

Regulatory Requirements for Medical Devices and IVDs in India

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Lecture – L1


Medical Device and IVD: Introduction

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Welcome to Regulatory Requirement for Medical Devices and In Vitro Diagnostics in India. Lecture 1 that is Medical Devices and In Vitro Diagnostic Introduction what we will learn in this lecture? We will learn what is the medical devices? What is an in vitro diagnostics? Which law regulates medical devices and in vitro diagnostics, difference between drugs and devices notified and non-notified medical devices, which in vitro diagnostic kits are regulated? Whether all medical devices are regulated? All these topic we will cover in this lectures. Now, come to the first topic. What is medical devices? Is it regulated?

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WHAT IS MEDICAL DEVICE?

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Anything used for therapeutic and/or diagnostic purpose in humans, which is not a drug (means that is not dependent upon being metabolised for the achievement of any of its primary intended purposes). The intended primary mode of action of a medical device on the human body, in contrast with that of medicinal products, is not metabolic, immunological, or pharmacological.

The term 'medical devices' includes everything from highly sophisticated computerised medical equipment (MRI machine) down to simple tongue depressors.

Other examples of medical devices include:
Orthopedic implants, pacemaker, cochlear implants, catheters, blood glucose meter, pregnancy test kits, perfusion sets, sutures etc.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

In general term medical devices means anything used for therapeutic and or diagnostic purpose in humans, which is not a drugs that we can say that is the medical devices. It means that it is not dependent upon being metabolised for the achievement of any of its primary intended purpose. The intended primary mode of action of the medical devices on human body, in contrast with that of medical products is not a metabolic, immunological or pharmacological. It means the medical device does not have any pharmacological, immunological or metabolic action to the human body.

The term medical device includes everything from highly sophisticated computerized medical equipment like MRI machine down to simple tongue depressors. The other examples of medical devices includes orthopedic implants, pacemakers, IV cannulae, internal prosthetic replacements, surgical dressings, mechanical contraceptives, needles, perfusion sets etcetera. So, what is the definition of the medical devices? If we will compare the medical device definition with the other regulatory authorities definitions you will see there is a differences in the definitions of the medical device.

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DEFINITION BY WORLD HEALTH ORGANISATION

■ 'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- Investigation, replacement, modification, or support of the anatomy or of a
- Physiological process, supporting or sustaining life
- Control of conception
- Disinfection of medical devices
- Providing information by means of *in vitro* examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

But the main content of the definition will be the same. Just have you look on the definition of the medical devices as per the WHO. WHO defines medical devices means any instrument, operators, implement, machine, appliances, implant, reagents, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used alone or in combination for human being, for one or more of the specific medical purpose of. What are those medical purposes?

For diagnosis, prevention, monitoring, treatment or alleviation of disease. Diagnosis, monitoring, treatment, alleviation or compensation for an injury. Investigation, replacement, modification or support of an anatomy or a physiological process, supporting or sustaining life or control of conception or disinfection of medical devices. Providing information by means of *in vitro* examination of specimen derived from human body and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may assist in its intended function by such means. This is the WHO definition and universally the medical device definition is same as we have seen here.

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WHY WE NEED NEW REGULATIONS?

In India, medical devices are regulated as 'drugs'. This sector is very small by size as compared to the rest of manufacturing industry.

Medical device imports supply around 77% of the market. The Indian market is growing at CAGR of 15%, making India one of the fastest growing markets in the world. Strong drivers for this robust growth of medical technology industry exist in India.

However, the lack of regulatory systems, harmonised standards, accreditation, legal requirements, proper guidance on quality and best practices are affecting the medical device industry adversely.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, why need for new regulation for medical devices? In India, medical devices are regulated as a drug. This sector is very small by size as compared to other manufacturing industry. The medical device imports supply around 77 percent of the market. So, this market is dependent on the import we do not have the indigenous; much indigenous facility to cater the need of the population of the India. The Indian market is growing at CAGR of 15 percent, making India one of the fastest growing market in the world. So, strong drivers for this robust growth of the medical technology industry exist in India.

However, the lack of the regulatory system, harmonised standards, accreditation, legal requirement, proper guidance on quality and best practices etcetera are affecting the medical device industry adversely. The regulatory framework for pharmaceuticals and devices differ substantially. We understand that the regulatory authority in the different region of the world recognize different class of the devices, based on their design complexity, their use characteristic, their potential for harm if misused.

However, in India this medical device is regulated under the provision of Drugs and Cosmetic Act, in 1942. Under this act an Drugs and Cosmetic rule 1945, there were no specific requirement for import, manufacture, clinical investigation of the medical devices and in vitro diagnostics.

This concern where raised in various forum by the sector and finally, the Government of India has come up with the new medical device rules to harmonise regulatory

requirement at par with the globally accepted regulator requirement. Under this medical device rule 2017 this specific provision for import, a specific provision for manufacture, a specific provision for clinical investigation, a specific provision for labeling of the medical devices, risk base classification all those provision has been made.

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The slide features the CDSA logo in the top right corner. The title 'WHAT IS A MEDICAL DEVICE' is centered at the top. Below the title is a dark blue box containing the text 'Medical devices are:'. Underneath this box is a light grey box containing a list of five points describing medical devices. At the bottom of the slide is a dark blue footer bar with the text 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA'.

WHAT IS A MEDICAL DEVICE

Medical devices are:


- Specialised product – need different regulatory environment then drugs due to their inherent and characteristic differences
- Complex and can be very individualistic. It can have **batch of one device**
- Criticality is risk based – can not equate Implantable devices with syringes or hospital beds
- The medical devices are critical care products, it needs to be regulated
- Looking for specific and independent identity from drugs

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

So, what is required for the medical devices, what regulation is required for the medical devices? Medical devices are a specialized product; we understand that it need different environment, regulatory environment then the drug due to their inherent and characteristic differences. Medical devices are complex and can be vary individualistic. It can have batch of one batch only one device of one batch.

However, in the drugs it is not so. Criticality of the medical devices is risk based you cannot equate high risk medical devices like implantable devices with the low risk medical devices, like syringes or hospital beds. But the medical devices are critical care products and it needs to be regulated properly. And therefore, this sector is looking for this specific and independent identity from the drugs.

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MEDICAL DEVICE REGULATORY FRAMEWORK

PARAMETER	DRUG	MEDICAL DEVICE
Use	<i>in vivo</i> use	<i>in vivo</i> and/or <i>ex vivo</i> use
Active components	Based on chemistry & pharmacology	Generally based on mechanical, electrical, and materials engineering.
Diagnostic or therapeutic intended uses	Therapeutic intended uses	Diagnostic or therapeutic intended uses
Quality depends on	Safety and efficacy	Safety and performance
Trials	Clinical trials	Clinical evaluation
Manufacturing requirement	GMP (Good Manufacturing Practice)	QMS (Quality Management System)
Animal toxicity	Local and systemic toxicity	Biocompatibility
Adverse events due to	Drug interactions	Device malfunction

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, the drugs and medical devices regulatory system, differs because of the because of their inherent and characteristic differences. And some of the example for this differences, we will discuss here. If you see the drug, in the drug generally drugs are used *in vivo*; however, the medical devices may be used *in vivo* or *in vitro* also.

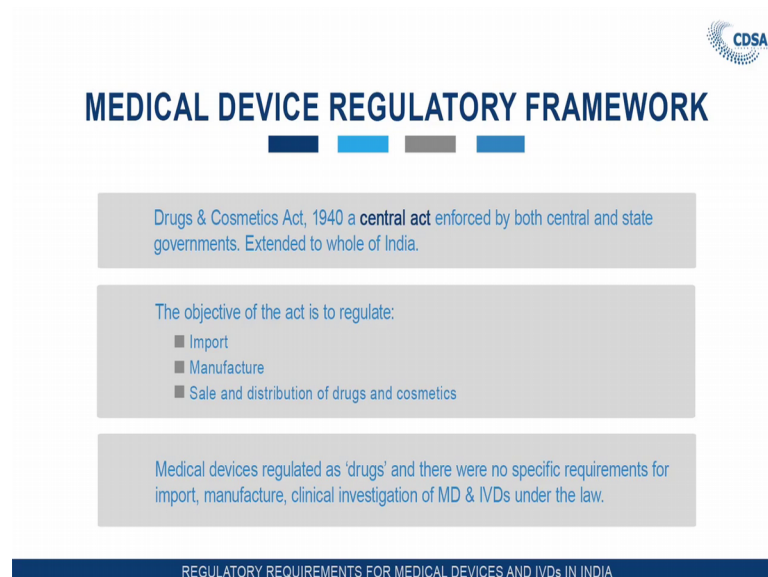
The active component of the drugs is based on the chemistry and pharmacology. However, the medical devices it is generally based on the mechanical, electrical and material engineers. Drugs are intended for therapeutic use; however, the medical devices or therapeutic as well as diagnostic use. The safety and efficacy of the drugs depends on the quality the quality depends on these two parameters safety and efficacy. However, for medical devices it depends on the safety and performance of the devices.

For drugs, clinical trials are applicable to establish the safety and efficacy, and for medical devices clinical investigation where pilot or study pivotal studies require to be carried out to for the establishment of safety and performance of the medical devices.

In the drug for manufacturing of the drugs, the requirement of good manufacturing practices is applicable. However, for medical devices the requirement of quality management system is applicable as regard to the safety of the medical devices; biocompatibility test is applicable for the medical devices; however, for the drugs it is local and systematic toxicity.

In the drugs the adverse events are due to drug interactions; however, for medical devices it is due to the device malfunctions. So, these are the basic difference of the drugs and devices therefore, this sector require separate entity and separate regulation for the devices, other than the medical; other than the drugs.

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What is the medical device regulation in India? Presently the medical devices are regulated as a drug under the provisions of Drugs and Cosmetic Act 1940. This Act is just intellect enforced by both central as well as state the control department, the state governments and this act is extended to whole of the India. What is the objective of this Drug and Cosmetic Act? The objective of this act is to regulate import, manufacture, sale and distribution of drugs and cosmetics. And medical devices as already told you it is regulated as a drug therefore; under the definition of drug that medical device is regulated. And there were no specific requirement for the import, manufacture, clinical investigation of medical devices and in vitro diagnostic kits under the Drugs and Cosmetic Act and rules there under.

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MEDICAL DEVICE REGULATORY FRAMEWORK

In order to have specific requirements for medical devices, medical device rules, 2017 have been published. These rules are framed under the existing Drugs and Cosmetics Act, 1940.

The requirements for import, manufacture, clinical investigation, sale and distribution of regulated medical devices have been prescribed in medical device rules, 2017. These rules have been implemented from January 1, 2018.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Therefore, in order to have the specific requirement for medical devices, the medical device rule, 2017 have been published. And these rules are frame under the existing Drugs and Cosmetic Act, 1940. The specific requirement for import, manufacture, clinical investigation, sale and distribution of the regulated medical devices has been prescribed in the medical device rule, 2017. And these rules have been implemented from 1st January 2018.

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DEFINITION

Medical devices are regulated as drugs under the definition of 'Drug' as per Drugs and Cosmetics Act, 1940

Section 3(b) 'drug' includes:

- All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.
- Substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animals, as may be notified from time to time by the Central Government by notification in the Official Gazette.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

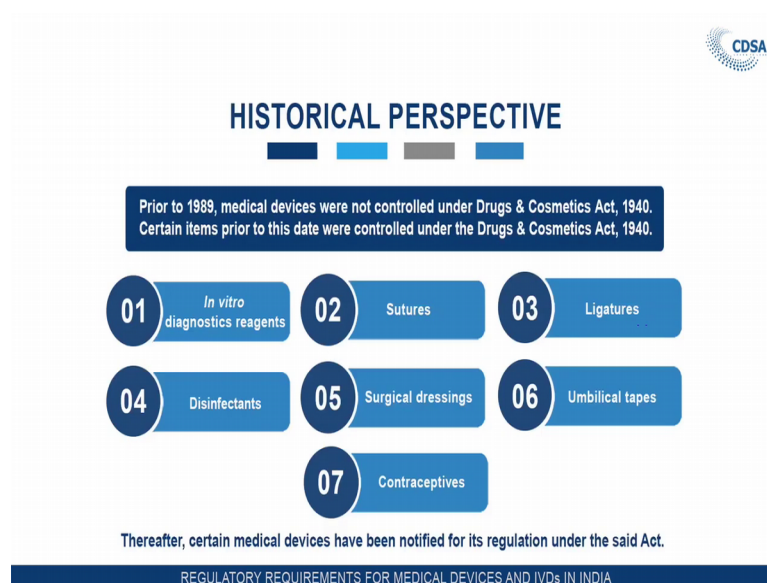
So, under this Drugs and Cosmetic Act; the medical devices are regulated as a drug. So, definition of the drugs covers the medical devices. The section 3 b of the Drugs and Cosmetic Act define the definition of the drugs.

So, under the section the medical devices which are regulated we can go through the definition of the drugs under section 3 b. The section 3 b i of the Act which states that all substances intended to be used for or in diagnosis, treatment, mitigation or prevention of any disease or disorder in human being or animals. This section 3 b i where all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human being or animals, that substances covered under this section. Section 3 b ii of the definition which states that such substances intended to affect the structure of any function of human body, as may be notified from time to time by the central government by notification of the official gazette notification.

Under the section certain medical devices are regulated. The devices which are regulated under these sections are mechanical contraceptives, disinfectant and under section 3 b i the devices which are regulated or all the diagnostic kits, in vitro diagnostic kits, all the surgical dressings, sutures, blood bag, with or without anticoagulant solution. These are the medical devices which are regulated under section 3 b i of the drug definition.

Now, the section 3 b iv of the definition states that, such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in the human being or animal as may be notified from time to time by the central government by notification in the official gazette doctor consultation with the board. Under this section, certain medical devices has been notified by the Ministry of Health and Family Welfare Government of India. And that notified medical devices have come under the sections and regulated under the provision of Drugs and Cosmetic Act, and rules there under. So, under section 3 b of the drugs the devices which covered under these definitions are regulated as on date.

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Now, historical perspective of the medical devices if you see, prior to 1989 the medical devices were not controlled under the Drugs and Cosmetics Act, 1940. However, the certain items prior to this date were controlled under the Drugs and Cosmetic Act, 1940. These are the in vitro diagnostic reagents, all type of in vitro diagnostic kits reagents are regulated prior to this. All the sutures, ligatures, disinfectant, surgical dressings, umbilical tapes and contraceptives, these medical devices are regulated as a drug prior to 1989 under the provision of Drugs and Cosmetic Act 1940. Thereafter, certain medical devices have been notified for its regulation under the provision of the said Act.

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**LIST OF MEDICAL DEVICES NOTIFIED BY
MINISTRY OF HEALTH & FAMILY WELFARE (MOH&FW),
GOVERNMENT OF INDIA**

S. No.	Name of the device	Date of notification
1	Disposable hypodermic syringes	17-03-1989
2	Disposable hypodermic needles	17-03-1989
3	Disposable perfusion sets	17-03-1989
4	In vitro diagnostics for HIV, HbsAg, HCV and blood grouping sera	27-08-2002
5	Cardiac stents	06-10-2005
6	Drug eluting stents	06-10-2005
7	Catheters	06-10-2005
8	Intra ocular lenses	06-10-2005

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, in the year 1989 the Ministry of Health as notified three medical devices under section 3 b iv and those devices are disposable hypodermic syringes, disposable hypodermic needles, disposable perfusion sets. These three medical devices were notified in the year 1989 and regulated since then. Thereafter, in the year 2002 the IVD for HIV, HbsAg, HCV and blood grouping sera, these four in vitro diagnostics have been notified and regulated as a notified in vitro diagnostic kits.

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**LIST OF MEDICAL DEVICES NOTIFIED BY
MINISTRY OF HEALTH & FAMILY WELFARE (MOH&FW),
GOVERNMENT OF INDIA**

S. No.	Name of the device	Date of notification
9	I.V. cannulae	06-10-2005
10	Bone cements	06-10-2005
11	Heart valves	06-10-2005
12	Scalp vein set	06-10-2005
13	Orthopaedic implants	06-10-2005
14	Internal prosthetic replacements	06-10-2005
15	Ablation devices	25-01-2016


REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

In 2005 the Ministry of Health and Family Welfare has notified 10 more additional medical devices under section 3 b iv. And these medical devices are cardiac stents, regulating stents, catheters, intraocular lenses, I.V. cannulae, bone cement, heart valves, scalp vein set, orthopedic implant, internal prosthetic replacement.

So, these 10 new medical devices were notified in the year 2005 and in 2006, one more medical devices that is ablation medical devices have been notified by the Ministry of Health and Family Welfare for its regulations. So, as on date total 15 category of the medical devices have been notified under the provisions of Drugs and Cosmetic Act, and these 15 devices are presently under regulations.

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**LIST OF MEDICAL DEVICES NOTIFIED BY MINISTRY OF
HEALTH & FAMILY WELFARE (MOH&FW), GOVERNMENT OF INDIA
WHICH WILL BE EFFECTIVE FROM THE YEAR 2020**



S. No.	Name of the device	Date of notification
1*	Nebulizer	03-12-2018
2*	Blood pressure monitoring devices	03-12-2018
3*	Digital thermometer	03-12-2018
4*	Glucometer	03-12-2018
5**	All implantable medical devices	08.02.2019
6**	CT scan equipments	08.02.2019

* The effective date of implementation is 01.01.2020
* The effective date of implementation is 01.04.2020


REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Recently the Ministry of Health and Family Welfare also notified four additional medical devices in the month of December, and these medical devices are nebulizer's, blood pressure monitoring devices, digital thermometers and glucometers.

The implementation for regulation of these 4 new medical devices will be from January 2020. So, 12 month time has been given for implementation of this new category of the medical devices and further the Ministry of Health and Family Welfare has notified it more devices on 8th February 2009, for which the implementation date will be 1st April 2020. And this eight new category of the medical devices are all implantable medical devices, CT scan equipments, MRI equipments, defibrillators, dialysis machine, PET equipments, X-ray machine, bone marrow cell separators. So, these eight new medical devices have again notified by the Ministry of Health and Family Welfare.

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**LIST OF MEDICAL DEVICES NOTIFIED BY MINISTRY OF
HEALTH & FAMILY WELFARE (MOH&FW), GOVERNMENT OF INDIA
WHICH WILL BE EFFECTIVE FROM THE YEAR 2020**



S. No.	Name of the device	Date of notification
7**	MRI equipment	08.02.2019
8**	Defibrillators	08.02.2019
9**	Dialysis machine	08.02.2019
10**	PET equipments	08.02.2019
11**	X- Ray machine	08.02.2019
12**	CT Scan Equipments	08.02.2019

* The effective date of implementation is 01.01.2020
* The effective date of implementation is 01.04.2020


REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The Ministry of Health and Family Welfare is also working for notification of more medical devices to come under the regulations, and from time to time through gazette notification the same is being published for regulations. The new category of the medical devices which have been notified on 8th February 2019, that is all implantable medical devices. Here the earlier devices which have already been notified by the Ministry of Health and Family Welfare and those are the implantable devices.

Already that implantable devices are regulated, but whatever the implantable devices which is not yet notified by the Ministry of Health and Family Welfare all will come under this category and that regulation will be effective from April 2020.

So, this is all about the notified medical devices. So, far total 27 category of the medical devices have been notified by the Ministry of Health and Family Welfare. Out of 27, 12 categories of the medical devices, the effective date will be January 2020 onwards; however, the remaining 15 medical devices are under regulation.

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WHO USES MEDICAL DEVICE?

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Medical devices are used by everyone, sometimes or other in his/her lifetime. The use can be temporary, permanent, used by a professional, used by a person without supervision.

Temporary use	Cervical collar, Walking stick during injury	Permanent use	Cardiac stent, Orthopedic implants
Professional use	Blood assay monitor	Unsupervised use	Walking sticks

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, who uses the medical devices? The medical devices are used by everyone in their day to day life. The use can be temporary, permanent, used by the professional or used by the person without supervision. The example of these medical devices are temporary use devices walking stick during the injury, cervical collar. Permanent used devices that is cardiac stent, device like orthopedic implants, professional use devices blood assay monitor, unsupervised use of medical devices that walking sticks. So, these are the some examples of the devices which is used temporary, permanent or unsupervised use.


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WHAT IS A MEDICAL DEVICE?

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**As per Drugs & Cosmetics Act, 1940,
medical devices are:**




1. Substances used for *in vitro* diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i) of Section 3 of the Drugs and Cosmetics Act, 1940.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, we have already understand which medical devices are presently under regulation. So, we will again review the regulation of the medical devices in the line of the section 3 b of the medical devices. The section 3 b of the definition of the drugs, the substances used for in vitro diagnosis; in vitro diagnostics surgical dressings, surgical blades, surgical staplers, surgical sutures, ligatures, blood and blood collection bag with or without anticoagulant solution. These are the medical devices which have been covered under section 3 b i of the definition of the drugs.


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WHAT IS A MEDICAL DEVICE?

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**As per Drugs & Cosmetics Act, 1940,
medical devices are:**




2. Substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants notified under sub-clause (ii) of Section 3 of the Drugs and Cosmetics Act, 1940.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The other type of medical devices that is mechanical contraceptives like condoms, intrauterine devices, tubal rings and disinfectant solution, these devices are covered under the section 3 b ii of the definition of the drugs and regulated we have already discussed this in the previous slides.

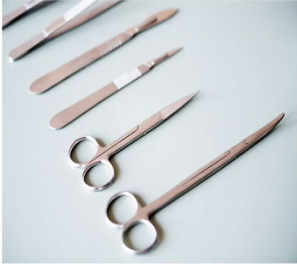
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WHAT IS A MEDICAL DEVICE?

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**As per Drugs & Cosmetics Act, 1940,
medical devices are:**




3. Devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification after consultation with the board under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, certain notified medical devices that is I.V. cannulae, scalp vein set, heart valve, ablation devices, cardiac stent, bone cements, scalp vein sets, perfusion sets, surgical needles all these medical devices has been notified and regulated under section 3 b iv of the Drugs and Cosmetic Act.

So, these are the devices which are presently regulated under the provisions of Drugs and Cosmetic Act and rules there under. Again there is a constantly this rules does not cover regulation of all type of the medical devices. Because in the Drugs and Cosmetic Act, there is a no separate provision for definition of the medical devices has been incorporated so far.

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HOW DO MEDICAL DEVICES VARY?

Medical devices vary according to their intended use and indications

Examples:

- **Simple devices** such as tongue depressors, medical thermometers, and disposable gloves
- **Advanced devices** such as MRI equipment which assist in the conduct of diagnosis
- The design of medical devices constitutes a major segment of the field of mechanical engineering and plastics technology

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, how do medical device vary? The medical device vary according to their intended use and indications example, so simple devices such as tongue depressors, thermometers, medical thermometers and disposable gloves. These are simple devices and used differently as per the intended use of the medical devices. Some advanced medical devices such as MRI equipments which assist in the conduct of the diagnosis of the disease. The design of the medical device constitute a major segment of the field of mechanical engineering and plastic technology.

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MEDICAL DEVICE: CURRENT SCENARIO

In India, currently only notified medical devices are regulated as 'Drugs' under the Drugs and Cosmetics Act 1940 and Rules made thereunder.

Ministry of Health and Family Welfare on January 31, 2017 issued Gazette Notification GSR 78(E) under Drugs & Cosmetics Act 1940 and Rules 1945 as 'medical devices rules 2017', which came into force from January 1, 2018.




REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

So in India, only notified medical devices are presently regulated as a drug under the provisions of Drugs and Cosmetic Act. We understand that also the Ministry of Health and Family Welfare has published medical device rules 2017 through the Gazette Notification GSR number 78 E under the Drugs and Cosmetics Act which come into force from the January 2018.

This legislation the Ministry of Health and Family Welfare Government of India have introduced to harmonise our regulatory requirement of the medical devices at par with the globally accepted regulation. And to harmonise the regulation at par with the globally standards and also to boost the medical device sector, that will make India more lucrative for the medical device development to encourage national and multinational companies to manufacture their product in India.

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MEDICAL DEVICES AND IN VITRO DIAGNOSTIC KITS

- Under medical device rules, 2017, the medical device and IVDs have been classified based on their risk and a list of medical devices and *in vitro* diagnostic kits had been published subjected to the following information:
 - ▶ General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of medical devices rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
- In this list, a medical device may be generally recognised for a particular use, however a manufacturer may modify the use of the device for a related use which is not mentioned in the classification list. In such cases, additional data may have to be supplied for such uses to the Central Licensing Authority for approval and its inclusion in the list.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

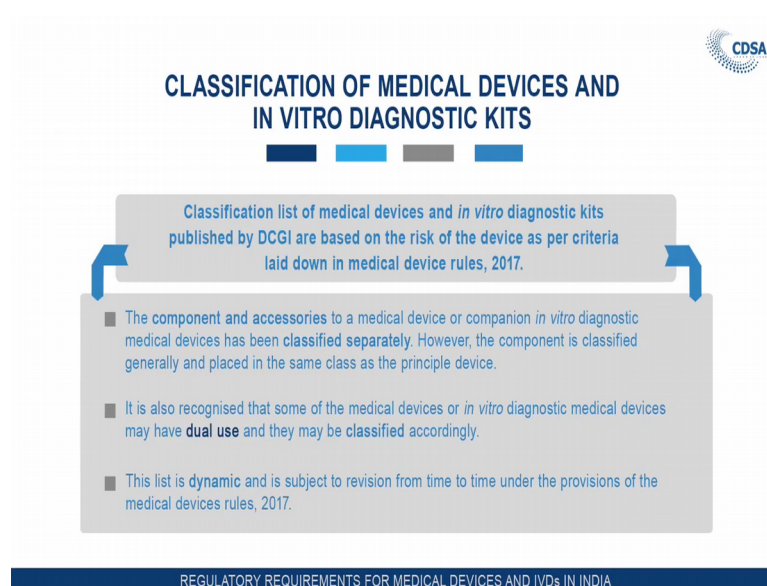
So, this initiative that Ministry of Health and Family Welfare has been has taken till we have the comprehensive regulation on the medical device in the country. Under this medical device rule 2017, the medical devices and in vitro diagnostics have been classified based on the risk as mentioned in the first schedule of the medical device rule 2017.

This list of the medical devices and in vitro diagnostic kits had been published on the website of the central drugs standard control organization that is the Central Licensing Authority. Under this classification list general intended use given against each of the

devices that is for the guidance of the applicant intend to furnish the application for import, manufacture of medical devices and in vitro diagnostics.

However, the devices may specific intended use as a specified by the manufacturers. In case, the medical devices may be generally recognized for a particular use, a manufacturer may modified the use of the devices for that related use. And in such cases, additional data may have to be supplied to the Central Licensing Authority for such uses so, that the Central Licensing Authority based on the evidence. They will approve the same and they will include in the classification list of medical devices and in vitro diagnostic kits.

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So, the classification list of the medical devices and in vitro diagnostic published by the Central Licensing Authority is based on the risk of the devices and the component as well as accessory of the medical devices or companion in the in vitro diagnostic medical devices has been classified separately.

However, the component is classified generally and placed in the same class as the principle devices. It is also recognized that some of the medical devices or in vitro diagnostic medical devices may have the dual use and they may be classified accordingly. This list is dynamic and subject to the revision and the Central Licensing Authority from time to time that list is being revised. So, based on the classification list the applicant has to submit their application to the Central Licensing Authority, and

based on the risk of the class of the medical devices, the specific technical requirement, specific piece have been given in the medical device rule 2017.

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DEFINITION

Medical devices are regulated as drugs under the definition of 'Drug' as per Drugs and Cosmetics Act, 1940


Section 3(b) 'drug' includes:

- All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.
- Substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animals, as may be notified from time to time by the Central Government by notification in the Official Gazette.


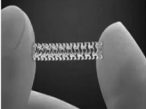
REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, we have understand what are the devices regulated under the Drugs and Cosmetic Act, 1940. So, we will have some exercise on those medical devices. You can see this medical devices and identify whether this medical devices is regulated or not regulated.

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WHICH OF THESE ARE MEDICAL DEVICES?

A	B	C	D
			
✓ Disposable hypodermic needles	✓ Disposable hypodermic syringe	✓ Cardiac stent	✓ Drug eluting stent

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

What is this medical devices? This is hypodermic disposable needles, this device is notified devices and regulated under Drugs and Cosmetic Act, 1940. This device what is

this device? This device is hypodermic syringes, it is a notified devices and also regulated. Now this is implantable devices, what is the devices? It is a cardiac stent, which is also notified and this device is regulated presently. This is another implantable devices, this devices name as drug eluting devices it is also regulated it is notified devices. So, by this exercise at least we understand [FL] which devices are notified and regulated under the provisions of Drugs and Cosmetics Act and rules there under.

Now, come to the in vitro diagnostics. What is an in vitro diagnostics? In the general definition of the medical devices we understand then vitro diagnostics is also covered under the definition of the medical devices.

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WHAT IS AN IN VITRO DIAGNOSTIC (IVD) PRODUCT?

IVDs are considered as 'Drugs'

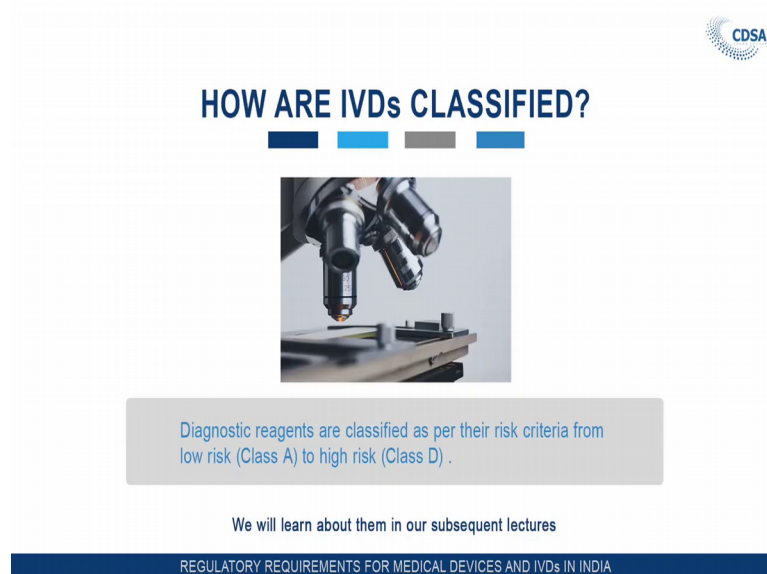
IVDs are substances that are intended to be used in diagnosis of disease or disorders in human being or animals.

Defined under sub-clause (i) of clause (b) of Section 3 of Drugs and Cosmetics Act 1940.


REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

However, as per the Drugs and Cosmetic Act, this in vitro diagnostics are considered as a drugs, they are the substance that are intended to be used in the diagnosis of disease or disorder in human being or animals. So, in vitro diagnostic kits as per Drugs and Cosmetic Act is a drugs and defined under the section 3 b i of the drug definition.

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HOW ARE IVDs CLASSIFIED?



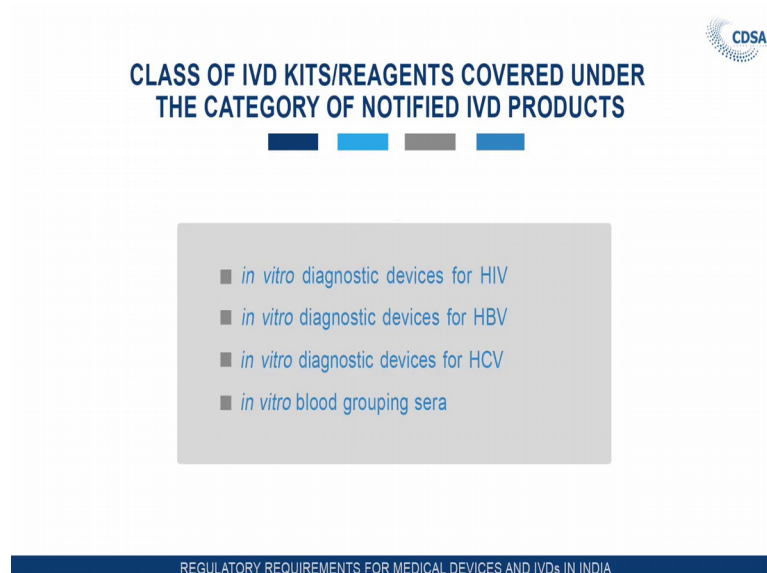
Diagnostic reagents are classified as per their risk criteria from low risk (Class A) to high risk (Class D) .

We will learn about them in our subsequent lectures

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

What are the classification for the in vitro diagnostic kits? The in vitro diagnostic kits are classified by the Central Licensing Authority as per the risk criteria from low risk to high risk that is class A to class D devices. We will discuss this classification in the subsequent lectures.

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CLASS OF IVD KITS/REAGENTS COVERED UNDER THE CATEGORY OF NOTIFIED IVD PRODUCTS

- *in vitro* diagnostic devices for HIV
- *in vitro* diagnostic devices for HBV
- *in vitro* diagnostic devices for HCV
- *in vitro* blood grouping sera

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, what is the notified in vitro diagnostic products during the previous lectures we have discussed which in vitro diagnostic kits has been notified by the Central Government. So, the devices which have been notified under section 3 b I, 3 b iv of the

Drugs and Cosmetic Act are considered as a notified in vitro diagnostic devices or products. And these notified in vitro diagnostic kits are in vitro diagnostic devices for HIV, in vitro diagnostic devices for HBV, in vitro diagnostic devices for HCV, in vitro blood grouping sera. So, these are the 4 in vitro diagnostic devices which have been notified under the section 3 b iv and considered as a notified in vitro diagnostic products.

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CLASS OF IVD KITS/REAGENTS COVERED UNDER THE CATEGORY OF NON-NOTIFIED IVD PRODUCTS

All excluding those listed under notified category are covered under the category of non-notified IVD products.

In vitro diagnostic reagents for all tests are covered. However, instruments required for estimation are not presently covered.
Some examples are blood glucose test strips, pregnancy test kits, receptacles for blood etc.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

What is the non-notified in vitro diagnostic products? As we understand [FL] only notified, four notified in vitro diagnostic kits are notified; however, all the in vitro diagnostic kits which covered under the section 3 b i of the drug definitions are regulated under the provisions of Drugs and Cosmetic Act and rules there under. So, the devices the in vitro diagnostic devices which have not been notified under section 3 b iv those in vitro diagnostic devices are considered as a non-notified in vitro diagnostic products. What are those non notified in vitro diagnostic products? Except the four notified medical devices all in vitro diagnostics are considered as a non-notified in vitro diagnostic products.

The in vitro diagnostic reagents for all test are covered. However, the instrument required for estimation are not presently covered. Example, blood glucose test strips, pregnancy test kits, receptable for the bloods. These in vitro diagnostic reagents kits they are covered; however, the equipment which is used with this in vitro diagnostic reagent kits

have not been regulated, the blood glucose test strip that is regulated as a non-notified in vitro diagnostic devices.

However, the gluco-meter which is the instrument to be used with the blood glucose test strip is not regulated as on date for under the provision of Drugs and Cosmetic Act and rules there under. However, as we also understand in the new notification this gluco-meter have been already notified and the effective date for regulation of this glucometer will be from January 2020. So, these are some example of the non-notified in vitro diagnostic products.

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Can you name these in vitro diagnostic kits? This one is a in vitro diagnostics, yeah it is a blood grouping reagent that is notified in vitro diagnostic kits. This product is a ointment, it is not a in vitro diagnostic product. So, it is not consider as a IVDs this is a ointment, this one is a HIV, diagnostic kits, reagent kits this is regulated, this notified in vitro diagnostic kits.

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SUMMARY

In lecture L1 we briefly learnt about:

- Medical device is any instrument, apparatus, appliance, software, material, or other article whether used alone or in combination, including the software to be used for diagnostic and/or therapeutic purposes in human.
- IVDs are substances that are intended for the use in diagnosis of disease or disorders in human being or animals.
- Not all devices are presently regulated under the law.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

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SUMMARY

In lecture L1 we briefly learnt about:

- Only notified medical devices and all IVDs are regulated under the law.
- New 'medical devices rules, 2017' has been introduced (w.e.f. January 1, 2018) (G.S.R. 78 (E) dated the January 31, 2017) to have specific requirements for import, manufacture, sale and distribution of medical devices and *in vitro* diagnostics in the country.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

So, now we have the basic idea about the medical device regulation what are the medical devices which are regulated under the provisions of Drugs and Cosmetic Act, what are the devices category as non notified in vitro diagnostic devices? What are the devices categorized as notified in vitro diagnostic devices? Which rules is applicable for import, manufacture, sale, distribution of the medical devices? What is the general definition of the medical devices, we also understand that. And also what is the difference between the drugs and the devices we have understand.

So, hope you have basic idea about the introduction of the medical device regulation, devices which are presently regulated, devices which are not presently regulated what are the notified medical devices all those thing you have some basic idea. So, we will finish this topic here and we will go for the next lecture to cover other topic of the medical device regulation.

Thank you very much.