

**Regulatory Requirements for Medical Devices Including in Vitro Diagnostics in India (Version 2.0)**  
**Prof. Aseem Sahu**  
**Central Drugs Standard Control Organization**  
**Department of Biotechnology**  
**Indian Institute of Technology, Madras**

**Lecture – 01**  
**Medical Device and In Vitro Diagnostics: Introduction and types of devices including combination device**

Welcome to Regulatory Requirement for Medical Devices Including in Vitro Diagnostics in India version 2, lecture 1 that is Medical Devices and In Vitro Diagnostics: Introduction and types of the devices including combination devices.

(Refer Slide Time: 00:26)

**CDSA** **NPTEL**

**LEARNING OBJECTIVES** Be aware of what is a medical device and *in vitro* diagnostic.

**EXPECTED OUTCOME**

Able to understand:  
What is a medical device?  
What is an *in vitro* diagnostic (IVD)?  
Difference between drugs & medical device.  
Notified and non notified medical devices & IVDs in India.  
Regulatory requirements for medical devices & IVDs in India.

**TARGET AUDIENCE** Personnel working in the medical device & IVD industries. Innovators or start ups involved in medical device or IVD kit industry, regulatory affairs personnel, human ethics committee members, clinical trial team members, researchers, academicians, students etc. and for persons generally interested in medical devices.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

Learning objectives of this presentation be aware what is the medical devices and in vitro diagnostics. The expected outcome of this lecture; we will be able to know what is a medical devices, what is aIn vitro diagnostics, what is the difference between drugs and devices? What are the notified medical devices and notified in vitro diagnostics, what are the regulatory requirement for medical devices and in vitro diagnostics in India?

The target audience: The personnel working in the medical devices and in vitro diagnostics industry, start up, innovators, academicians, researchers, regulatory affairs personnels, ethics committee members, clinical trial team members, students and the persons generally interested in the medical devices and in vitro diagnostics.

(Refer Slide Time: 01:39)



CDSA NPTEL

### WHAT WILL WE LEARN IN LECTURE 1?

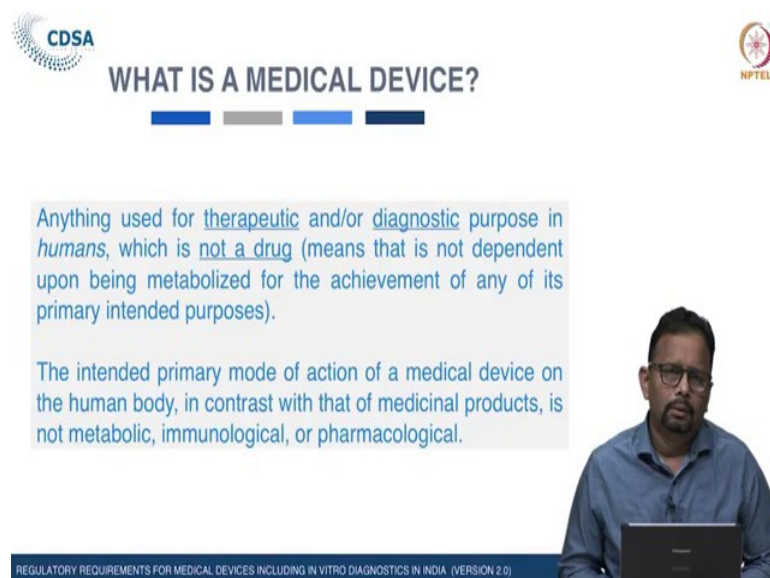
What is a medical device?	What is an <i>in vitro</i> diagnostic?	Various types of medical devices
Which law regulates medical devices & <i>in vitro</i> diagnostics?	Difference between drug and device	Whether all medical devices are regulated ?

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

A presenter is visible in the bottom right corner of the slide.

What we will learn in this lecture? We will learn- what is a medical devices, what are the various types of the medical devices and in vitro diagnostics. What is the current regulation on medical devices in India? What are the challenges in the medical device sectors? Whether all the medical devices are regulated? all those topic we will discuss in this lecture. Now, come to the first lecture that what is the medical devices?, is that regulated?

(Refer Slide Time: 02:28)



CDSA NPTEL

### WHAT IS A MEDICAL DEVICE?

Anything used for therapeutic and/or diagnostic purpose in *humans*, which is not a drug (means that is not dependent upon being metabolized 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.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

A presenter is visible in the bottom right corner of the slide.

So, what is the definition of the medical devices? If you see the medical devices, in general we can say anything used for diagnostic or therapeutic purpose in human being which is not a drug. Simple word we can say it is not a drug, but it is used for the purpose of therapeutic or diagnostics in human being or animals. It means it dependent upon being metabolized or achievement of any of its primary intended purpose through immunological or pharmacological.

The intended primary mode of action of the medical devices on human body in contrast with the drug items or medicinal products is not metabolic, not immunological or pharmacological. This is general definition of the medical devices.

(Refer Slide Time: 03:48)

**CDSA** **NPTEL**

## WHAT IS A MEDICAL DEVICE?

The term **"medical devices"** includes everything from highly sophisticated computerized 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 kit, perfusion sets, sutures, etc.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

And, the medical device includes everything which is not a drug and it is used for the diagnostic or therapeutic purpose. It varies from highly sophisticated computerized medical equipment like MRI machines or the simple medical devices that is tongue depressors, very vast range of the medical devices.

Other examples of this medical devices if you see, various medical devices that is being used in the diagnosis or therapeutic purpose for human being that are the orthopedic implants, Other examples are pacemakers, cochlear implant, catheters and various diagnostic kits, in vitro diagnostic kits. These are generally refer as medical devices and diagnostics.

(Refer Slide Time: 04:56)

**CDSA** **EU DEFINITION** **NPTEL**

'Medical device' means any instrument, apparatus, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the following specific medical purpose(s):

- Diagnosis, prevention, monitoring, treatment or alleviation of **disease**;
- Diagnosis, monitoring, treatment, alleviation of or compensation for **an injury or disability**;
- Investigation, replacement or modification of the **anatomy or of a physiological or pathological state**;

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

Now, if you see the official definition of the medical devices. let us see we can take the definition of the European Union. What is the medical device definition? The medical device as per the definition of the medical devices, it is a instrument, apparatus, software, implant, reagent material or other article intended by the manufacturer to be used alone or in combination for human being for one or more of the certain medical purposes. very big definition is there. We can discuss one by one.

This is the first part of the definition which state that it is a instrument, apparatus, software, implant, reagent, materials or other article intended by the manufacturer to be used alone or in combination for human being, for one or more of the certain specific medical purposes.

Now, what are those purposes?

It is for the diagnosis, prevention, monitoring, treatment or alleviation of disease. this is the first purpose.

Other purpose of these products it is for the diagnosis, monitoring, treatment, alleviation or compensation for an injury or disability.

Other purpose, it is for the purpose of investigation, replacement or modification of the anatomy or of a physiological or pathological state.

(Refer Slide Time: 07:05)

**CDSA**

**EU DEFINITION**

- Providing information by means of *in vitro* examination of specimens derived from the human body including organ, blood, tissue etc.;
- Device for the control of conception;
- Products for cleaning, disinfection of medical devices.

And which 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 INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

Next purposes of this products; it provides information by means of in vitro examination of the specimen derived from the human body including organ, blood or tissues etc. It is for the purpose of in-vitro examination and it is for the purpose of control of conception. It is for the purpose of cleaning or disinfection of medical devices or medical equipment.

So, these are the purposes of the medical devices and it does not achieve its primary intended action by pharmacological, immunological, metabolic means in or on the human body, but which may be assisted in its intended functions by such means.

(Refer Slide Time: 08:07)

**CDSA**

**EU DEFINITION**

**'Medical Device means** - a product for human use which has a **medical purpose, which act on diseases, injuries or disability, anatomy or a physiological or pathological state, or providing information by means of *in vitro* examination.**

**It should not be a drug.**

It is also intended for the purpose of **control of conception**, or for **cleaning, disinfection** of medical devices.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

This is the definition as per the European Union regulation, this is the EU definition. So, if you see the definitions and you can summarize the definition in such a way, it is a product for human use which has a medical purposes and which act on the disease, injuries or disability or anatomy or physiological or pathological state or providing information by means of in vitro examination.

But, it should not be a drug.

It is also intended for the purpose of control of conception or cleaning or disinfection of the medical devices and equipments. So, this is the official definitions of the medical devices, though in India as per our patient law we don't have such detailed definition for the medical devices in the in our law.

(Refer Slide Time: 09:19)



**CDSA** **WHY DO WE NEED NEW REGULATIONS?** **NPTEL**

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.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

If you see the Indian regulation w.r.t the medical devices, in India medical devices are regulated as a 'drug'. This sector is a small sector as compared to the pharmaceutical or medicinal products. This sector mainly depends on the import more than 75 percent of the material or the devices are being imported into the country.

(Refer Slide Time: 10:03)

**CDSA** **WHY DO WE NEED NEW REGULATIONS?** **NPTEL**

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

The regulatory framework for pharmaceuticals and devices differ substantially. The regulatory authorities in different regions of the world recognize different classes of medical devices (MDs), based on their design complexity, their use characteristics, and their potential for harm, if misused.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

The factor which affect this industry are various such as that is lack of proper regulatory system, harmonized standards, accreditations, proper guidance all those factors are there earlier So, because of this the industry has not achieved what the other sectors has achieved, but this industry is growing at the rate of 50 percent that is very good potential in this industry. Since, it is regulated as a drug as per the medical Drugs and Cosmetic Act, 1940 which is the law of the country So, there was a lot of challenges w.r.t regulatory requirement for the medical devices in the country.

(Refer Slide Time: 11:09)

**CDSA** **WHY DO WE NEED NEW REGULATIONS?** **NPTEL**

In the Drugs & Cosmetics Act 1940 and Rules 1945, there were no specific requirements for import, manufacture, clinical investigation etc. of medical devices and *in vitro* diagnostics (IVDs).

The concerns were raised in various forum and finally the Government of India has come up with new medical device rules to harmonize the regulatory requirements at par with the globally accepted regulation and to develop ecosystem in the country to boost the medical device sector in the country.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

So, these challenges that the stakeholders, what they have faced in the various forum they have discussed these issues and finally, the Government of India, Ministry of Health and Family Welfare(MoHFW) they have come up with the new regulation and, this new regulation was come into effect from January 2018 and that is called as Medical Device Rule 2017.

This is actually the requirement for the medical devices in India, in this Medical Device Rule 2017 the specific requirement for import, manufacture, clinical investigation, sale and distribution of the medical devices and in vitro diagnostics products have been clearly defined based on the complexity of the medical devices and in vitro diagnostics. the requirement has been led down which is at par with the globally accepted requirement. So, in the Medical Device Rule 2017 the requirement for import, manufacture, clinical investigation, sale and distribution of this medical devices and in vitro diagnostic have clearly defined. .

However, is still in this rule there is a certain limitations, under this rule it is there only notified medical devices are regulated, not all the type of medical devices are presently under regulation. And, also the separate definition for the medical devices at par with the globally accepted definition is not included so far in this medical device rule 2017. But, the requirements and provisions are harmonized internationally at par with the globally accepted regulatory requirement. We will discuss this new Medical Device Rule 2017 in subsequent slides. Before that just we have to see what is required for the medical devices.



(Refer Slide Time: 13:28)

CDSA

## WHAT IS REQUIRED?

NPTEL

Medical devices are:

- Specialized product – need different regulatory environment than drugs due to their inherent and characteristic differences.
- Complex and can be very individualistic. It can have BATCH OF ONE DEVICE.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

We know that medical device is a specialized product, it is different from the drugs, it is very complex product, It varies from simple product to highly sophisticated, high and medical equipments, it is used by everyone.

(Refer Slide Time: 13:59)

CDSA

## WHAT IS REQUIRED?

NPTEL


Medical devices:

- Their criticality is risk based – can not equate implantable devices with syringes or hospital beds.
- As critical care products, they need to be regulated .
- Are specific, have independent identity from drugs.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

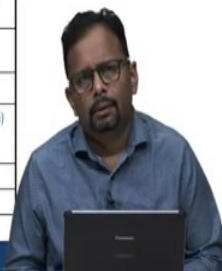
So, this medical device sector they require independent identity from the drugs. Why it is different from the drugs?

(Refer Slide Time: 14:07)



**DIFFERENCE BETWEEN DRUG & DEVICE**

PARAMETERS	DRUG	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 INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

As already we have discussed in the definition there are other parameter also, if you see the difference between drugs and devices; there are a lot of difference. if you see the uses the drugs are *in vivo* use; however, the devices it is used *in vivo* or *ex vivo* or *in vitro* also. The active component of the drugs is based on the chemistry and pharmacology, in the medical devices it is based on the mechanical, electrical and material engineering. Intended purpose of the drugs, it is for the therapeutic intended purpose, the devices may be used both for therapeutic as well as diagnostic purpose.

The quality of the drugs it depends on the safety and efficacy of the drugs, varies for the medical devices and *in vitro* diagnostics it is based on the performance evolution of the devices. If you see the requirement at the clinical trial in the drugs there is a Phase 1, Phase 2, Phase 3 trial. However, in the medical devices it is not like drugs, it is a clinical evaluation, clinical investigation or clinical performance. The manufacturing requirement if you see the drugs for manufacturing of drug the requirement of the good manufacturing practices are there.

However, in the medical devices *in vitro* diagnostics, the requirement of quality management system for manufacturing and marketing of the medical devices and *in vitro* diagnostics. If you see the toxicity profile or toxicity evaluation, for drug local and systematic toxicity is to be carried out whereas in the diagnostics the biocompatibility, biological evolution of the devices or the bio material used in the particular medical

devices that need to be evaluated. In the drugs the adverse event are due to the drug interaction.

However, mostly in the medical devices these adverse events are due to malfunctioning of the medical devices or improper use of the medical devices. So, these are the basic differences between drugs and devices and thus this sector require different identity from the drugs.

(Refer Slide Time: 17:29)

The slide features the CDSA logo on the left and the NPTEL logo on the right. The title 'REGULATORY FRAMEWORK IN INDIA' is centered at the top. Below the title, there are four colored bars (blue, grey, blue, dark blue). The main content is a light blue box with the following text:

- Drugs & Cosmetics Act, 1940 is a central Act enforced by both Central and State Governments. It is extended to whole of India.
- The objective of the Act is to regulate:
  - ✓ Import
  - ✓ Manufacture
  - ✓ Sale and distribution of drugs and cosmetics
- Medical devices were regulated as 'drugs'. There were no specific requirements for import manufacture, clinical investigation of MD & IVDs under the law.

At the bottom of the slide, there is a dark blue bar with the text: 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)'. A man in a blue shirt is visible in the bottom right corner, sitting at a laptop.

Now, what is the medical device regulation? If you show the regulation in the previous slides we have discussed what is the new regulation. But, actual regulation if you see the medical devices and in vitro diagnostics these are regulated as a drug as we have already discussed. And, the law under which these devices and in vitro diagnostics are regulated are Drugs and Cosmetic Act 1940. Earlier the rules that is the Drugs and Cosmetic Rules 1945 was there.

However, this rule has been replaced with the new regulation that is Medical Device Rule 2017 which is a new regulation. And, this objective of this law, this act that is the Drugs and Cosmetic Act is to regulate import, manufacture, sale and distribution of the drugs and cosmetics. And, under the definition of the drugs since medical devices is included therefore, the import, manufacture, sale and distribution of the medical devices are also are regulated under the Drugs and Cosmetic Act, 1940.

(Refer Slide Time: 18:31)

**CDSA**

**REGULATORY FRAMEWORK IN INDIA**

**NPTEL**



- 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 1st January, 2018.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

Why this new require requirement of the Medical Device Rule 2017? We have discussed cases in the Drugs and Cosmetic Rules 1945, there is no specific requirement for the medical devices. Whatever the requirements are described that is applicable only for the drugs and biological products.

So, since there is no specific requirement for import, manufacture or clinical investigation of the medical devices and in vitro diagnostics therefore, the requirement of the new regulation was there. And, this new regulation has been framed and prepared and published in the year in the year 2017 and effective date for this new regulation was 1st January 2018 and, this new regulation is presently implementing for the regulation of the medical devices and in vitro diagnostic in the country.

(Refer Slide Time: 19:32)



### DEFINITION



---

MEDICAL DEVICE ARE REGULATED AS DRUGS UNDER THE DEFINITION OF "DRUG" AS PER DRUGS AND COSMETICS ACT, 1940



If you see the definition of the medical devices under the definition prescribed in the Drugs and Cosmetic Act, we have discussed internationally what is the medical device definition.

(Refer Slide Time: 19:55)



### DEFINITION

---

Section 3(b)  
"drug" includes-

- (i) 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;



If you see, if you compare this definition with our device definition which is prescribed in the Drugs and Cosmetic Act, 1940; the drug definition is defined in the section 3 b of the act. And, this section have four different part and the devices are covered under this definition. If you see the part i of the drug definition which includes all substances

intended to be used for or in the diagnosis of disease or disorder in the human being or animals.

So, under this clause all the in vitro diagnostics, all the surgical products and in vitro diagnostics kits are covered under this part of the definition.

(Refer Slide Time: 20:54)



## DEFINITION



(ii) such 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 specified from time to time by the Central Government by notification in the Official Gazette;



The part ii of the drug definition under section 3 b which states the substances which affect the structure or any function of the human body as may be specified from time to time by the Central Government through notification in the Official Gazette. Under this clause only two categories of the devices have been notified so far.

(Refer Slide Time: 21:23)



## DEFINITION



*(iii) all substances intended for use as components of a drug including empty gelatin capsules; and*

(iv) such 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 in the Official Gazette, after consultation with the Board;

Note: Part (iii) of the definition is not related to medical device (red colour, italic).



And, these are the mechanical contraceptives and disinfectants. So, these two categories of the medical devices are regulated under this clause of the drug definitions. And, if you see the fourth clause of the definition of the drugs under section 3 b which states that any devices intended for internal or external use in the diagnosis, prevention, treatment, mitigations of disease or disorder in human being or animals, as may be notified by the Central Government through Gazette notification from time to time after consultation with the board.

Board here board means Drug Technical Advisory Board(DTAB), this is the statutory board, this board recommend based on the criticality of the medical devices from time to time they have the expert of this board they have discussed in many times. And, certain medical devices from time to time based on the need they are notifying, they are recommending and based on the recommendation of the board the Ministry of Health and Family Welfare, Government of India.

They are publishing the notification for regulation of the new category of the medical devices. So, these three clauses of the drug definition covers all the in vitro diagnostics and the certain medical devices which are notified, only those devices and in vitro diagnostics are present in the regulation.

(Refer Slide Time: 23:24)

**CDSA** **HISTORICAL PERSPECTIVE** **NPTEL**

Prior to 1989, medical devices were not controlled under the Drugs & Cosmetics Act, 1940. However, certain items prior to this date were controlled under the Drugs & Cosmetics Act, 1940.

These are:

1. *in vitro* diagnostics reagents
2. Sutures
3. Ligatures
4. Disinfectants
5. Surgical dressings
6. Umbilical tapes
7. Mechanical contraceptives

Thereafter, certain medical devices were notified for its regulation under the said Act.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

If you see the history perspective of the medical devices under the Drugs and Cosmetic Act , 1940 and Drugs and Cosmetic Rules 1945, the first notification of the medical devices certain medical devices was done in the year 1989.

(Refer Slide Time: 23:41)

**CDSA** **LIST OF MEDICAL DEVICES NOTIFIED** **NPTEL**

#	Name of the device	Date
1	Disposable hypodermic syringes	17-03-1989
2	Disposable hypodermic needles	17-03-1989
3	Disposable perfusion sets	17-03-1989
4	IVDs 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 INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

And, in the year 1989 the three different categories of the medical devices have been notified under the class 4 of the drug definition. And, those three devices are hypodermic needle, hypodermic syringes and perfusion sets. And, before that notification of these three medical devices certain the devices like contraceptives, surgical dressings and in



vitro diagnostic kits, only those products are regulated under the Drugs and Cosmetic Act, 1945.

So, medical devices three medical devices were notified in the year 1989 and since then only till the 2002 only three devices have been notified and regulated as a medical devices. Thereafter, after long time in the year 2002; in 2002 the 4 categories of in vitro diagnostic kits that is in vitro diagnostic kits for HIV, in vitro diagnostic kits for hepatitis B surface antigen, hepatitis C and blood grouping sera. These four types of the in vitro diagnostic kits and devices have been notified.

And, thereafter in the year 2005, 10 other category of the medical devices were notified and regulated. So, if you see the present regulation the 16 notified devices so far have been notified under the class 4 of the section 3 b of the drug definition. And, this 16 notified medical devices are regulated presently and if you see the what are the 16 medical devices, that is the disposable hypodermic syringes, disposable hypodermic needles, disposable perfusion sets, HIV kits for HIV, HCV, HbsAg, and blood grouping sera, cardiac stents, drug eluting stent, catheters, intraocular lenses.

(Refer Slide Time: 26:22)

**CDSA** **LIST OF MEDICAL DEVICES NOTIFIED** **NPTEL**

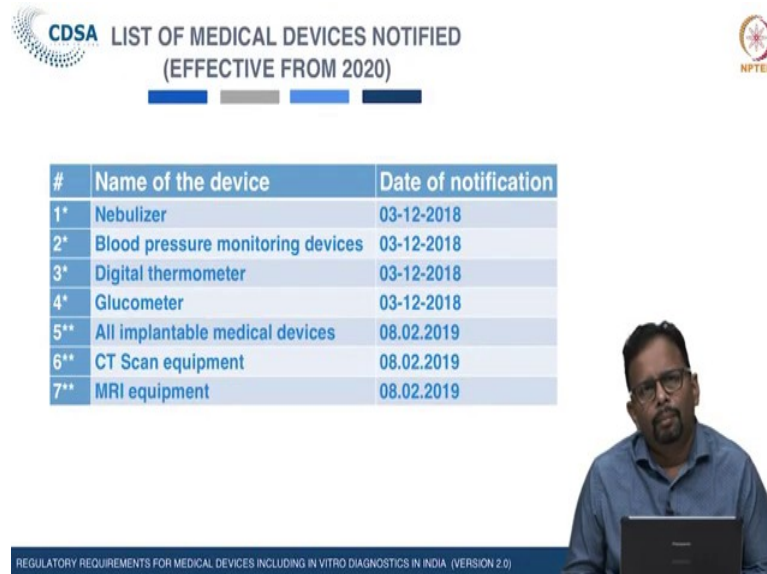
#	Name of the device	Date
9	I.V. cannulate	06-10-2005
10	Bone cements	06-10-2005
11	Heart valves	06-10-2005
12	Scalp vein set	06-10-2005
13	Orthopaedic implants	06-10-2005
14	Internal prosthetic replacements	06-10-2005
15	Ablation devices	25-01-2016
16	Organ preservative solution	02.04.2018

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

Bone cements, heart valves, scalp vein sets, orthopedic implants, internal prosthetic replacement, ablation catheter which was notified in the year 2016 and in 2018 the organ preservative solutions also notified as a devices. So, these 16 categories of the medical devices are under regulations presently. Further in the past in the year December 2018

four different categories of the medical devices, that is a medical equipments that four medical equipments have been notified for regulations.

(Refer Slide Time: 27:20)

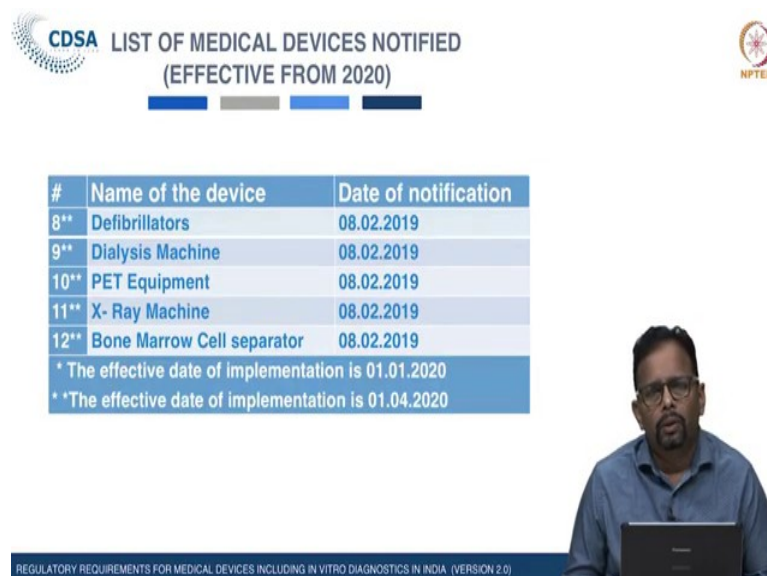


The slide features the CDSA logo on the left and the NPTEL logo on the right. The title is "CDSA LIST OF MEDICAL DEVICES NOTIFIED (EFFECTIVE FROM 2020)". Below the title is a table with three columns: "#", "Name of the device", and "Date of notification". The table lists seven categories of medical devices. A presenter is visible in the bottom right corner, and a footer at the bottom reads "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

#	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 equipment	08.02.2019
7**	MRI equipment	08.02.2019

And, in the month of February 2019, 8 new categories of the medical devices are also notified.

(Refer Slide Time: 27:31)



The slide features the CDSA logo on the left and the NPTEL logo on the right. The title is "CDSA LIST OF MEDICAL DEVICES NOTIFIED (EFFECTIVE FROM 2020)". Below the title is a table with three columns: "#", "Name of the device", and "Date of notification". The table lists five categories of medical devices. Below the table, there are two footnotes: "\* The effective date of implementation is 01.01.2020" and "\*\*The effective date of implementation is 01.04.2020". A presenter is visible in the bottom right corner, and a footer at the bottom reads "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

#	Name of the device	Date of notification
8**	Defibrillators	08.02.2019
9**	Dialysis Machine	08.02.2019
10**	PET Equipment	08.02.2019
11**	X-Ray Machine	08.02.2019
12**	Bone Marrow Cell separator	08.02.2019

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

And, the implementation date of this new categories of the medical devices, will be in the January 2020. So, certain time period has been given to the stakeholders for implementation of regulation of this new categories of the medical devices.

(Refer Slide Time: 27:58)

**CDSA** WHO USES MEDICAL DEVICE? **NPTEL**

Medical devices are used by everyone. The use can be temporary, permanent, used by a professional, used by a person without supervision.

**For example:**

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 INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

Now, who uses the medical devices?

If you see the uses of the medical devices, it is used by everyone you be aware of that, the use can be temporary, the use maybe permanent, it is used by the professional or the used by the person without any supervision. Example: if you see the example of the temporary use medical devices the cervical collars, walking sticks. When it is used during the injury, it is a medical devices; it is a simple devices. It is for temporary use. permanent devices: cardiac stents, orthopedic implants, heart valves.

There are so, many implantable devices which is used permanently, professional use devices certain devices that is used only by the professional like blood assay monitor or a MRI machines. And, also some devices which is used by the person without any supervision like walking sticks, this is the complexity of the medical devices. It is very simple to high risk and high end medical equipments, it varies from simple devices to complex devices.

(Refer Slide Time: 29:48)

 AS PER DRUGS & COSMETICS ACT, 1940, MEDICAL DEVICES ARE:



(i) 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 clause (b) of section 3 of the Drugs and Cosmetics Act, 1940.

Surgical dressings   Surgical staples   Surgical sutures   Blood collection bag   Ligature



REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

Now, let us see we have discussed the definition of the medical devices under the provisions of Drugs and Cosmetic Act, 1940 and we also understand that the under the definition of the drugs the Class 3 b part i, part ii and part iv that relates to the medical devices and in vitro diagnostics. So, under this clause what are the devices which are covered?

If you see part i of the class b of the section 3 of the Drugs and Cosmetic Act, the substances used in vitro diagnostics and purpose in surgical dressings; surgical dressings like surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulants. These are the devices and in vitro diagnostics covered under the part i of the section 3 b of the drug definition.

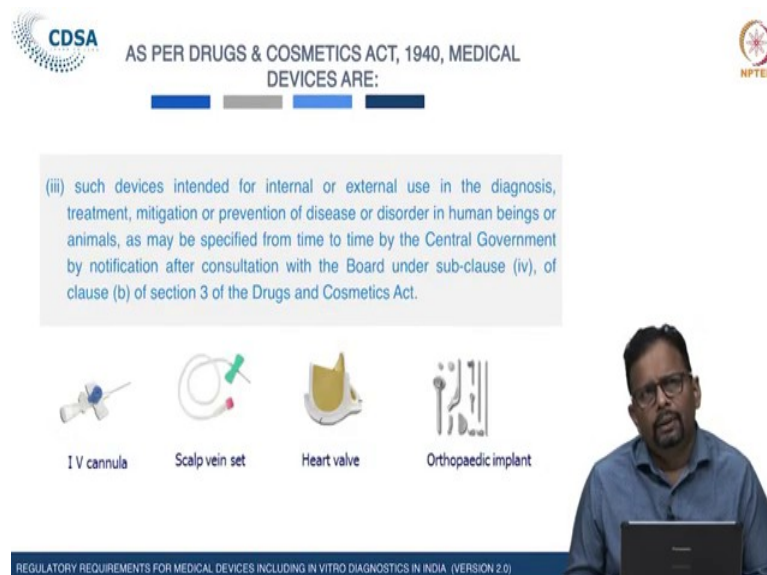
(Refer Slide Time: 31:17)



The slide features the CDSA logo on the top left and the NPTEL logo on the top right. The main heading reads "AS PER DRUGS & COSMETICS ACT, 1940, MEDICAL DEVICES ARE:". Below this, a text box contains the following text: "(ii) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants notified under sub-clause (ii) of clause (b) of section 3 of the Drugs and Cosmetics Act of section 3 of the Drugs and Cosmetics Act, 1940." Below the text box are four images with labels: "Condoms" (a pink and blue condom), "Intrauterine device" (a hand holding a small device), "Tubal rings" (two white rings), and "Disinfectant solution" (a yellow and green bottle). A presenter is visible in the bottom right corner, and a footer at the bottom reads "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

Part ii we have already discussed, the part ii of the definition of the drugs which covers the condom, mechanical contraceptive, other contraceptives or intrauterine devices, tubal rings and the disinfectant solution.

(Refer Slide Time: 31:38)



The slide features the CDSA logo on the top left and the NPTEL logo on the top right. The main heading reads "AS PER DRUGS & COSMETICS ACT, 1940, MEDICAL DEVICES ARE:". Below this, a text box contains the following text: "(iii) such 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." Below the text box are four images with labels: "I V cannula" (a blue and white cannula), "Scalp vein set" (a green and white set), "Heart valve" (a yellow and white valve), and "Orthopaedic implant" (a set of surgical tools). A presenter is visible in the bottom right corner, and a footer at the bottom reads "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

And, as we already discussed under part iv of the drug definitions the devices intended for the internal or external use in the diagnosis, prevention, mitigation, treatment of disease or disorder in animals or human beings as maybe notified from time to time by the Ministry of Health and Family Welfare, Government of India. Under this clause

various notified categories of the medical devices have been regulated and we have also discussed what are the notified medical devices.

Total 28 medical devices have been notified under this clause and we have also discussed, some of the example of this notified medical devices are in vitro diagnostic devices for the HIV, HCV and HbsAg, heart valves, scalp vein set, I Vv cannula orthopedic implants, prosthetic replacements. These are the devices which are notified under this clause and regulated.

(Refer Slide Time: 32:54)

CDSA AS PER DRUGS & COSMETICS ACT, 1940 NPTEL

IVDs are considered as "Drugs"

They 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 INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

If you see that in vitro diagnostics products also we have discussed that the substances that is intended to be used for diagnosis of disease or disorder in human being or animals. And, this in vitro diagnostics are covered under sub clause i sub of clause b of the section 3 b as we have discussed earlier. Now, let us see whether you have understand or not, whether this devices are regulated or you have to just confirm.

(Refer Slide Time: 33:25)

The slide is titled "CLASS OF IVD KITS/REAGENTS" and features the CDSA logo on the left and the NPTEL logo on the right. Below the title is a horizontal bar with four colored segments: blue, grey, blue, and dark blue. The main content is a list of four categories of in vitro diagnostic devices:

- a) *in vitro* diagnostic devices for HIV
- b) *in vitro* diagnostic devices for HBV
- c) *in vitro* diagnostic devices for HCV
- d) *in vitro* blood grouping sera

To the right of the list is a collage of images showing various diagnostic kits, including test tubes, vials, and reagent bottles. Below the collage, it is noted that these are "Notified as 'Drugs' under Drugs and Cosmetic Act 1940". A presenter is visible in the bottom right corner of the slide, and a footer at the bottom reads "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

The devices which is showing on the presentation whether it is regulated Yes, it is regulated, it is a disposable hypodermic needles which is a notified medical devices. Now, this is disposable hypodermic syringes, it is also regulated. Now, this one is cardiac stent which is also notified and regulated. And, this is the last one it is a drug eluting stent and this drug eluting stent is also notified and it is under regulation. So, these are the various categories of the medical devices which are regulated under the provisions of Drugs and Cosmetic Act 1940.

However, only the certain medical devices it is not that all the medical devices are presently under regulation. If you see the *in vitro* diagnostics kits though *in vitro* diagnostic kits are regulated, all the *in vitro* diagnostic kits. However, the equipments for diagnostic equipments, presently it is not regulated though the Government of India has notified certain equipment diagnostic equipment like blood glucose meter the, but the regulation will be effective only from January 2020. Now, what is non notified *in vitro* diagnostic products?

(Refer Slide Time: 35:08)

**CDSA** **NON-NOTIFIED IVD PRODUCTS** **NPTEL**

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

1. *in vitro* diagnostic reagents for all tests are covered, However, instruments required for estimation are not presently covered.
2. Some examples are blood glucose test strips, pregnancy test kits, urine analysis test kits etc.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

We have discussed devices which are under regulations and also we have understand all the in vitro diagnostic, devices and diagnostic kits are under regulations. And, out of all the in vitro diagnostics the only certain devices which has been notified under part iv of the drug definition under class 3 b. And, under this class only the four types of in vitro diagnostic that is HIV, HbsAg kits, HCV kits and blood grouping sera only these are the notified.

So, these four categories of the in vitro diagnostic kits is considered as a notified in vitro diagnostic kit as far as Drug and Cosmetic Act is concerned. And, other than these four notified in vitro diagnostics, all the in vitro diagnostic kits, reagent kits and the products are considered as a non-notified in vitro diagnostic products though it is a regulated. But, it is considered we can say it is a non-notified in vitro diagnostic products.

And, the example except this four notified in vitro diagnostic kits all in vitro diagnostic kits that is blood glucose test strips, pregnancy test strips, urine analysis test kit like that there are so many in vitro diagnostic reagent kits are there. All these kits are regulated and it is also considered as a non-notified in vitro diagnostics.



(Refer Slide Time: 37:01)

**CDSA** WHICH OF THESE ARE IVDS? **NPTEL**

**A** Blood grouping reagents

**B** No, this is not an IVD. This is a drug (ointment)

**C** IVD for HIV

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

May also for the in vitro diagnostic kits you have to see whether these products which is showing on the presentation is regulated or not yes it is a. What is this devices? This is in vitro diagnostic kits, these kits is known as blood grouping reagents and it is regulated. Now, the another one that is the ointment, it is a drug. So, it is not in vitro diagnostics, it is not under medical devices, it is a drug. Now, the last one that is in vitro diagnostic kits for HIV.

(Refer Slide Time: 37:47)

**CDSA** CURRENT REGULATION **NPTEL**

In India, at present only notified medical devices and *in vitro* diagnostic reagent kits are regulated as 'drugs' under the Drugs and Cosmetics Act 1940 and Rules made thereunder. Drugs and Cosmetics Act 1940 and Rules made thereunder.

The Ministry of Health and Family Welfare, Government of India introduced new legislation to harmonize the regulatory requirements at par with the globally accepted regulation.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

And, as already we have discussed this is notified in vitro diagnostic kits and it is regulated. So, these are the different categories of the in vitro diagnostic kits which are under regulation, under which clause of the drug definition it is regulated we have discussed in detail. And, also we have discussed the current regulation, the currently the Medical Device Rule, 2017 which was published on 31st January 2017 through the Gazette Notification that is known as GSR 78 E.

(Refer Slide Time: 38:28)



**CURRENT REGULATION**

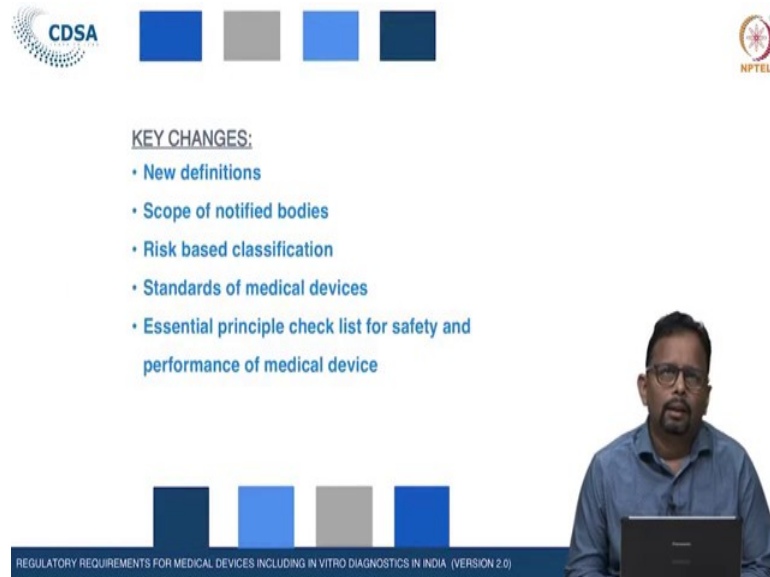
The aim was to harmonize the regulatory requirements at par with the globally accepted regulation and to develop ecosystem in the country to boost the medical device sector, that will make India more lucrative for medical device development to encourage national and multi-national companies to manufacture their products in India.

This regulation was published by the Govt. on 31<sup>st</sup> January 2017 vide Gazette Notification No. GSR 78(E) under Drugs & Cosmetics Act 1940 and Rules 1945 as "Medical Devices Rules 2017", which came into force from 1<sup>st</sup> January 2018.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

And this gazette notification which is called as a Medical Device Rule 2017 which come into force from the January 2018. In the new regulations we have also discussed in this new regulations the specific requirement of import, manufacture, clinical investigation and sale and distribution of the medical devices and in vitro diagnostic kits have been prescribed which is at par with the globally accepted requirements, regulatory requirements. So, we will discuss that Medical Device Rule 2017 in subsequent lecture.

(Refer Slide Time: 39:20)



The slide features the CDSA logo on the top left and the NPTEL logo on the top right. Below the logos is a horizontal bar with four colored segments: blue, grey, light blue, and dark blue. The central text, titled 'KEY CHANGES:', lists five bullet points: 'New definitions', 'Scope of notified bodies', 'Risk based classification', 'Standards of medical devices', and 'Essential principle check list for safety and performance of medical device'. At the bottom, a presenter is visible from the chest up, wearing a blue shirt and glasses, sitting at a desk with a laptop. A dark blue footer bar at the very bottom contains the text 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)'. Below the footer bar is another horizontal bar with four colored segments: dark blue, light blue, grey, and blue.

**KEY CHANGES:**

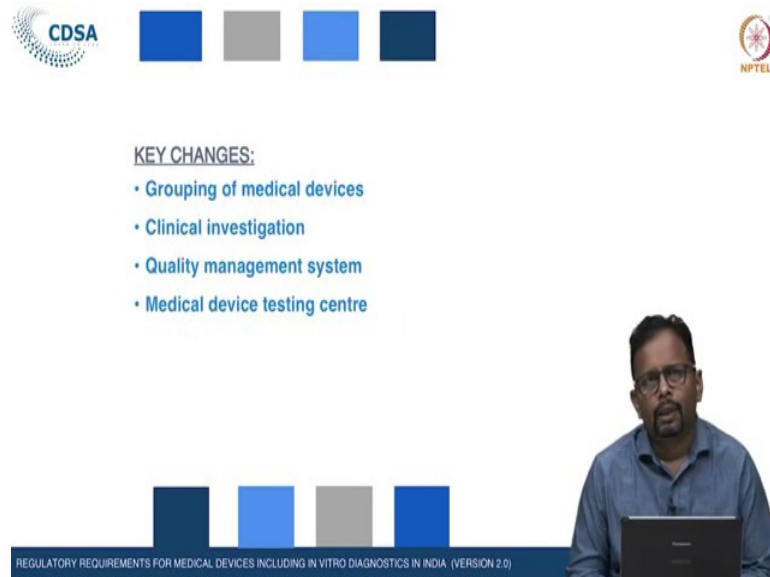
- New definitions
- Scope of notified bodies
- Risk based classification
- Standards of medical devices
- Essential principle check list for safety and performance of medical device

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

But, in short we have to understand what are the key changes incorporated in this Medical Device Rule 2017. If you see this Medical Device Rule 2017, the key changes in this Medical Device Rule various definitions related to medical devices and in vitro diagnostics diagnostic kits have been prescribed which were not in the earlier regulation.

In the Medical Device Rule the provision of the scope of the notified body for audit of the QMS audit of the class A and class B of the devices that has been prescribed. In the Medical Device Rule 2017 the risk based classification of the medical devices and in vitro diagnostics have been incorporated, the standards of the medical devices, the requirement of the essential principle for safety and performance of the medical devices.

(Refer Slide Time: 40:29)



The slide features the CDSA logo on the left and the NPTEL logo on the right. Below the logos are four colored squares: blue, grey, light blue, and dark blue. The central text reads "KEY CHANGES:" followed by a bulleted list: "• Grouping of medical devices", "• Clinical investigation", "• Quality management system", and "• Medical device testing centre". At the bottom, there is a video feed of a man in a blue shirt sitting at a laptop. A dark blue footer bar at the very bottom contains the text "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

The provision for the grouping of the medical devices, provision for clinical investigation of the medical devices, provision for quality management system. The provision for medical device testing center, this is specific provision that has been incorporated and these are the key changes. We will discuss all those key changes in the subsequent lecture.

(Refer Slide Time: 41:02)



The slide features the CDSA logo on the left and the NPTEL logo on the right. Below the logos are four colored squares: blue, grey, light blue, and dark blue. The central part of the slide contains two images: on the left, a person in a white lab coat and gloves is working with laboratory equipment; on the right, a person in a white lab coat and gloves is holding a red test tube. Below the images, the text reads: "Medical devices and diagnostic reagents are classified as per their risk criteria from low risk (Class A) to high risk (Class D) ." and "We will learn about them in our subsequent lectures". At the bottom, there is a video feed of a man in a blue shirt sitting at a laptop. A dark blue footer bar at the very bottom contains the text "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

If you see the classification of the medical devices, globally how these medical devices and in vitro diagnostics have been classified; it is based on the risk criteria. And, in the

Medical Device Rule 2017 also the same criteria has been adopted, provision have been made, risk criteria has been defined. And, based on the risk criteria from the low risk to high risk if the low risk devices is classified, then it is classified as class A.

And, the high risk medical devices or in vitro diagnostic kits will be classified as Class D devices. And, low to moderate and moderate to high, low to moderate is classified as class B, moderate to high is classified as a class B devices and the criterion parameter is already clearly mentioned on the Medical Device Rule 2017.

(Refer Slide Time: 41:59)

The slide features the CDSA logo on the left and the NPTEL logo on the right. The title 'CLASSIFICATION' is centered at the top. Below the title, there is a horizontal bar with four colored segments: blue, grey, blue, and dark blue. The main text on the slide reads: 'Under the new 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:'. Below this, a smaller text block states: '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.' A presenter is visible in the bottom right corner of the slide frame. At the bottom of the slide, there is a footer: 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)'.

And, the responsibility for classification is lies with the Central Licensing Authority(CLA) that is Drugs Controller General India, who is the center licensing authority, also heading the Central Drug Standard Controller Organization that is the central government bodies for regulation of the Medical Device 2017.

(Refer Slide Time: 42:27)

**CDSA** **CLASSIFICATION** **NPTEL**

Classification list of medical devices and *in vitro* diagnostic kits published by DCG(I) are based on the risk of the device as per criteria laid down in Medical Device Rules, 2017.

- i. The component and accessories to a medical device or companion *in vitro* diagnostic medical devices has been classified separately. However, the component is classified generally and placed in the same class as the principle device.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

And, based on the criteria laid down in the MDR rule 2017, the center licensing authority has classified the devices and in vitro diagnostics. And, these classification list has been uploaded in the website for the stakeholder which includes the manufacturers or importers. And, based on the classification the stakeholder will fulfill the requirement as prescribed in the Medical Device Rule 2017.

(Refer Slide Time: 42:54)

**CDSA** **CLASSIFICATION** **NPTEL**

- ii. It is also recognised that some of the medical devices or *in vitro* diagnostic medical devices may have dual use and they may be classified accordingly.
- iii. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

This classification list, it is a dynamic classification list. If certain devices or in vitro diagnostic kits is classified in a particular class, the classification of that particular

medical devices or in vitro diagnostics will vary based on the evidence or document produced to the center licensing authority. And, it may change it from low risk to high risk or high risk to low risk based on the evidence or the documentary evidence of the particular devices.

(Refer Slide Time: 43:31)

**CAN YOU NAME THEM?**

**A** ✓ Disposable hypodermic needles

**B** ✓ Disposable hypodermic syringe

**C** ✓ Cardiac stent

**D** ✓ Drug eluting stent

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

The components and accessories of the medical devices also classified under these categories. Now, categories of the medical devices.

(Refer Slide Time: 43:39)

**CATEGORIES OF MEDICAL DEVICE**

A device according to the definition can be anything from as simple as a walking stick to an ultrasound machine.

In India, the regulations and controls apply to devices which are "notified" in the Gazette of India as well as all *in vitro* diagnostic reagent kits. The regulations apply to manufacture, import, sale and distribution in the country.

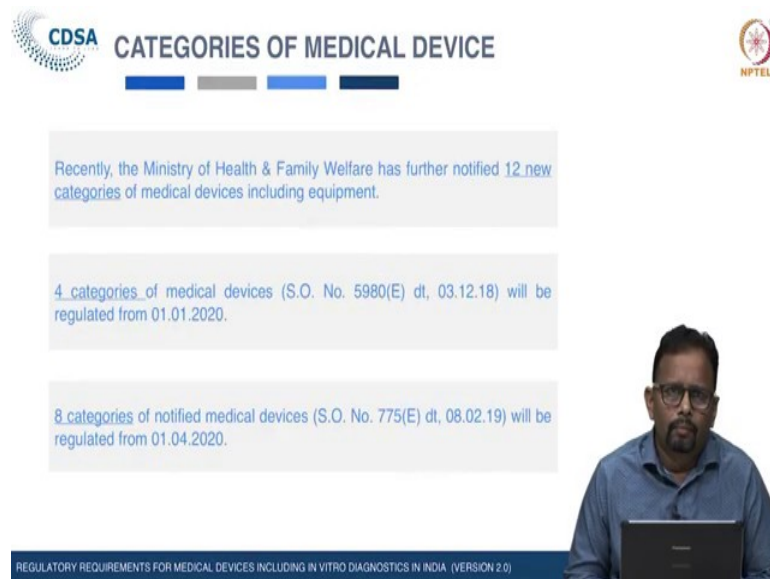
We are now aware that there are 16 categories of devices which are notified and controlled under the law (Drugs & Cosmetics Act 1940 & MDR, 2017), which also includes 4 notified in vitro diagnostics.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

We have discussed medical devices, what is the in vitro diagnostic kits, what is the global definition of the medical devices, what is the definition of the devices under the Drugs and Cosmetic Act, 1940; classification under the regulate medical device regulation Medical Device Rule 2017.

The different categories of the medical devices has been notified and regulated. And, the regulation and control applies to the devices which are presently under regulation.

(Refer Slide Time: 44:31)



The slide features the CDSA logo on the left and the NPTEL logo on the right. The title 'CATEGORIES OF MEDICAL DEVICE' is centered at the top. Below the title, there are three text boxes providing regulatory updates:

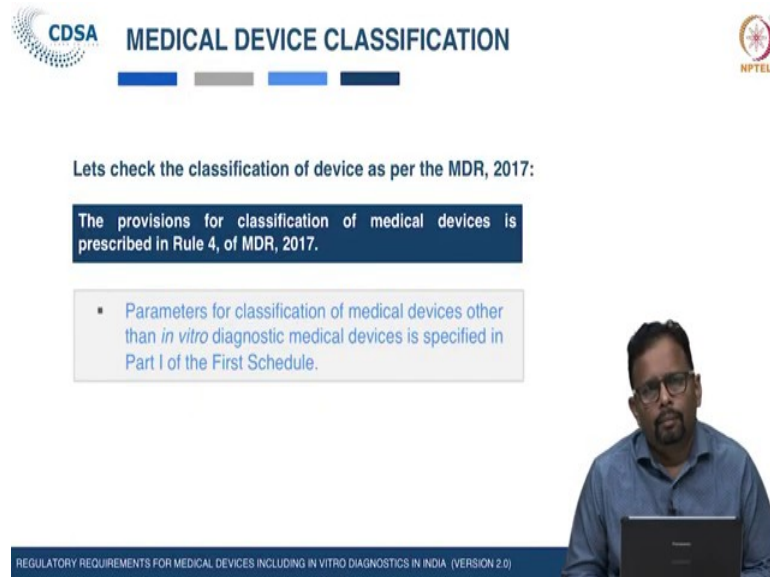
- Recently, the Ministry of Health & Family Welfare has further notified 12 new categories of medical devices including equipment.
- 4 categories of medical devices (S.O. No. 5980(E) dt, 03.12.18) will be regulated from 01.01.2020.
- 8 categories of notified medical devices (S.O. No. 775(E) dt, 08.02.19) will be regulated from 01.04.2020.

A presenter is visible in the bottom right corner of the slide, and a footer at the bottom reads 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)'.

And, these different categories based on the notification of the Government of India, Ministry of Health and Family Welfare; these different categories of the medical devices has been classified based on the risk associated with the devices or in vitro diagnostics as well as its intended use. And, under different categories of the notified medical devices various types of the medical devices have been classified. And, more than 300 different types of the in vitro diagnostic kits and medical devices have been published and it is regulated and these devices and in vitro diagnostics are regulated.



(Refer Slide Time: 45:27)



CDSA MEDICAL DEVICE CLASSIFICATION

NPTEL

Lets check the classification of device as per the MDR, 2017:

The provisions for classification of medical devices is prescribed in Rule 4, of MDR, 2017.

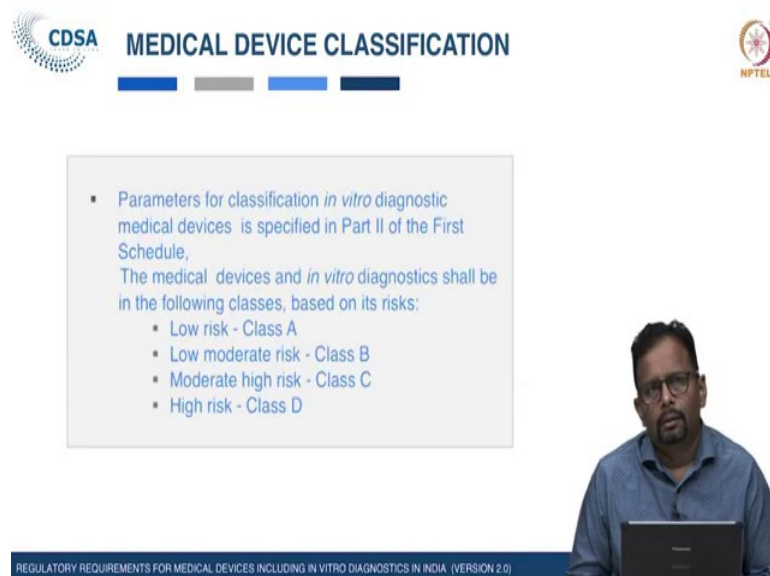
- Parameters for classification of medical devices other than *in vitro* diagnostic medical devices is specified in Part I of the First Schedule.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

A man in a blue shirt is sitting at a desk with a laptop, presenting the slide.

Medical device classification we have also discussed, the provision have already been made in the Medical Device Rule 2017 under rule iv which gives the power to the Central Licensing Authority for notification of the medical, notification of the classification list for the stakeholders. And, the parameter for classification has been defined in the first schedule of the Medical Device Rule 2017, the first schedule will have two different part.

(Refer Slide Time: 45:59)



CDSA MEDICAL DEVICE CLASSIFICATION

NPTEL

- Parameters for classification *in vitro* diagnostic medical devices is specified in Part II of the First Schedule,  
The medical devices and *in vitro* diagnostics shall be in the following classes, based on its risks:
  - Low risk - Class A
  - Low moderate risk - Class B
  - Moderate high risk - Class C
  - High risk - Class D

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

A man in a blue shirt is sitting at a desk with a laptop, presenting the slide.

Part I wherein the criteria and parameter for classification of the medical devices and part II of this schedule includes the parameter and classification of the in vitro diagnostic kits. As already we have discussed the based on the risk of the classes, low risk devices will be classified as a class A, low to moderate will classify as class B, moderate to high risk will classify as class C and high risk medical devices will be classified as a class D devices.

(Refer Slide Time: 46:30)

**CDSA** **MEDICAL DEVICE CLASSIFICATION** **NPTEL**

Lets check the classification of device again as per the MDR, 2017:

The provisions for classification of medical devices is prescribed in Rule 4, of MDR, 2017 .

- The Central Licensing Authority classify devices based on the intended use of the device and other parameters specified in the Schedule and published the list on the website of the Central Drugs Standard Control Organization. The Central Licensing Authority may, from time to time, modify the class of any medical device.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

In the Medical Device Rules though the definition of the medical device has been defined, but that definition is only w.r.t the definitions of the drugs as defined in section 3 b of Drugs and Cosmetic Act, 1940.

(Refer Slide Time: 46:56)

**CDSA MEDICAL DEVICE DEFINITION**

The medical device regulations (MDR, 2017) further refined the definition of medical devices as the definitions as per the Drugs Act is not comprehensive.

**"Medical device" means**

- 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).

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

So, this Medical Device Rules all the devices which are notified and covered under the definition of the drugs are only regulated.

Now, come to types of the devices, the devices we have discussed the category of the devices.

(Refer Slide Time: 47:17)

**CDSA MEDICAL DEVICE DEFINITION**


- Substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii).
- Devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Act.

**Explanation:** For the purpose of these rules, substances used for *in vitro* diagnosis shall be referred as *in vitro* diagnostic medical device.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

We have discussed the classification of the devices, now various types of the devices. The medical devices it is a very complex devices.

(Refer Slide Time: 47:30)



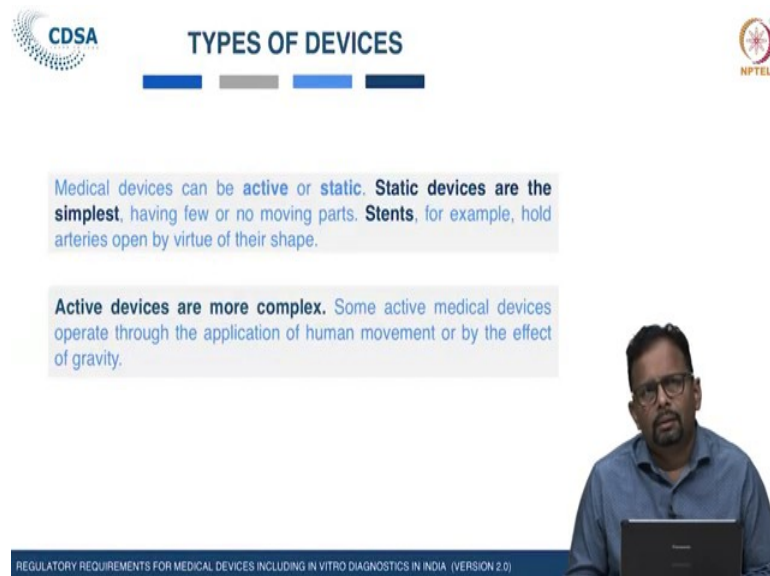
**CDSA** **SOME FACTS ABOUT MEDICAL DEVICES** **NPTEL**

- Devices constitute a huge variety of items.
- Devices can be as simple as a walking stick to a complex item as a MRI.
- Even software used for analyzing data is a medical device.
- Due to late entry into the regulatory framework, general awareness among the professionals in the country is low.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

It can be active or statics it varies, statics devices these devices are the simplest devices with having few or no moving parts. Example of this statics devices are cardiac stents, other types of the devices active devices are more complex.

(Refer Slide Time: 47:54)



**CDSA** **TYPES OF DEVICES** **NPTEL**

Medical devices can be active or static. **Static devices are the simplest**, having few or no moving parts. **Stents**, for example, hold arteries open by virtue of their shape.

**Active devices are more complex.** Some active medical devices operate through the application of human movement or by the effect of gravity.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

The active devices that operate through the applications of the human movement or effect defect of the gravity. If you see the example of the active devices, if you see the syringes, syringes is powered by the force applied by the patient or the medical professionals.

(Refer Slide Time: 48:12)

**CDSA** **TYPES OF DEVICES** **NPTEL**

A **syringe** is powered by the force applied by the patient or medical technician, while an **IV drip** is powered by gravity. Other devices can be activated by a patient's natural body movements, such as walking or breathing. These devices are categorized as **'passive'**.

**Active implantable medical devices** are powered devices that are inserted into a patient's body, through either a natural orifice or by surgical means, and are intended to remain in the patient's body after the procedure. Such devices are usually battery powered.  
Example: **Pacemaker**.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

While, in I V drip it is powered by the gravity, other devices can activated by the patient natural movement such as walking or the breathing. These devices are categorized as a passive devices, other types of the devices that is known as active implantable medical devices. These are the power devices, these devices are inserted into the patient body through either natural orifice or through surgical means. And, it is intended to remain in the patient body after the procedures. An example of this active implantable medical devices that is the pacemaker.

(Refer Slide Time: 49:11)

**CDSA** **TYPES OF DEVICES** **NPTEL**

**Non-invasive devices** are those that do not involve a break in the skin. There is no contact with the mucous membrane or internal body cavity other than through a natural or artificial body orifice.  
Examples: BP apparatus, CT scan, MRI, ECG etc.

**Combination medical device** is a device that involves a medical device and/or a drug and/or a biologic, combining any two of these product categories, and sometimes even all three.  
Examples: Drug-eluting stent (DES), which is a scaffold coated with a drug to prevent scar tissue from growing in an artery.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

Other types of the devices, non-invasive medical devices that devices there is a no contact with the mucous membrane or the internal body cavity. The example of non-invasive devices are BP apparatus, CT scan, ECG machines, MRI machines. Another types of the medical devices, the combination medical devices wherein the devices that involves the medical devices with the drugs or with the biological or combination of the devices, biologicals and drug materials.

The example one of the simple example of this combination devices that is Drug Eluting Stent(DES) wherein, the drug is coated on the surface of the cardiac stent made up of cobalt chromium, stainless steel or titanium.

(Refer Slide Time: 50:19)


**CDSA** **TYPES OF COMBINATION DEVICES** **NPTEL**

#	Description	Common example(s)
1	Convenience kit or co-package drug and device are provided as individual constituent parts within the same package.	Drug or biological product vials packaged with device(s) or accessory kits (empty syringes, auto-injectors, transfer sets), first aid or surgical kits containing devices and drugs.
2	Prefilled drug delivery device/ system drug is filled into or otherwise combined with the device and the sole purpose of the device is to deliver drug.	Prefilled drug syringe, auto-injectors, transdermal systems.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)


If you see the Medical Device Rule 2017, the Medical Device Rule 2017 we have also discussed that certain definitions related to the medical devices and in vitro diagnostic kits have been incorporated in the Medical Device Rule 2017.

(Refer Slide Time: 50:37)



### TYPES OF COMBINATION DEVICES

#	Description	Common Example(s)
3	Device coated/impregnated/ otherwise combined with drug. Device has an additional function in addition to delivering the drug.	Drug-eluting stents, condoms with spermicide, antimicrobial coated catheters/sutures, bone cements with antibiotics.
4	Other type of Part 3 combination product (e.g., Drug/Device/ Biological Product) combination product not otherwise described.	All 3 articles are combined in a single product (e.g., prefilled syringe containing an antibody-drug conjugate).



REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

So, certain definitions of various types of the medical devices which we have discussed just now is also prescribed in the Medical Device Rule 2017.

(Refer Slide Time: 50:55)



### MEDICAL DEVICES RULES, 2017 INCLUDES

**"Active diagnostic medical device"** means any active medical device used, whether alone or in combination with other medical devices, to supply information for detecting, diagnosing or monitoring, or to provide support in the treatment of, any physiological condition, state of health, illness or congenital deformity.

**Examples:** Hepatitis or IV tests, clinical chemistry, coagulation test systems, urine test strips, pregnancy tests.



REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

If you see the active diagnostic medical devices, that definition of this devices has been defined as per the Medical Device Rule 2017. The active diagnostic medical devices mean any active medical devices used whether alone or in combination with other medical devices, to supply information for detecting diagnosis or monitoring or to provide support in the treatment of any physiological conditions, a state of health, illness

or congenital deformity. So, this definition has been defined, if you see the example of this active diagnostic medical devices; hepatitis or IV test, coagulation test.

(Refer Slide Time: 51:55)



The slide features the CDSA logo on the left and the NPTEL logo on the right. The title "MEDICAL DEVICES RULES, 2017 INCLUDES" is centered at the top. Below the title, a light blue box contains the definition: "Active medical device" means a medical device, the operation of which depends on a source of electrical energy or any other source of energy other than the energy generated by human or animal body or gravity. Below this, examples are listed: Cardiac pacemakers, defibrillators, cochlear implants etc. In the bottom right corner, there is a video inset of a man with glasses and a blue shirt sitting at a laptop. At the bottom of the slide, a dark blue footer contains the text "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

**CDSA** MEDICAL DEVICES RULES, 2017 INCLUDES

**NPTEL**

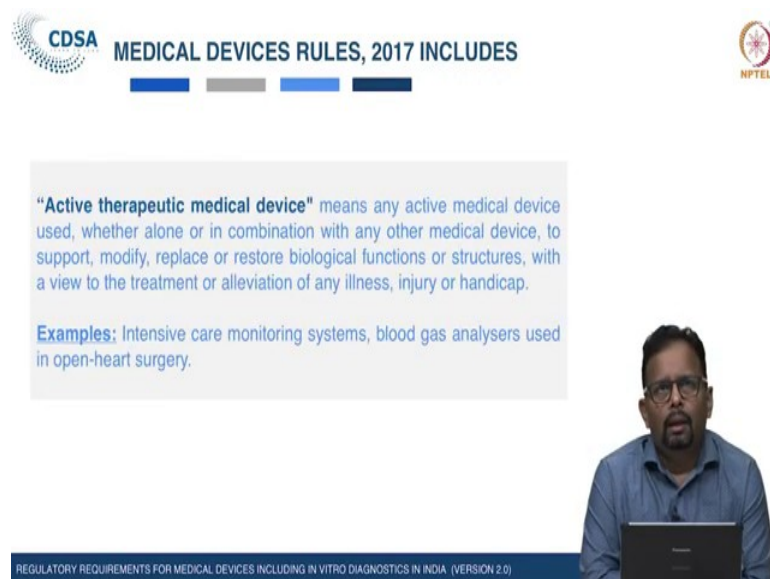
**"Active medical device"** means a medical device, the operation of which depends on a source of electrical energy or any other source of energy other than the energy generated by human or animal body or gravity.

**Examples:** Cardiac pacemakers, defibrillators, cochlear implants etc.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

Active medical devices, as per the definition prescribed in the Medical Device Rule 2017, it means medical devices; the operation of which depends on the source of the electrical energy or any other source of the energy other than the energy generated by human or animal body or gravity. The example cardiac pacemaker.

(Refer Slide Time: 52:20)



The slide features the CDSA logo on the left and the NPTEL logo on the right. The title "MEDICAL DEVICES RULES, 2017 INCLUDES" is centered at the top. Below the title, a light blue box contains the definition: "Active therapeutic medical device" means any active medical device used, whether alone or in combination with any other medical device, to support, modify, replace or restore biological functions or structures, with a view to the treatment or alleviation of any illness, injury or handicap. Below this, examples are listed: Intensive care monitoring systems, blood gas analysers used in open-heart surgery. In the bottom right corner, there is a video inset of a man with glasses and a blue shirt sitting at a laptop. At the bottom of the slide, a dark blue footer contains the text "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

**CDSA** MEDICAL DEVICES RULES, 2017 INCLUDES

**NPTEL**

**"Active therapeutic medical device"** means any active medical device used, whether alone or in combination with any other medical device, to support, modify, replace or restore biological functions or structures, with a view to the treatment or alleviation of any illness, injury or handicap.

**Examples:** Intensive care monitoring systems, blood gas analysers used in open-heart surgery.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)



Active therapeutic medical devices this definition is also included and the definition is prescribed that any active medical devices used whether alone or in combination with any other medical devices to support, modify, replace or restore biological functions or structure with the view to the treatment or alleviation of any illness injury or handicap. Active therapeutic medical devices if you see the examples: the blood gas analyzer.

(Refer Slide Time: 52:55)

CDSA MEDICAL DEVICES RULES, 2017 INCLUDES

**"Invasive device"** means a device which, in whole or part, penetrates inside the body, either through a body orifice or through the surface of the body.

**Examples:** Suture needles, hypodermic needles and syringes.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

Invasive devices this definition is also defined in the Medical Device Rule 2017, invasive devices means a devices which in whole or part penetrate inside the body either through the body verifies or through the surface of the body. The example of this devices are suture surgical sutures, hypodermic needles and syringes.

(Refer Slide Time: 53:20)



CDSA MEDICAL DEVICES RULES, 2017 INCLUDES

**"Active implantable medical device"** means a medical device which is intended to be totally or partially introduced, surgically or medically, into the human or animal body or by medical intervention into a natural orifice and which is intended to remain after the procedure.

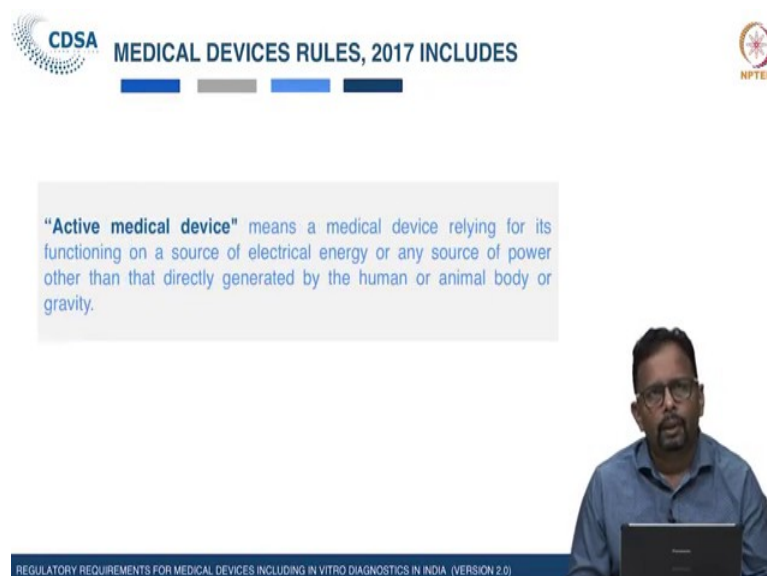
**Examples:** Cardiac pacemakers, defibrillators.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

The slide features a presenter in the bottom right corner and logos for CDSA and NPTEL in the top corners.

Active implantable devices also defined in the Medical Device Rule 2017 and the active medical devices which is the intended to be totally or partially introduced surgically or medically into the human body or the animal body or by the medical intervention into the nature of orifice and which is intended to remain after the procedures. And, that implantable devices examples are defibrillators, cardiac pacemakers. So, these definitions have already been defined in the Medical Device Rule 2017.

(Refer Slide Time: 53:57)



CDSA MEDICAL DEVICES RULES, 2017 INCLUDES

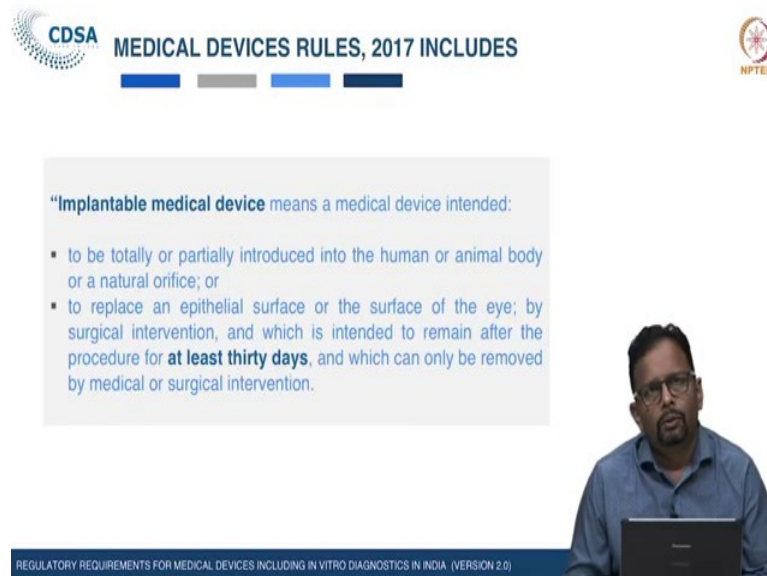
**"Active medical device"** means a medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human or animal body or gravity.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

The slide features a presenter in the bottom right corner and logos for CDSA and NPTEL in the top corners.

Active medical devices also defined, implantable medical devices it is also defined in the Medical Device Rule 2017.

(Refer Slide Time: 54:07)



CDSA MEDICAL DEVICES RULES, 2017 INCLUDES

NPTEL

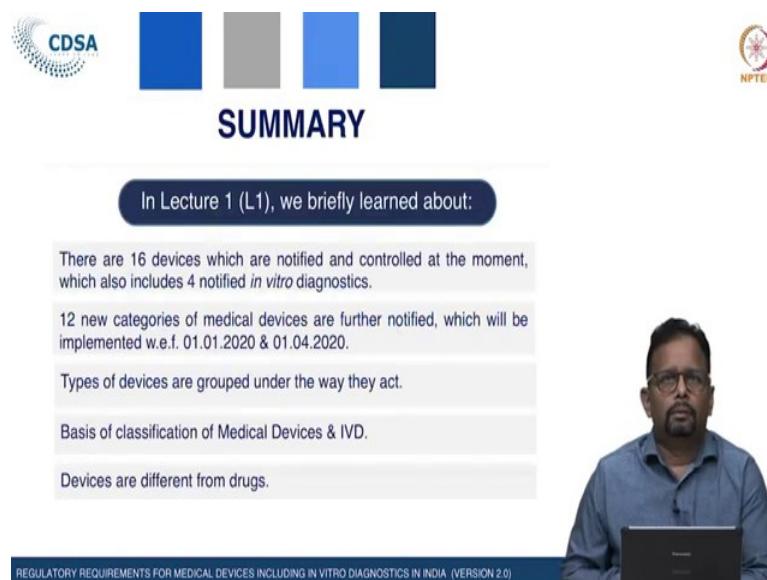
"Implantable medical device" means a medical device intended:

- to be totally or partially introduced into the human or animal body or a natural orifice; or
- to replace an epithelial surface or the surface of the eye; by surgical intervention, and which is intended to remain after the procedure for **at least thirty days**, and which can only be removed by medical or surgical intervention.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

So, these are the various types of the medical devices which is defined in the Medical Device Rule 2017.

(Refer Slide Time: 54:16)



CDSA

NPTEL

## SUMMARY

In Lecture 1 (L1), we briefly learned about:

- There are 16 devices which are notified and controlled at the moment, which also includes 4 notified *in vitro* diagnostics.
- 12 new categories of medical devices are further notified, which will be implemented w.e.f. 01.01.2020 & 01.04.2020.
- Types of devices are grouped under the way they act.
- Basis of classification of Medical Devices & IVD.
- Devices are different from drugs.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

In this lecture we have covered the general definition of the medical devices, we have covered what is the devices regulated under the Medical Device Rule 2017; so, Drugs and Cosmetic Act 1940, what are the different types of the devices, what are the devices

which have been notified by the Government of India for regulations. Why the requirement of the new regulation of Medical Device Rule 2017.

So, we have the general idea about the regulations and we also understand what is the difference between drugs and diagnostics. Why this sector is required separate identity other than the drugs we have discussed in details. Now, let us have some question answer session to know what you have understood..

(Refer Slide Time: 55:23)

**Question & Answer**

- 1 State whether the following statement is true or false  
Pacemaker is an example of active device  
True
- 2 Fill in the blanks  
\_\_\_\_\_ penetrating the human body surface  
are at a higher risk.  
Invasive device
- 3 State whether the following statement is true or false  
Only notified medical devices and IVDs are regulated  
under D & C Act.  
True

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

So, tell me whether the state which is mentioned here is correct or not. The devices pacemaker is the example of the active devices, whether it is true or false can anybody tell? It is true.. Now, which devices penetrating the human body surface are at higher risk, the category of the devices can anybody tell? That devices is known as invasive devices.

Now, also another question; under the Medical Device Rule 2017 in India whether only the notified medical devices and in vitro diagnostics are regulated, whether this statement is true or false. Yeah, only notified medical devices are regulated, it is true. So, with this question answer session we will conclude this lecture and we will discuss the details of other requirement of the medical device regulation in the subsequent lecture.

Thank you very much.