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### Regulation and Registration Requirements of Medical Device and its Comparison in Australia and India

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#### ABSTRACT

Medical devices have become more important in the health care sector. It is mostly used for diagnosis and prevention of public health. There are more than 8000 generic medical device groups, where some medical devices contain drugs. This increases the demand for better regulatory frameworks to ensure that products entering in the market are safe as well as efficient. One of the major issues for companies developing and producing medical devices is to be updated on the bases of regulatory requirements and to implement them in the process. This is particularly true in developing countries, where assessments of health technology are rare and where little regulatory controls exist to prevent the importation or use of substandard devices. So regulation of medical device is a vital need in Pharmaceutical Sector. This article mainly focuses on classification, classification rules, registration procedure, documents required for registration of medical device and fees for application of medical devices in Australia and India. In Australia medical devices are regulated by Therapeutics Good Administration (TGA) whereas in India medical devices are regulated by Central Drugs Standard Control Organization (CDSCO).

**Keywords:** Medical device, Regulation, Classification rules, Australia, India, CDSCO, TGA, ARGMD.

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## INTRODUCTION

Medical device is an instrument, implant, apparatus, appliance, in vitro reagent, or similar or related article which is used for diagnosis, prevention, or treatment of disease or other conditions, and does not achieve its purposes through chemical action within or on the body which would make it a drug.<sup>1</sup>

### **Medical device regulatory system in Australia**

In Australia medical devices are regulated by TGA (Therapeutic Goods Administration)<sup>2</sup>. The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, which are responsible for regulating medicines and medical devices. As per Therapeutic Goods 1989 Act, therapeutic goods supplied in Australia must meet acceptable standards of quality, safety and efficacy (performance). On the basis of scientific and clinical expertise to decision-making, TGA ensures any risk associated with the use of medicines and medical devices. The TGA relies on the healthcare professionals, public and industry to report problems with medicines or medical devices. TGA investigate the reports received and determine any necessary regulatory action.<sup>2</sup>

### **Definition**

As per Therapeutic Goods Act 1989 medical devices are:

“Any instrument, appliances, apparatus, material or any other articles (which are used alone or in combination, and including the software necessary for its proper application) intended by the person or manufacture under whose name it is to be supplied, to be used for human beings for the purposes of one or more of the following:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, prevention, monitoring, treatment and alleviation of or compensation for an injury or handicap,
- Investigation, modification or replacement of the anatomy or of a physiological process,
- Control of conception, and does not achieve its intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; or an accessory to such an instrument, apparatus, appliance, material or any other article.”<sup>2</sup>

### **Classification of medical device as per Australia**

Medical devices are classified in to 5 classes based on the level of risk. Depending on the intended purpose of medical devices, there are 22 classification rules. The higher the class, the more

regulatory control is required. <sup>2</sup> Depending on the level of risk, medical devices classification (Table 1).

**Table: 1; Classification of Medical Device as per Australia**

Classification	Risk level	Example
Class I	Low risk	Urine Collection Bottle, Non-sterile Dressings, Plaster Bandages, Cotton wool, Handheld dental mirrors, Scissors, Surgical microscopes
Class IIa	Low-Medium risk	Intravenous tubing, Anaesthesia Breathing Circuits, Blood transfusion sets, Adhesive for topical use, Oxygen Tubing and Mask, Contact lenses, Nasopharyngeal airways, Suturing needles and Clamps
Class IIb	Medium-High risk	Dressing for Chronic Extensive Ulcerated Wounds, Artificial Eyes, Personal insulin injectors, Bone cements, Lung ventilators, Condoms and Nebulizers
Class III	High risk	Cardiovascular Catheter, Prosthetic Heart valves, Cardiac Output Probes, Antibiotic bone cements
AIMD (Active Implantable Medical Device)		Pacemaker, Nerve stimulator, Cardiac defibrillator, Cardiac stents

#### Classification Rules of medical device as per Australia

- Schedule 2 of the medical device regulations describes the classification rules based on intended use (Table 2). <sup>3</sup>

**Table: 2; Classification rules as per Australia**

Rules	Class
Rule 1	Non- Invasive medical devices
Rule 2	Invasive medical devices
Rule 3	Active medical devices
Rule 4	Special rules

- Schedule 2, Part 2 of the medical device regulations describes the classification rules for non invasive medical devices (Figure 1).

- Rules for invasive medical devices

Any medical devices which are intended by manufacturer to be used in whole or in part to penetrate the body of a human being through the surface of the body or through a body orifice. These rules are described in schedule 2, Part 3 of the medical device regulation.

- Rule 3.1 – Non surgical Invasive medical devices (Figure 2).
- Rules 3.2 - surgically invasive – transient use medical devices:

Invasive medical devices are devices which are intended by manufacturer to be used in context of a surgical operation and to be used to penetrate the body of a human being in any way other than through a body orifice. Transient use medical devices are devices which are intended by manufacturer to be used continuously for less than 60 minutes. Schedule 2, Part 3 of the

medical device regulation describes the classification rules for surgically invasive – transient use medical devices (Figure 3).

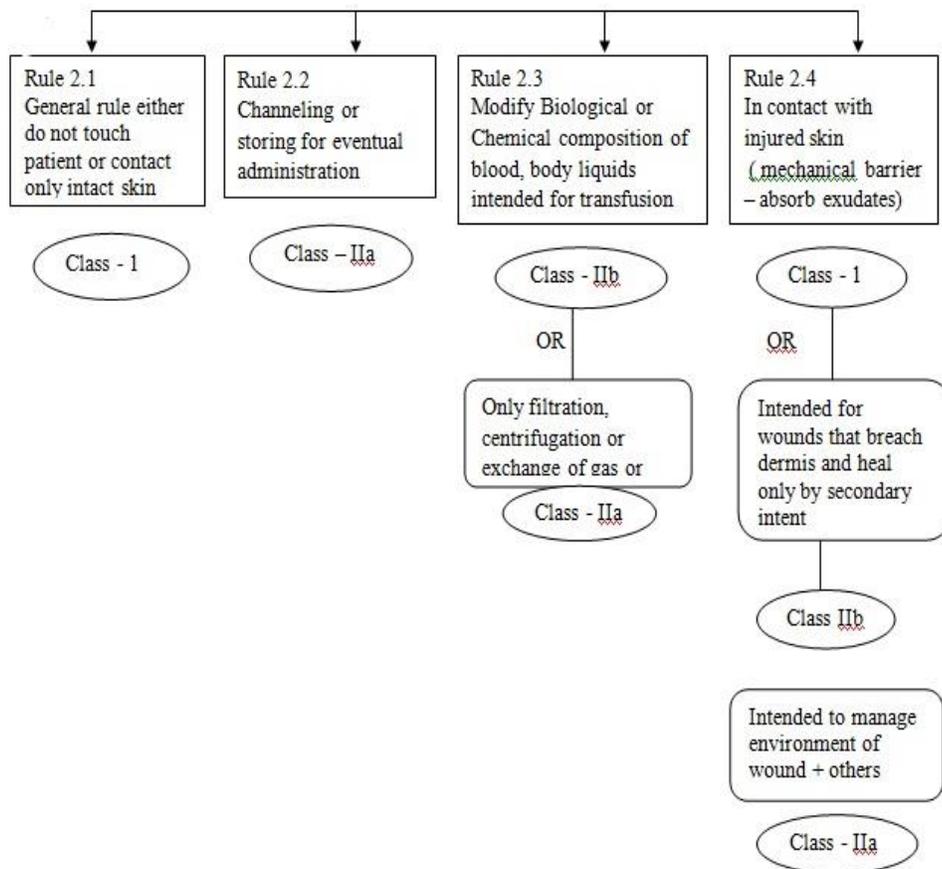


Figure 1: Rules for non invasive medical device

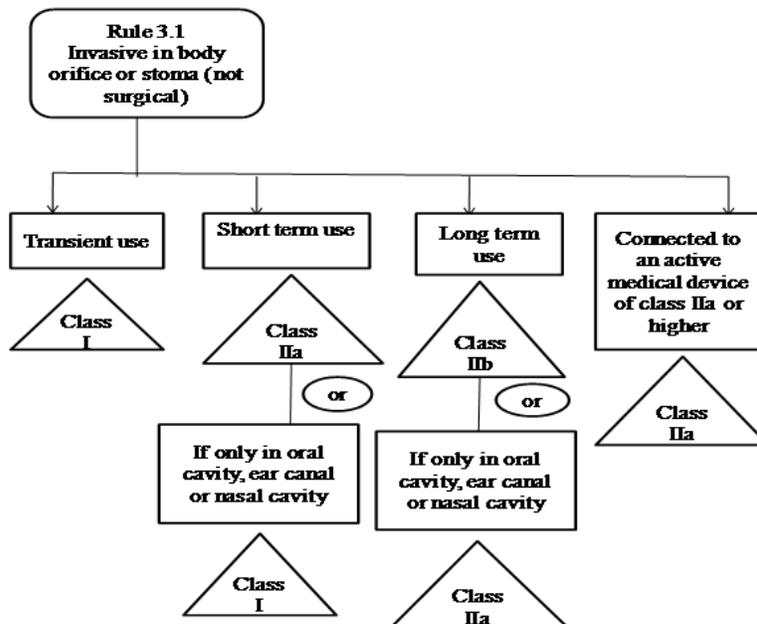
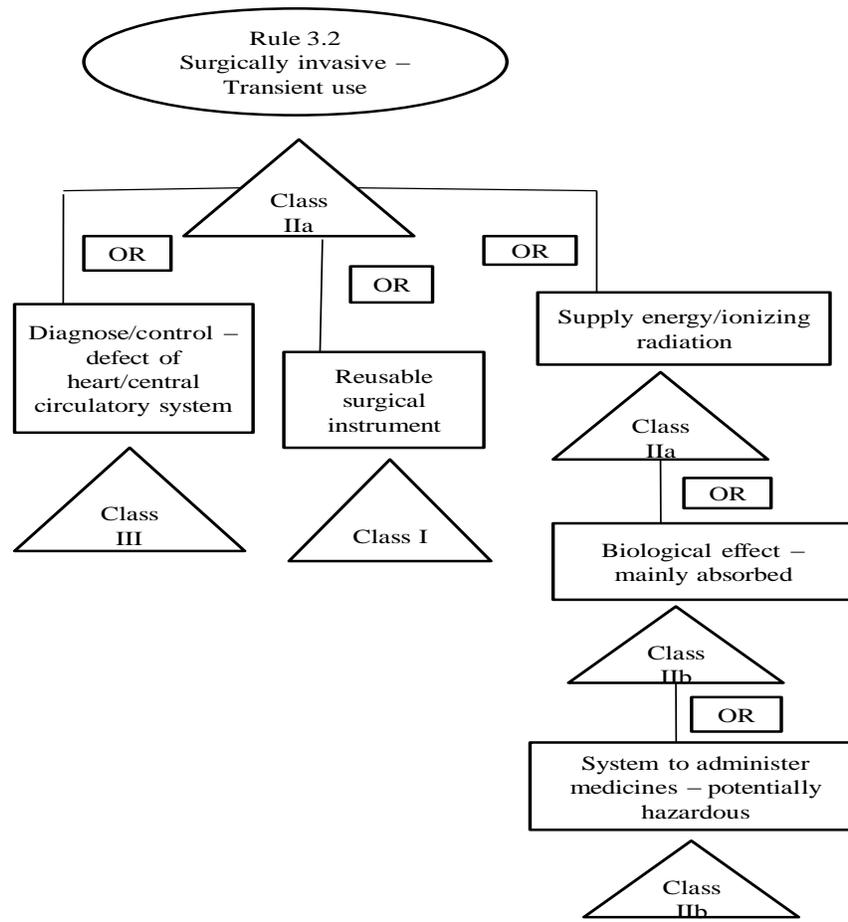


Figure 2: Rule 3.1 non surgical invasive medical device



**Figure 3: Rule 3.2 surgically invasive – transient use medical device**

- Rules 3.3 Surgically Invasive – Short term use medical devices

Short term use medical devices are devices which are intended by manufacturer to be used continuously for at least 60 minutes but not more than 30 days. These rules are described in schedule 2, Part 3 of the medical device regulation (Figure 4).

- Rules 3.4 surgically invasive – long term use medical devices:

Long term use medical devices are devices which are intended by manufacturer to be used continuously for more than 30 days. Schedule 2, Part 3 of the medical device regulation describes the classification rules for surgically invasive – long term use medical devices (Figure 5).

- Rules for active medical devices

A device that is intended by manufacturer depends for its operation or other source of energy or to act by converting this energy (Figure 6).

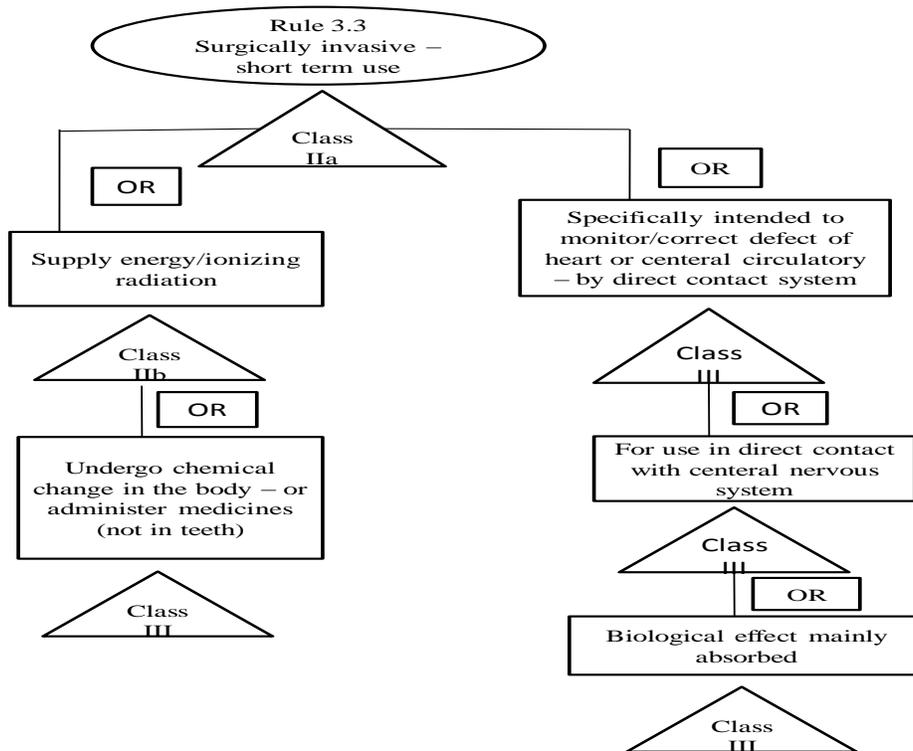


Figure 4: Rule 3.3 surgically invasive – short term use medical devices

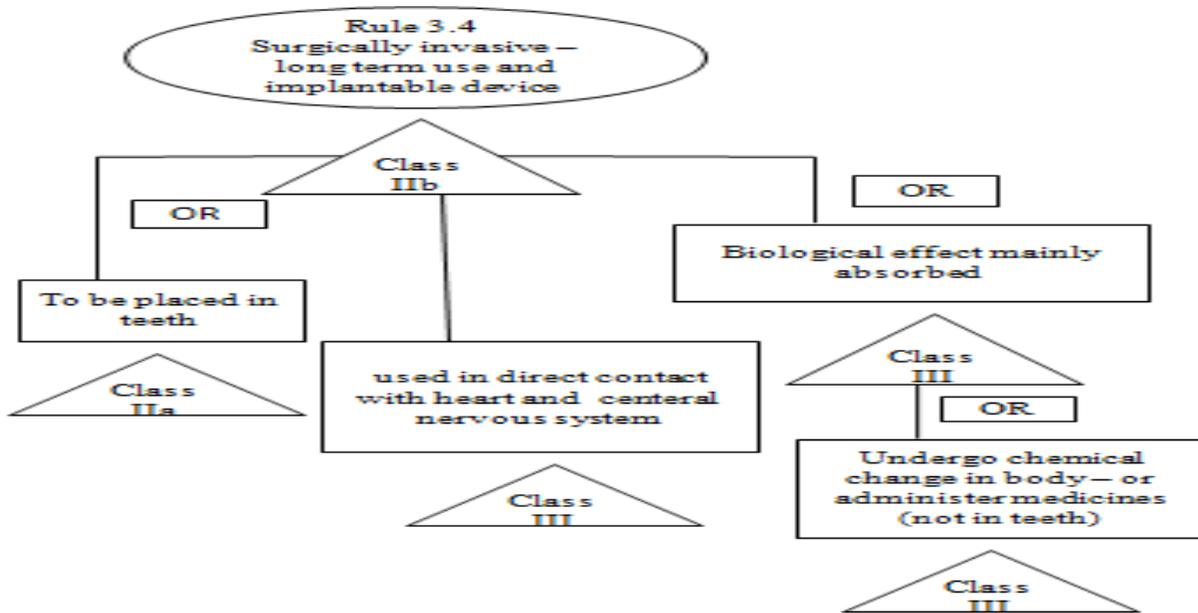
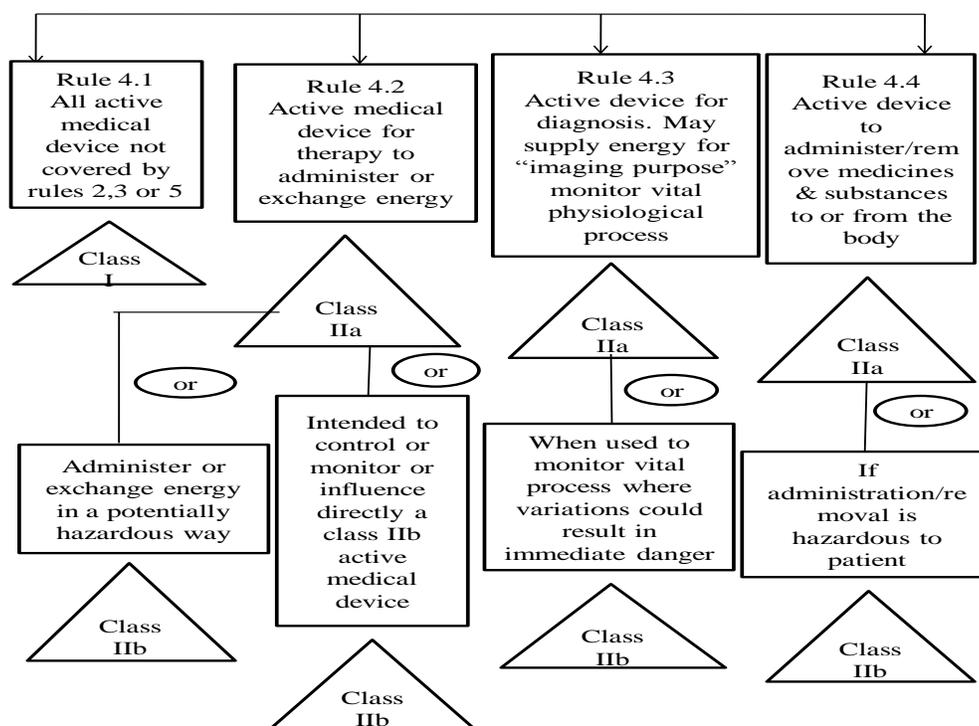


Figure 5: Rule 3.4 surgically invasive – long term use medical devices

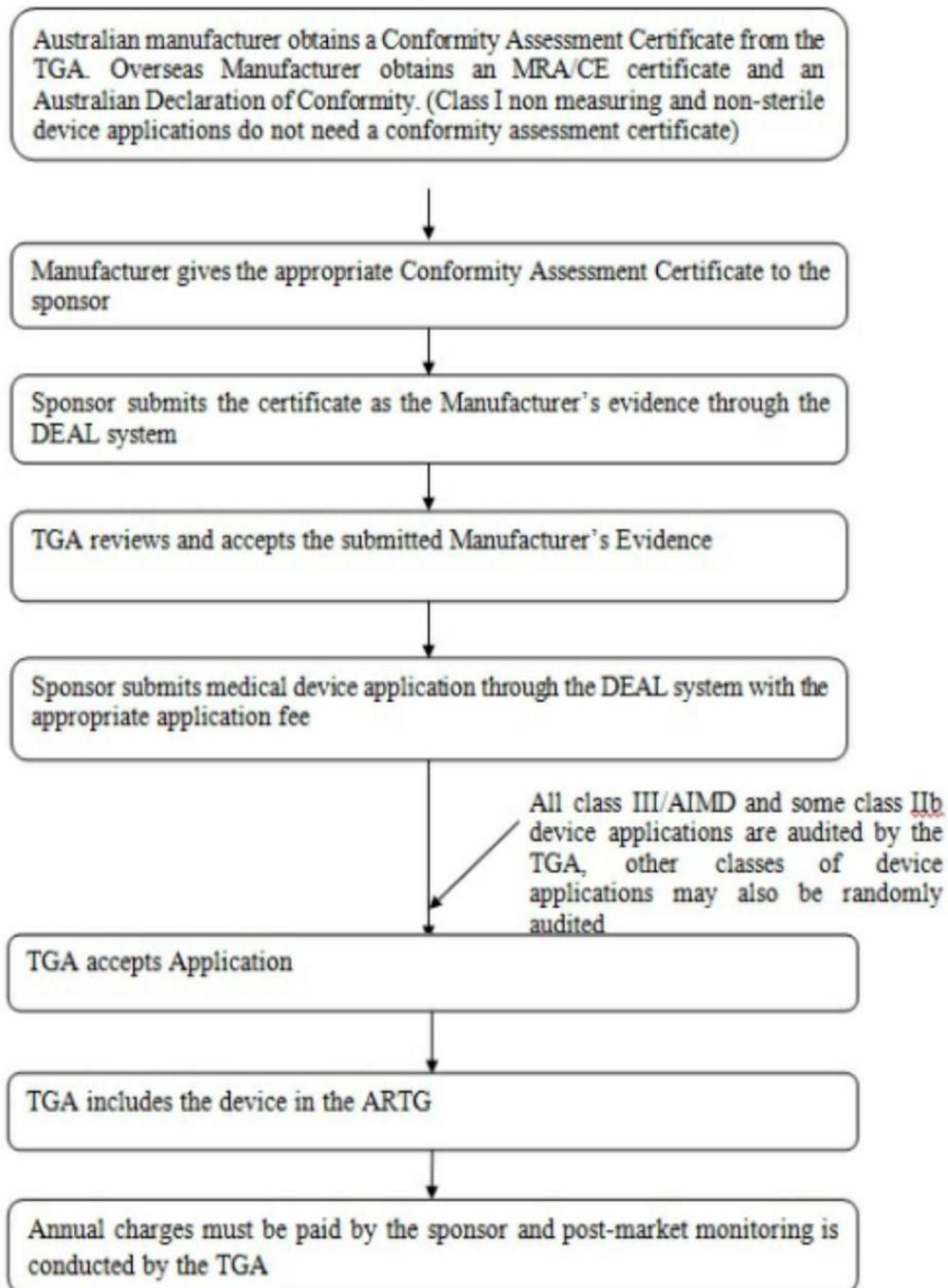


**Figure 6: Rules for active medical devices**

### Registration of medical device as per Australia

The sponsor is responsible for registering the medical device in the database Australian Register of therapeutic Goods (ARTG). Before registering the medical devices in the ARTG, the medical device must be classified according to the Australian system and suitable quality management systems (QMS) must be applied and risk analysis has been done for complying with the Essential principles.<sup>2</sup> Sponsor may use the Devices Electronic Application Lodgment system (DEAL system) for the applications. Sponsors are responsible for all activities concerning medical devices while manufacturers have obligations to fulfill the requirements. After registration medical devices have Global Medical Device Nomenclature (GMDN) codes<sup>2</sup>. A quality management system (QMS) is required for medical devices class IIa, IIb, III and AIMDs to get a conformity assessment certificate approved.<sup>2</sup> Australia has its own standard orders but the international ISO standards can be used. According to the Australian Essential principles which ensure the safety of the medical devices, manufacturer is required to have made a documented risk analysis of the product.<sup>3</sup> For class I medical devices conformity assessment certificate is not required and for Class III devices

and AIMDs conformity assessment certificate is required and manufacturer shall submit a Design Dossier. The registration of medical device is valid for five years. <sup>2</sup>



**Figure 7: Registration procedure of Australia**



**Figure 8: Registration procedure for India**

**Documents required:** <sup>2</sup>

- Manufacturer's details including name and address
- Client reference and details
- Conformity assessment certification including the certificates details and if there are any restrictions on the scope
- Class of the device
- Conformity assessment procedure
- Conformity assessment body
- GMDN code - The Global Medical Device Nomenclature (GMDN) code is a collection of terms, each with a unique code number, to describe and catalogue medical devices.
- Australian declaration of certificate

**Fees**

Application and annual fees for including a medical device on the ARTG (table 3). <sup>2</sup>

Conformity assessment fees for including a medical device on the ARTG (table 4). <sup>2</sup>

**Table 3: Application fees for Australia**

<b>Class</b>	<b>Application Fees (\$AUD)</b>	<b>Annual Fees (\$AUD)</b>
Class I	0	60.00
Class I (measuring)	730.00	480.00
Class I (sterile)	730.00	480.00
Class IIa	730.00	730.00
Class IIb	730.00	730.00
Class III	960.00	960.00
AIMD	960.00	960.00

**Table 4: Conformity Assessment fees for Australia**

<b>Conformity Assessment Procedure</b>	<b>Initial Assessment Changes (AUD\$)</b>	<b>Surveillance (AUD\$)</b>	<b>Audits (AUD\$)</b>
Schedule 3, Part 1- Full Quality Management System Audit	21,400.00	12,900.00	6,250.00
Schedule 3, clause 1.6 - Design Examination	42,400.00	25,500.00	-
Schedule 3, Part 2 - Type Examination (management of analysis, testing, and Reporting on examination)	29,500.00	17,800.00	-
Schedule 3, Part 3 – Verification (management of testing, reporting and analysis on verification tests)	20,700.00	-	-
Schedule 3, Part 4 - Production Quality Management System (QMS) Audit	18,800.00	11,300.00	6,250.00
Schedule 3, Part 5 - Product Quality Management System Audit	16,100.00	9,710.00	6,250.00

### **Vigilance system**

Main purpose of medical device vigilance system is to improving the health and safety of patients, users, and others by reducing the adverse events. This can be achieved by:

- Evaluation of reported adverse events
- Disseminating information (which are used to prevent or minimize the consequences of adverse events)
- By modifying the medical devices
- Removing the medical device from the market <sup>2</sup>

TGA takes actions on medical device supplied in Australia, such as:

- Adverse event reports
- Malfunctions of any devices
- Results of testing and any other information <sup>3</sup>

Manufacturer, sponsor and user may responsible for reporting adverse drug reaction of medical devices. Implantable medical device tracking system (IMDTS) is tracking system for ADR reporting. Manufacturer may report death and serious injury within 10 calendar days, non – adverse event or event not result in death or serious injury within 30 calendar days and any serious public health threats require prompt remedial action within in 48 hours (2 days).<sup>4</sup>

### Medical Device Regulatory system in India

In India medical devices are regulated by CDSCO (central drugs standard control organization).<sup>5</sup> The Central Drugs Standard Control Organization (CDSCO) is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act. CDSCO has six zonal offices, four sub-zonal offices, 11 port offices and six laboratories under its control.<sup>5</sup> In India medical devices are regulated by directorate general of health services, ministry of health and family welfare, government of India.<sup>6</sup> In India Drug Technical Advisory Board (DTAB) has recommended strict implementation of Indian Conformity Assessment Certificate (ICAC) for manufacturing, importing and marketing the medical devices on Indian market.<sup>6</sup> IMRDA (Indian Medical Device Regulatory Act) had been set up for their opinion and recommendation.<sup>6</sup> The import, manufacturing, distribution and sale of medical devices in India are overseen by drug and cosmetic act (1940) and rules (1945).<sup>6</sup> Inspections are carried out by CDSCO<sup>6</sup>.

### Definition

Medical device is an instrument, apparatus, implant, appliance, in vitro reagent or similar or related article, which is intended by manufacturer for use in diagnosis, cure, mitigation, prevention or treatment of disease or intended to affect the structure or any function of the body and which does not achieve its primary intended purposes through its chemical action within or on the body.<sup>5</sup>

### Classification of medical devices as per India

Medical devices may be classified in 4 categories (Table 5).<sup>6</sup>

**Table 5: Classification of Medical device as per India**

Classification	Risk level	Example
Class A	Low risk	Thermometers, Tongue Depressors
Class B	Low-Moderate risk	Hypodermic Needles , Suction Equipment
Class C	Moderate-High risk	Lung ventilator , Bone Fixation Plate
Class D	High risk	Heart valves, Pacemaker, Implantable Defibrillator

### Registration procedure of medical device as per India

Notified Medical Devices and New medical Devices require marketing Authorization from DCGI. Other medical devices such as Non-notified medical devices do not require manufacturing, sales,

import registration and can be freely placed on the market.<sup>5</sup> The registrations of medical devices are done according to Rule 24A of the Drugs and Cosmetic Act and Form 40 shall be filed. The applicant can be the manufacturer, the importer or the responsible agent in India.<sup>6</sup> Manufacturers of medical devices conduct suitable tests to prove the product quality. The quality systems shall concern design, development and manufacture.<sup>6</sup> Quality systems for medical devices do not exist, although CE-marked or FDA approved products are preferred because of their quality and performance. This kind of devices also requires risk management in form of ISO 14971<sup>6</sup>. Manufacturers of medical devices shall have documented procedures for distribution records, complaint handling, adverse incident reporting and product recall. A registration of a medical device defined as a drug is valid for five years.<sup>6</sup>

### **Documents required<sup>7</sup>**

- Covering Letter
- Authorization letter
- TR6 challan
- Power of Attorney
- Free Sale Certificate
- Manufacturer's detail
- Declaration of certificate
- Wholesale License

### **Fees**

The fees shall be paid through a TR6 challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch or branches of Bank of Baroda, from time to time, by the Central Government. Manufacturer shall pay direct payment of fees through electronic clearance system (ECS). A registration fees for the premises are \$US 1500 where the devices intended to be imported; A registration fees for a single medical devices are of \$US 1000 (which may include variation in sizes or shape without any change in the material or method of use), for each additional devices US\$1000 and for duplicate copy 300 \$US.<sup>7</sup>

### **Vigilance system**

Manufacturer may report adverse drug reaction of any of medical devices. There is a no tracking system for reporting of adverse drug reaction of medical device. Manufacturer may report death or serious injury or a serious public health threat within 10 days and other reportable event not later than 30 days.<sup>8</sup>

## Comparison of medical device regulation in Australia and India

Comparison of medical device regulation in Australia and India is as per table 6.

**Table 6: Comparison of medical device regulation in Australia and India**

Parameters	Australia	India
Regulatory Authority	Therapeutic Goods Administration (TGA)	<ul style="list-style-type: none"> <li>Central Drugs Standard Control Organization (CDSCO)</li> <li>CLAA is a main regulatory body for medical device</li> </ul>
Legislation and guideline follows	<ul style="list-style-type: none"> <li>Australian Regulatory Guideline for Medical Devices (ARGMD)</li> <li>TGA 1989 Act</li> <li>TGA Regulation 2002</li> </ul>	<ul style="list-style-type: none"> <li>By CDSCO</li> <li>Directorate General of Health of India (DCGI), Ministry of Health and Family Welfare Gov. of India</li> <li>IMRDA (Indian Medical Device Regulatory Act)</li> <li>Drug and Cosmetic Act (1940) and rules (1945)</li> </ul>
Classification	5 categories depends on level of risk: Class I - Low Risk Class IIa - Low to medium Risk Class IIb - Medium to high Risk Class III - High Risk Active Implantable Medical Devices (AIMD)	4 Categories depends on level of risk: Class A - Low Risk Class B - Low to medium Risk Class C - Medium to high Risk Class D - High Risk
Rules	Total 22 rules	Not specified
Essential Principles	Compulsory	Not applicable
Applicant	Manufacture./Australian based sponsor/Agent on behalf of Manufacturer and sponsor	Manufacturer/Authorized representative
Application in form of	Technical file	Technical file
Indicative mark required	<ul style="list-style-type: none"> <li>ARTG number</li> <li>CE mark – TGA refers CE mark as EC- European community certificate</li> </ul>	<ul style="list-style-type: none"> <li>ICAC marking – Indian Conformity Assessment Certificate</li> <li>CE mark and FDA approval is required</li> </ul>
Registration steps	<p>Step1-Manufacturer obtain conformity assessment certificate from TGA and gives to the sponsor.</p> <p>Step 2– Sponsor submits the application in to DEAL system with appropriate charges.</p> <p>Step 3- TGA review and accepts the application</p> <p>Step 4– TGA includes the device in ARTG.</p>	<p>Step1- Appoint Authorized agent.</p> <p>Step 2- Submit application with appropriate fees (in TR6 challan)</p> <p>Step 3- Compilation of registration dossier as per regulatory guideline</p> <p>Step 4- Submit product registration application at CDSCO Delhi Headquarter</p>

Registration done for	Five years	Three years
Fees	Application fees	Fees paid through TR6 (Treasury) challan or through electronic clearance system (ECS)
	Class I measuring – 0 AUD\$ Class I sterile - 730.00 AUD\$	Registration fees – 1500 US\$ For registration of single product – 1000 US\$
	Class IIa- 730.00 AUD\$ Class IIb- 730.00 AUD\$ Class III- 960.00 AUD\$ AIMD- 960.00 AUD\$	For additional products - 1000 US\$ For duplicate copy – 300 US\$
Conformity Assessment	<ul style="list-style-type: none"> <li>• Compulsory Prepared by authorized notified body and manufacturer and sponsor</li> </ul>	For class A – performed by manufacturer For other class by authorized notified body

## CONCLUSION

The Australian Medical device regulation is pre-established as compared with Indian regulation. Both the countries follow the regulation of medical device as per Global Harmonization task force guidelines. But both the countries have its own guidelines for the registration process, classification rules and conformity assessment procedure. Time duration limit for review of medical device registration fixed in Australia divergence to India regulation. Medical device registered for five year as per Australian regulation whereas in India only for three year. Australian application fees for registration seen costly as compared to Indian application fees. By comparing the regulatory requirements of both the countries, it has been seen that they have specific advantages on own specification of regulations.

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