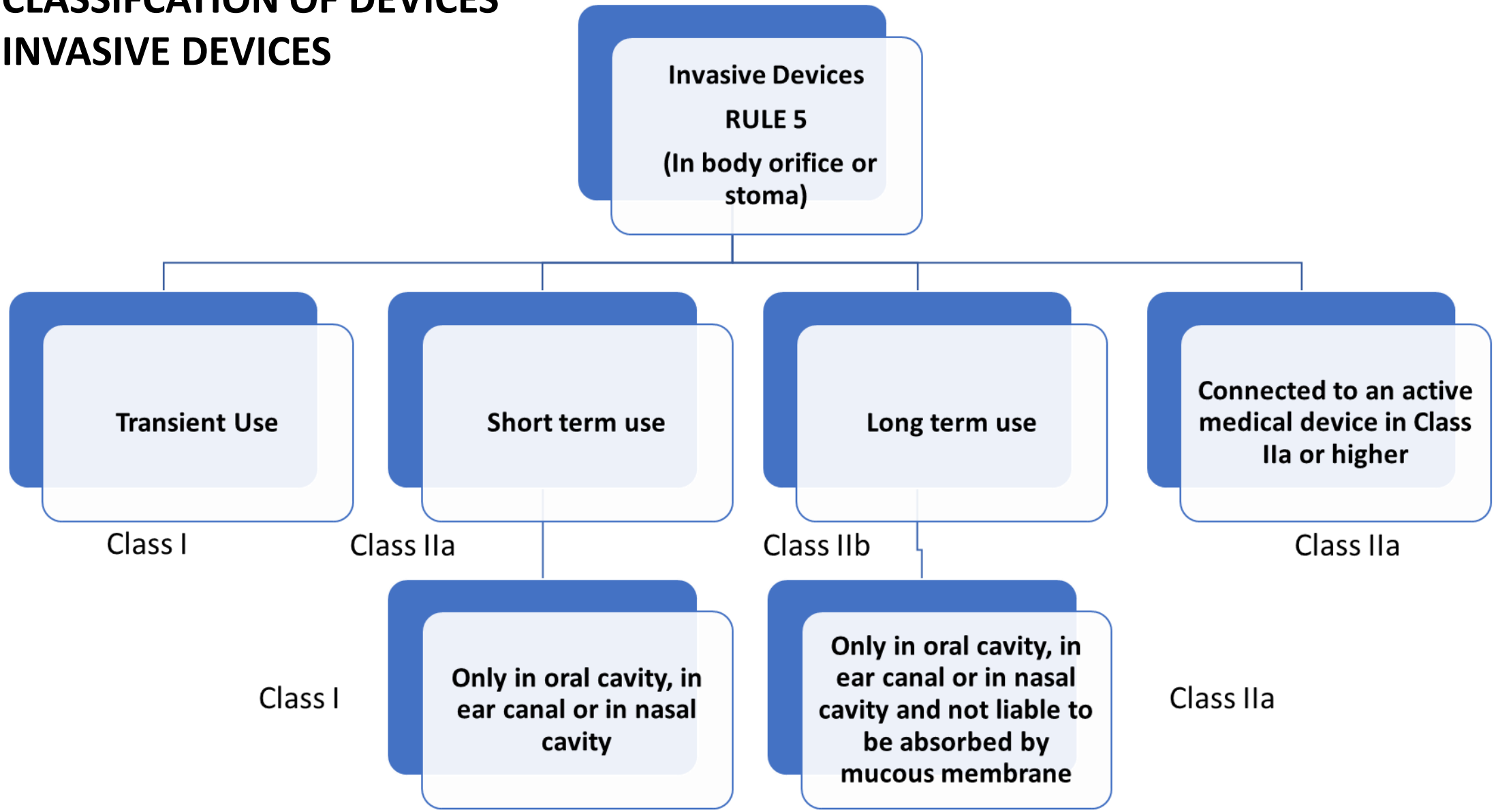
- Full details of Rules and Classification are available in the Regulations

# CLASSIFICATION OF DEVICES

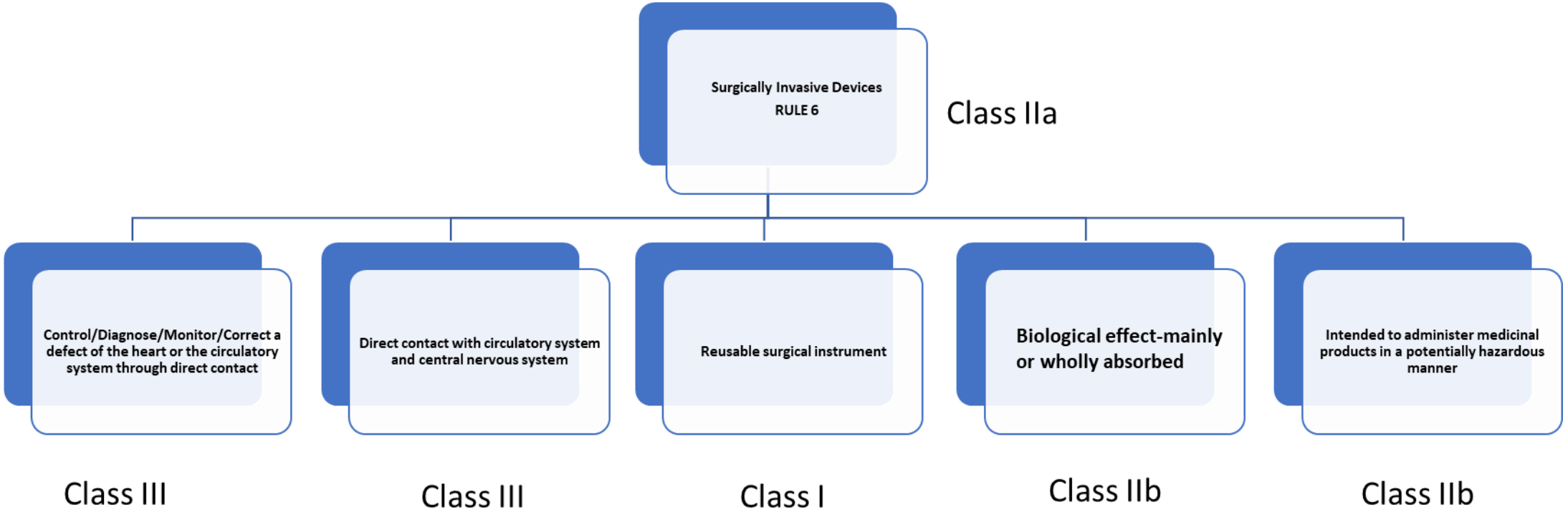
## Non-Invasive devices



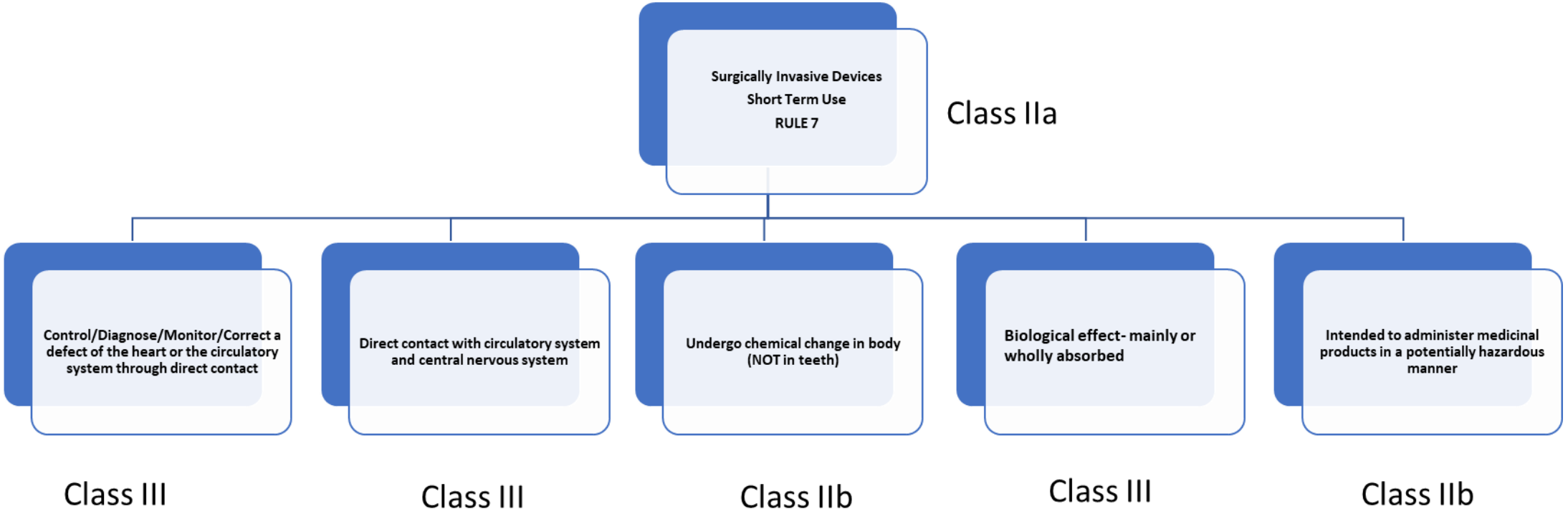
# CLASSIFCATION OF DEVICES
# INVASIVE DEVICES



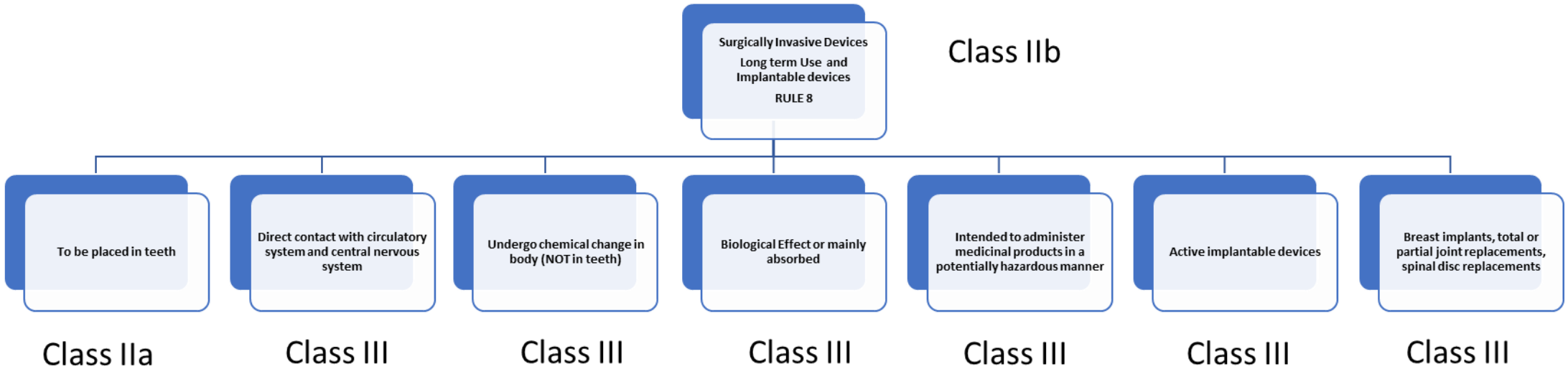
# CLASSIFICATION OF DEVICES
# SURGICALLY INVASIVE DEVICES



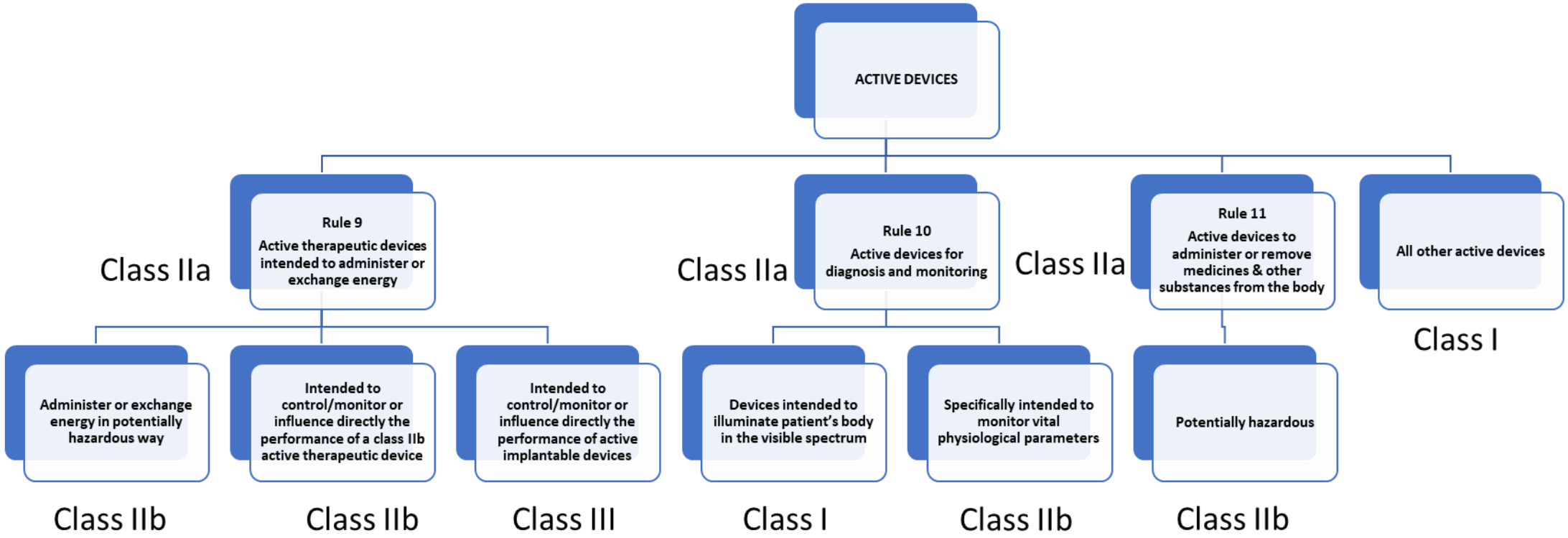
# CLASSIFICATION OF DEVICES
# SURGICALLY INVASIVE DEVICES (SHORT TERM)



# CLASSIFICATION OF DEVICES
# SURGICALLY INVASIVE DEVICES (LONG TERM)



# CLASSIFICATION OF DEVICES
# ACTIVE DEVICES



## SUMMARY

| Category | Rules |
|---|---|
| Non invasive devices | Rules 1, 2, 3, 4 |
| Invasive devices | Rules 5, 6, 7, 8 |
| Active Devices | Rules 9, 10, 11 |
| Special Rules | Rules 12, 13, 14, 15, 16 |

# FEES FOR CLINICAL TRIALS ON MEDICAL DEVICES

| | (Rs) | PILOT STUDY (Rs) | PIVOTAL STUDY (Rs) | POST APPROVAL (Rs) |
|---|---|---|---|---|
| Issue of trial license | 10 000 | | | |
| Issue of amended trial license | 20 000 | | | |
| Issue of duplicate license | 10 000 | | | |
| Annual service fee | 20 000 | | | |
| Class I medical device with low risk | | 10 000 | 20 000 | 10 000 |
| Class IIa medical device | | 20 000 | 40 000 | 20 000 |
| Class IIb medical device with moderate risk | | 40 000 | 80 000 | 40 000 |
| Class III medical device with high risk | | 100 000 | 200 000 | 75 000 |