Regulatory Requirements for Medical Devices Including in Vitro Diagnostics in India (Version 2.0)

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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.

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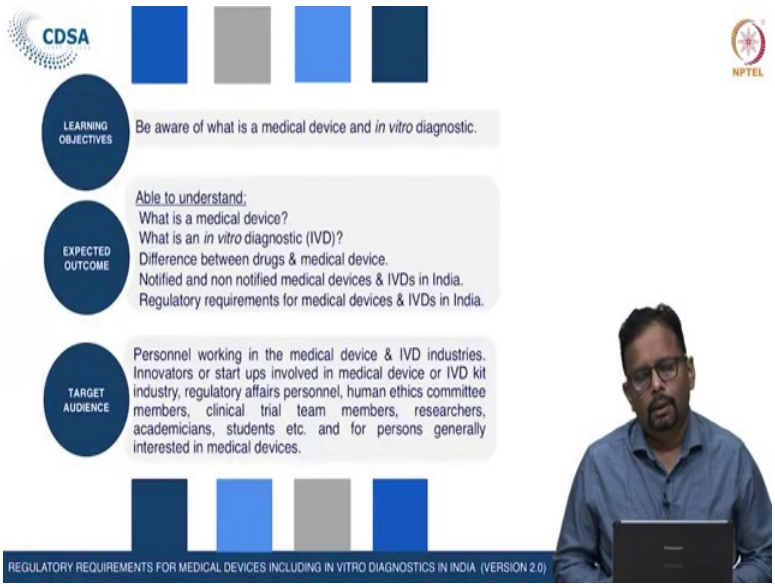

Learning objectives of this presentation be aware what is the medical devices and in vitro diagnostics. The expected outcome of this lecture; we will be able to know what is a medical devices, what is aIn vitro diagnostics, what is the difference between drugs and devices? What are the notified medical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

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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?

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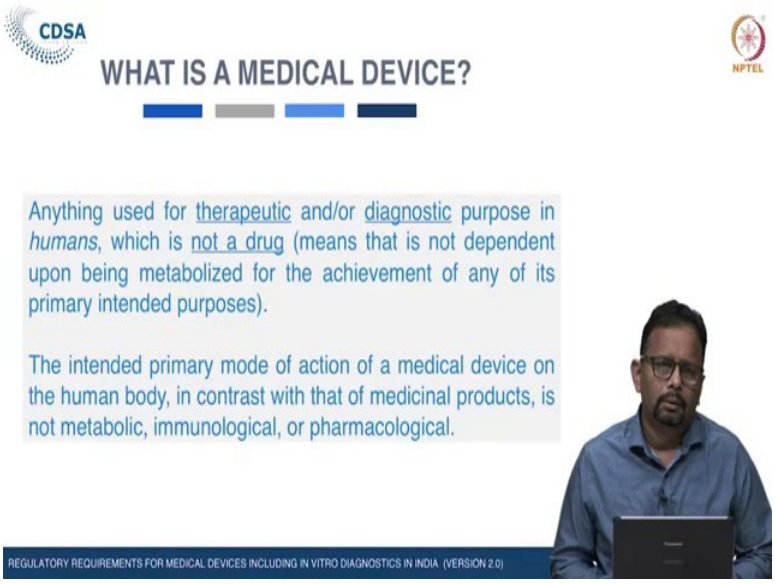

So, what is the definition of the medical devices? If you see the medical devices, in general we can say anything used for diagnostic or therapeutic purpose in human being which is not a drug. Simple word we can say it is not a drug, but it is used for the purpose of therapeutic or diagnostics in human 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.

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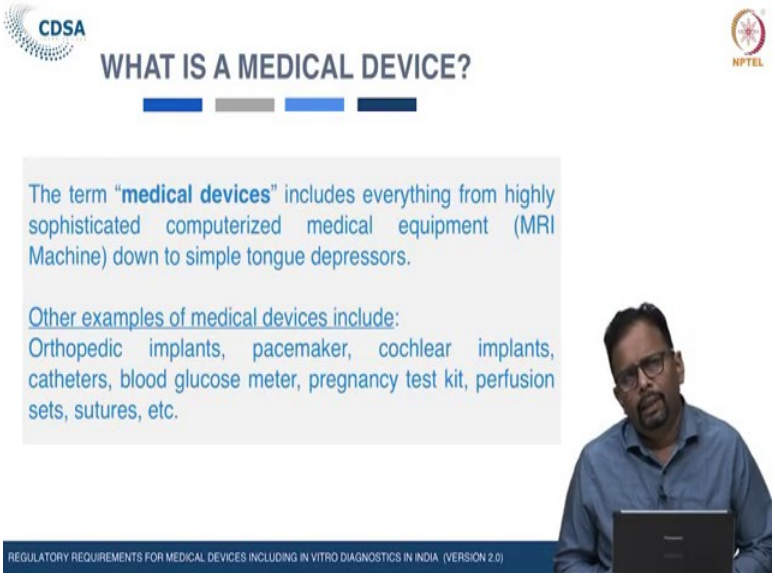

And, the medical device includes everything which is not a drug and it is used for the diagnostic or therapeutic purpose. It varies from highly sophisticated computerized medical equipment like MRI machines or the simple medical devices that is tongue depressors, very vast range of the medical devices.

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 reffer as medical devices and diagnostics.

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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.

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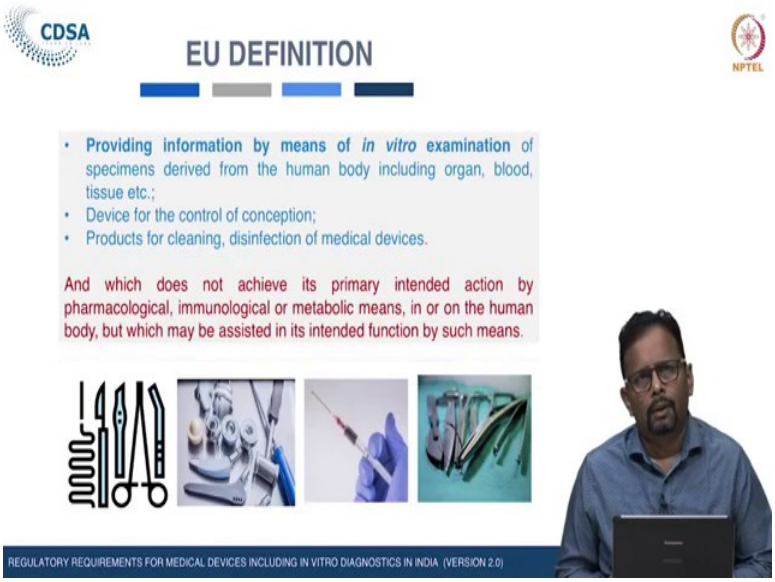

Next purposes of this products; it provides information by means of in vitro examination of the specimen derived from the human body including organ, blood or tissues etc. It is for the purpose of in-vitro examination and it is for the purpose of control of conception. It is for the purpose of cleaning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

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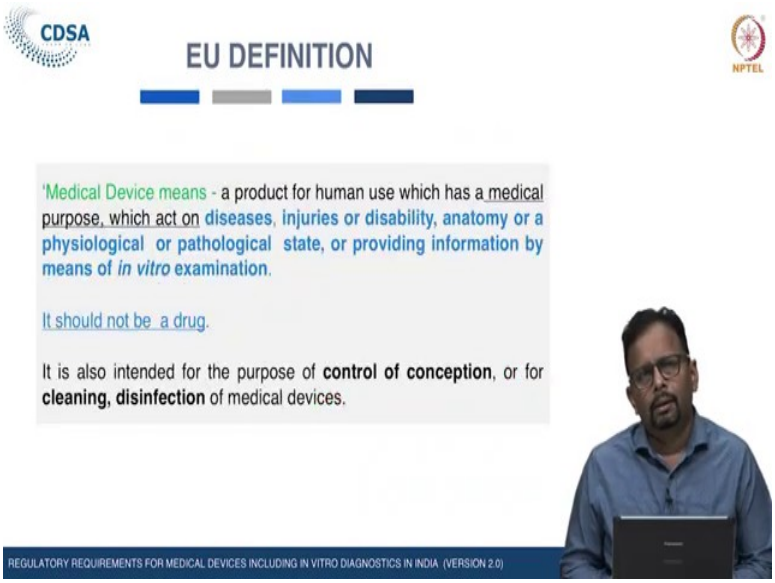

This is the definition as per the European Union regulation, this is the EU definition. So, if you see the definitions and you can summarize the definition in such a way, it is a product for human use which has a medical purposes and which act on the disease, injuries or disability or anatomy or physiological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

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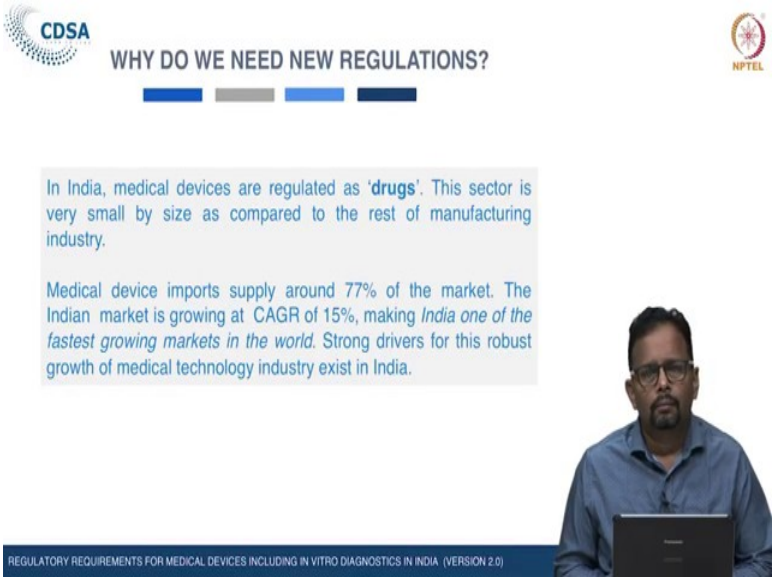

If you see the Indian regulation w.r.t the medical devices, in India medical devices are regulated as a 'drug'. This sector is a small sector as compared to the pharmaceutical or medicinal products. This sector mainly depends on the import more than 75 percent of the material or the devices are being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

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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.

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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 regulationand, 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 far 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.

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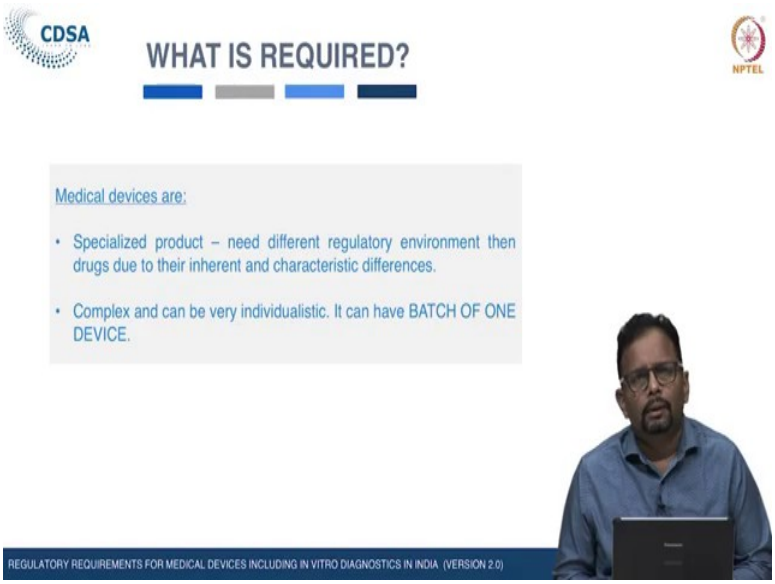

We know that medical device is a specialized product, it is different from the drugs, it is very complex product,It varies from simple product to highly sophisticated, high and medical equipments, it is used by everyone.

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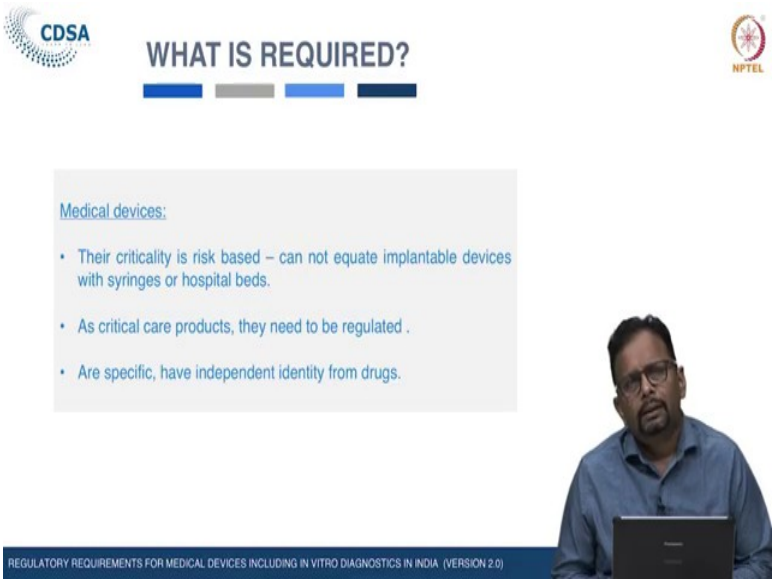

So, this medical device sector they require independent identity from the drugs. Why it is different from the drugs?

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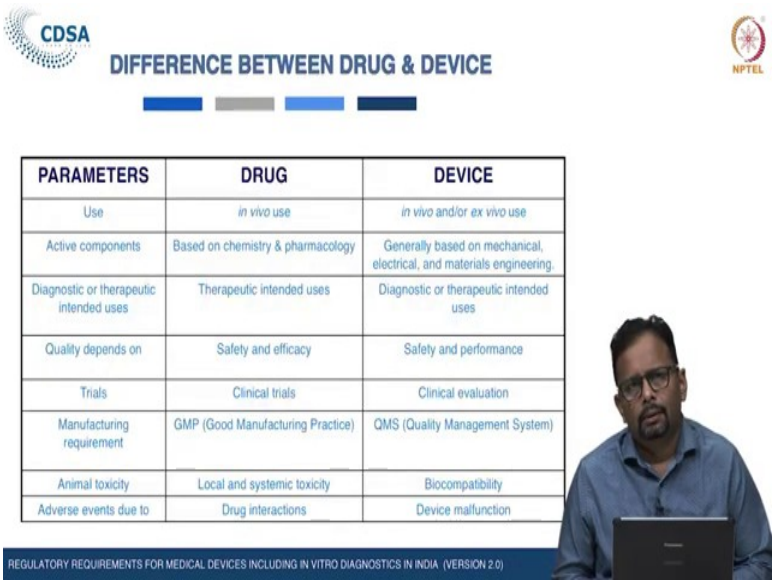

PARAMETERS	DRUG	DEVICE
Use	*in vivo* use	*in vivo* and/or *ex vivo* use
Active components	Based on chemistry & pharmacology	Generally based on mechanical, electrical, and materials engineering.
Diagnostic or therapeutic intended uses	Therapeutic intended uses	Diagnostic or therapeutic intended uses
Quality 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

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 whereasin 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.

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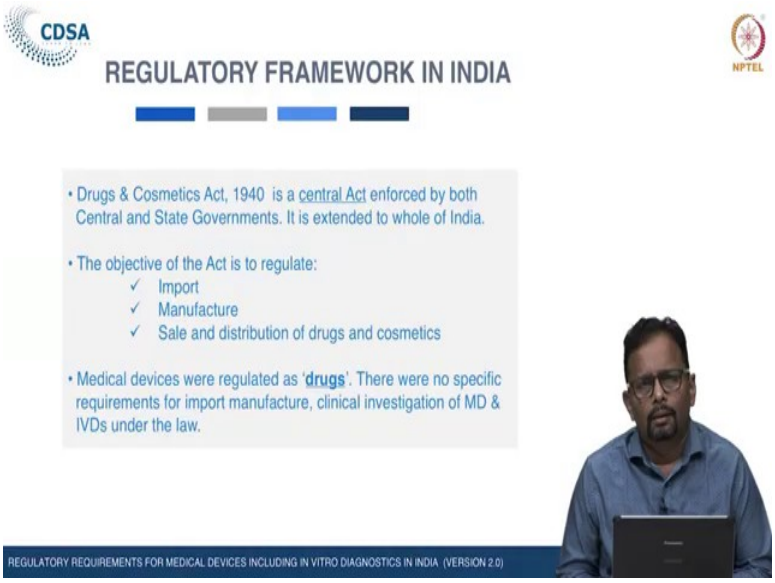

Now, what is the medical device regulation? If you show the regulation in the previous slides we have discussed what is the new regulation. But, actual regulation if you see the medical devices and in vitro diagnostics these are regulated as a drug as we have already discussed. And, the law under which 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.

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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.

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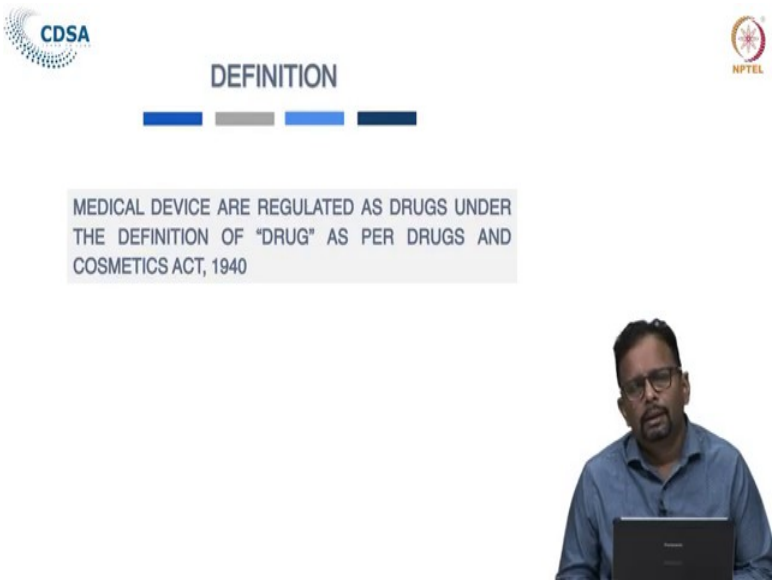

If you see the definition of the medical devices under the definition prescribed in the Drugs and Cosmetic Act, we have discussed internationally what is the medical device definition.

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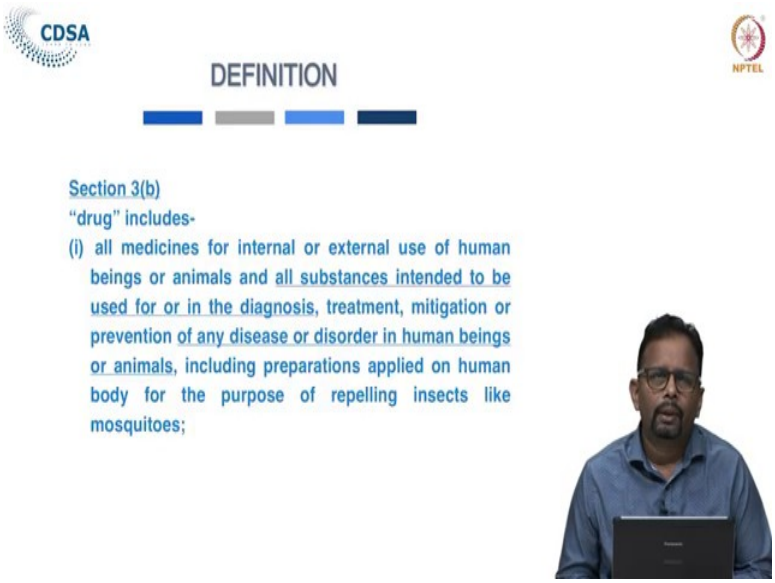

If you see, if you compare this definition with our device definition which is prescribed in the Drugs and Cosmetic Act, 1940; the drug definition is defined in the section 3 b of the act. And, this section have four different part and the devices are covered under this definition. If you see the part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

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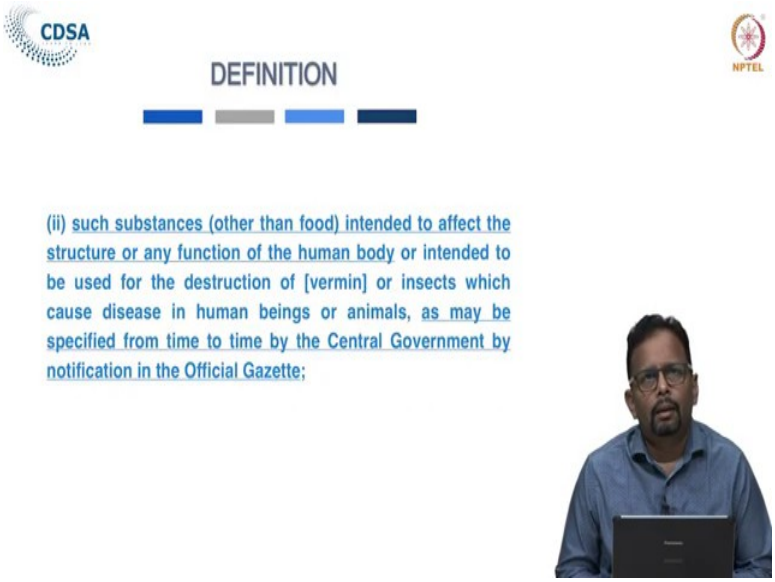

The part ii of the drug definition under section 3 b which states the substances which affect the structure or any function of the human body as may be specified from time to time by the Central Government through notification in the Official Gazette. Under this clause only two categories of the devices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

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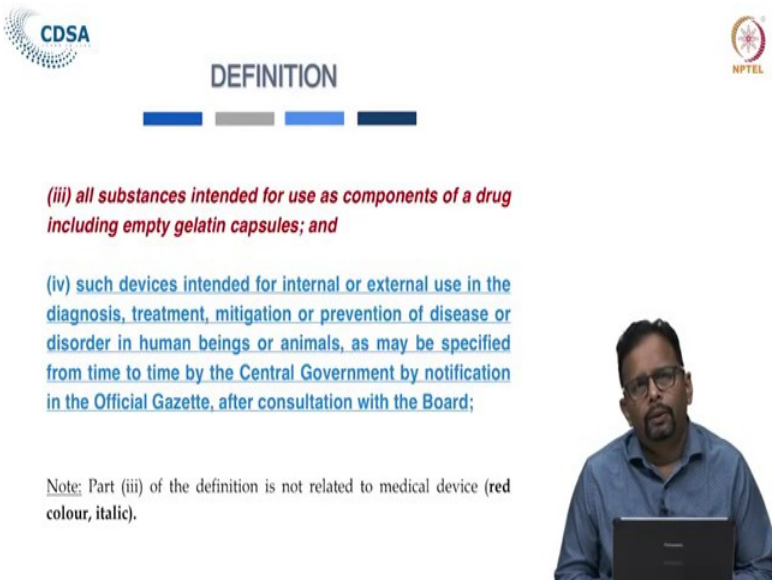

And, these are the mechanical contraceptives and disinfectants. So, these two categories of the medical devices are regulated under this clause of the drug definitions. And, if you see the fourth clause of the definition of the drugs under section 3 b which states that any devices intended for internal 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.

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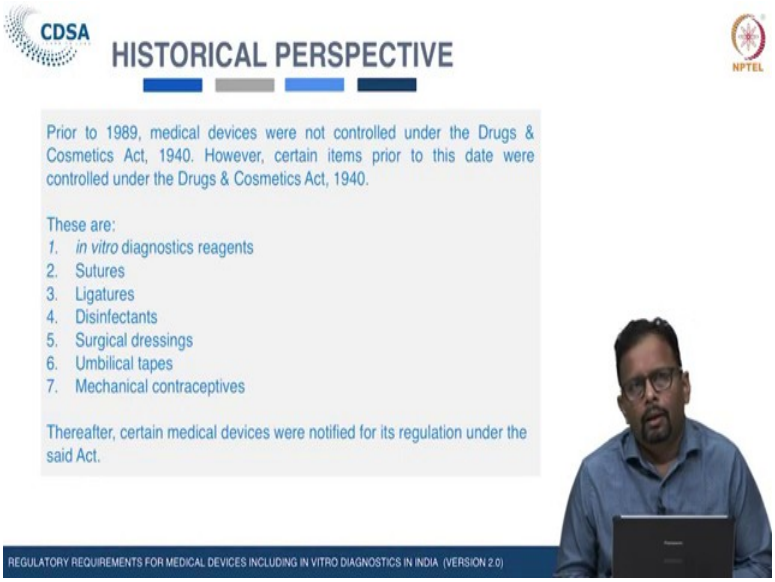

If you see the history perspective of the medical devices under the Drugs and Cosmetic Act , 1940 and Drugs and Cosmetic Rules 1945, the first notification of the medical devices certain medical devices was done in the year 1989.

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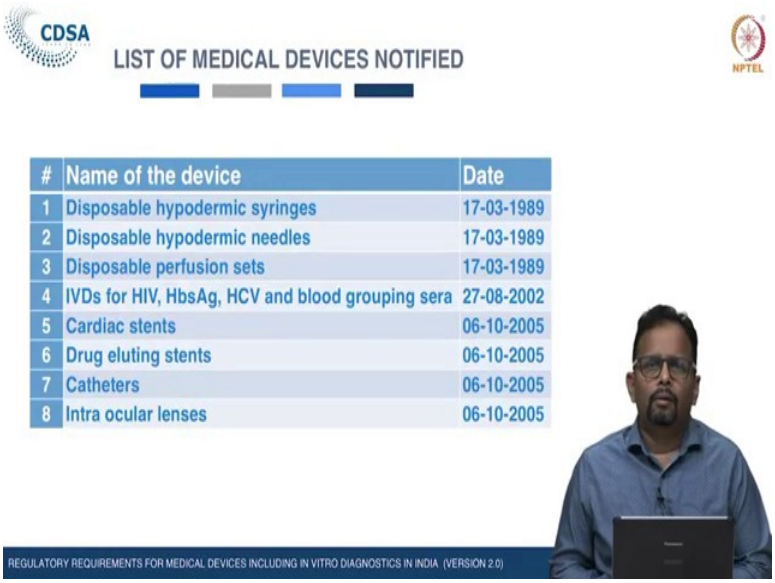

And, in the year 1989 the three different categories of the medical devices have been notified under the class 4 of the drug definition. And, those three devices are hypodermic needle, hypodermic syringes and perfusion sets. And, before that notification of these three medical devices certain the devices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

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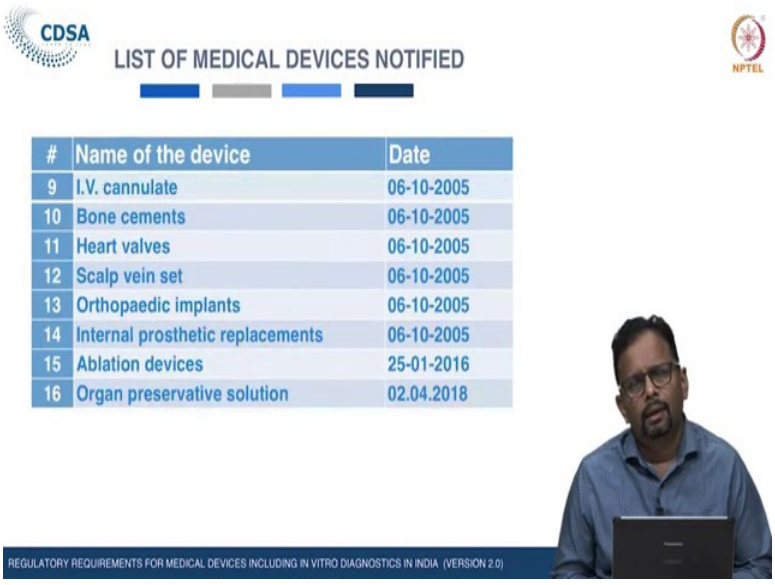

Bone cements, heart valves, scalp vein sets, orthopedic implants, internal prosthetic replacement, ablation catheter which was notified in the year 2016 and in 2018 the organ preservative solutions also notified as a devices. So, these 16 categories of the medical devices are under regulations presently.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

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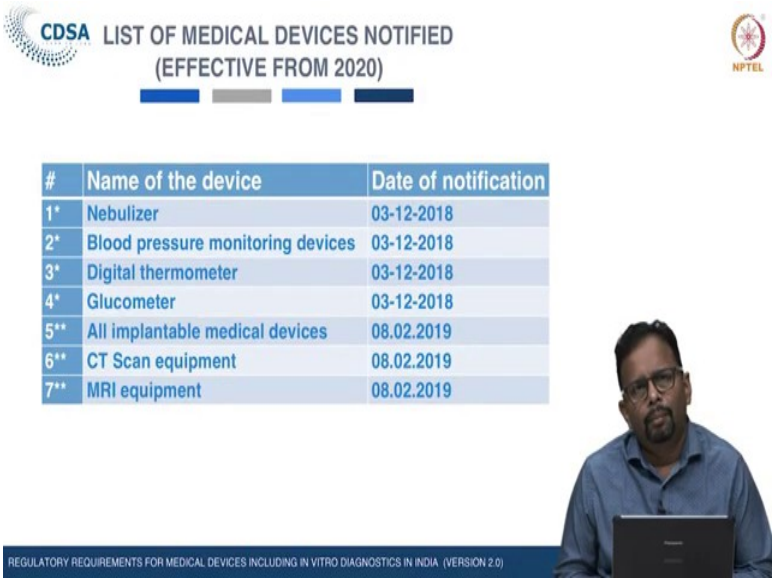

And, in the month of February 2019, 8 new categories of the medical devices are also notified.

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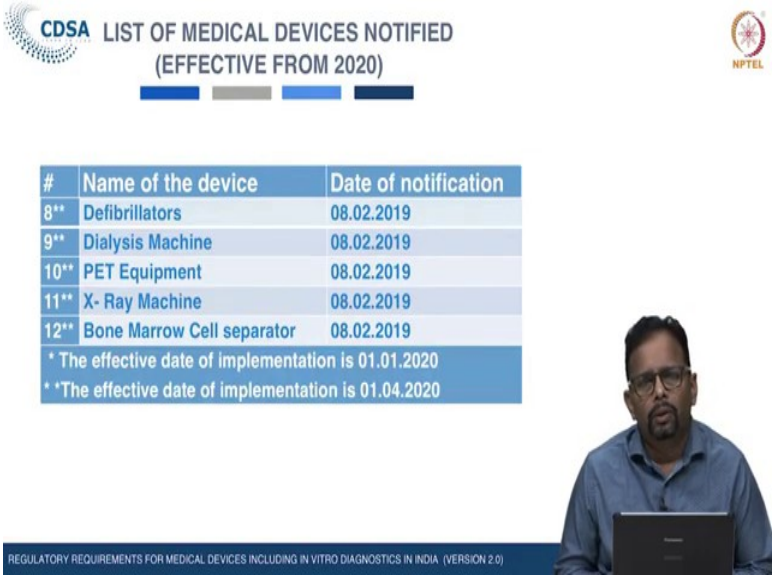

And, the implementation date of this new categories of the medical devices, will be in the January 2020. So, certain time period has been given to the stakeholders for implementation of regulation of this new categories of the medical devices.

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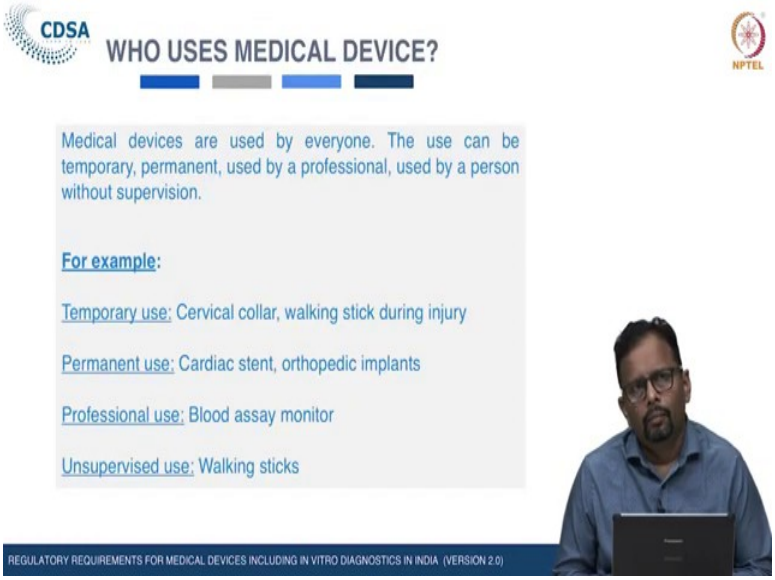

Now, who uses the medical devices?

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.

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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.

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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 disinfect disinfectant solution.

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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.

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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.

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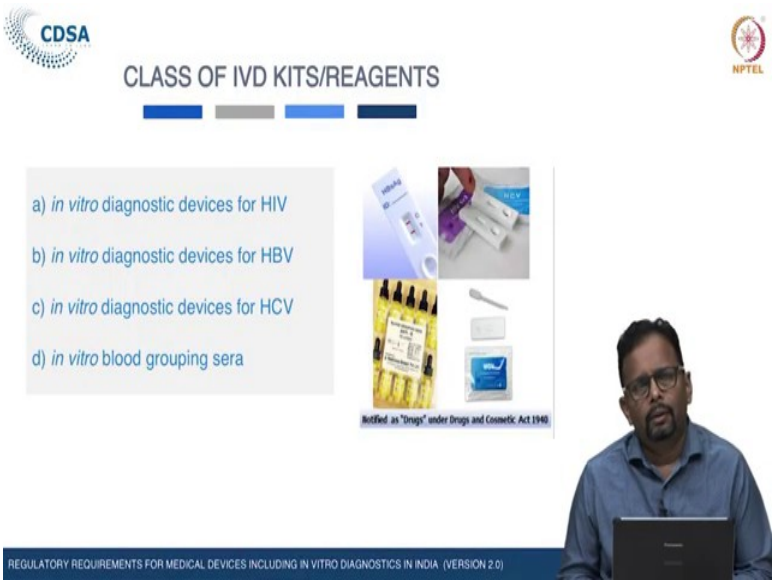

The devices which is showing on the presentation whether it is regulated Yes, it is regulated, it is a disposable hypodermic needles which is a notified medical devices. Now, this is disposable hypodermic syringes, it is also regulated. Now, this one is cardiac stent which is also notified and regulated. 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?

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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.

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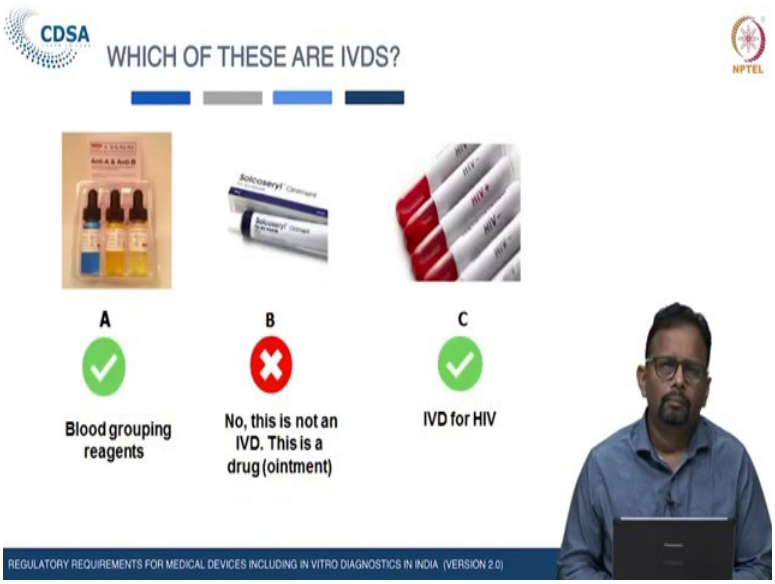

May also for the in vitro diagnostic kits you have to see whether these products which is showing on the presentation is regulated or not yes it is a. What is this devices? This is in vitro diagnostic kits, these kits is known as blood grouping reagents and it is regulated. Now, the another one that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

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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.

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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.

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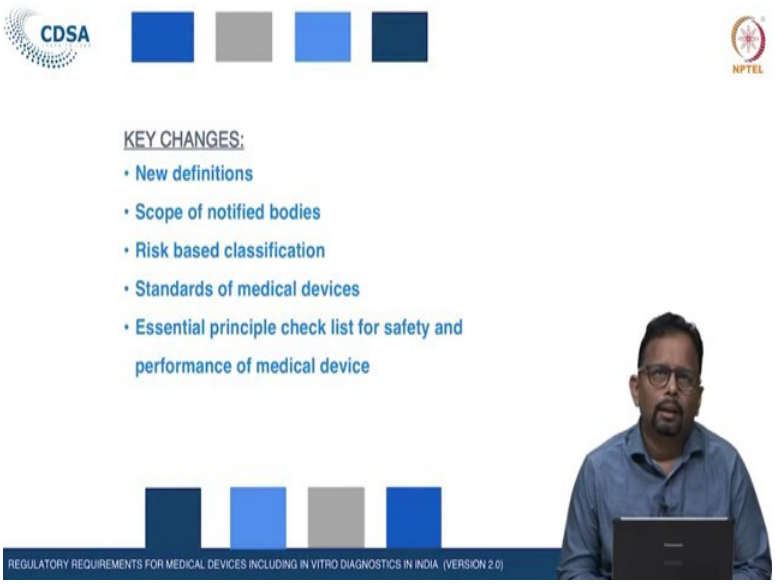

But, in short we have to understand what are the key changes incorporated in this Medical Device Rule 2017. If you see this Medical Device Rule 2017, the key changes in this Medical Device Rule various definitions related to medical devices and in vitro diagnostics diagnostic kits have been prescribed 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.

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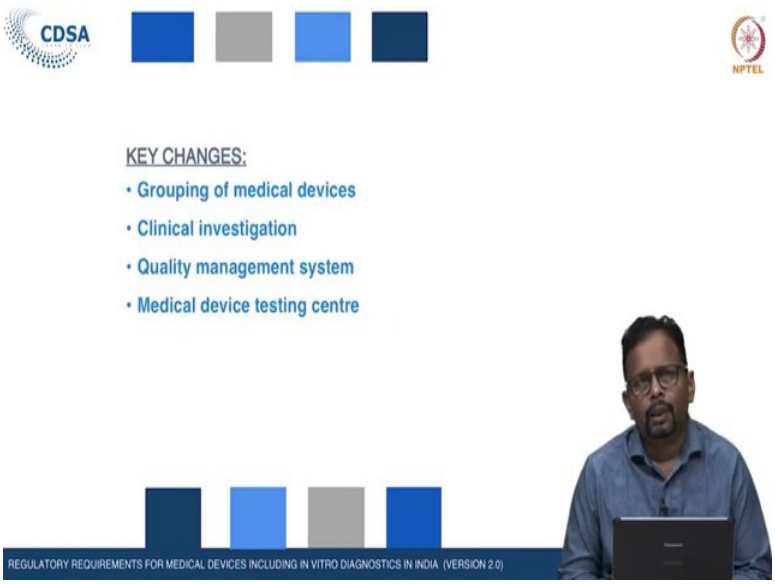

The provision for the grouping of the medical devices, provision for clinical investigation of the medical devices, provision for quality management system. The provision for medical device testing center, this is specific provision that has been incorporated and these are the key changes. We will discuss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

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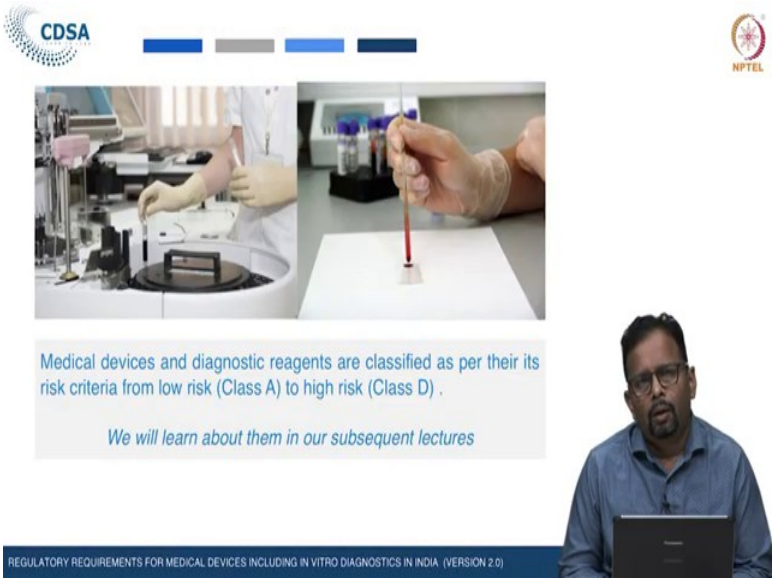

If you see the classification of the medical devices, globally how these medical devices and in vitro diagnostics have been classified; it is based on the risk criteria. And, in the

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.

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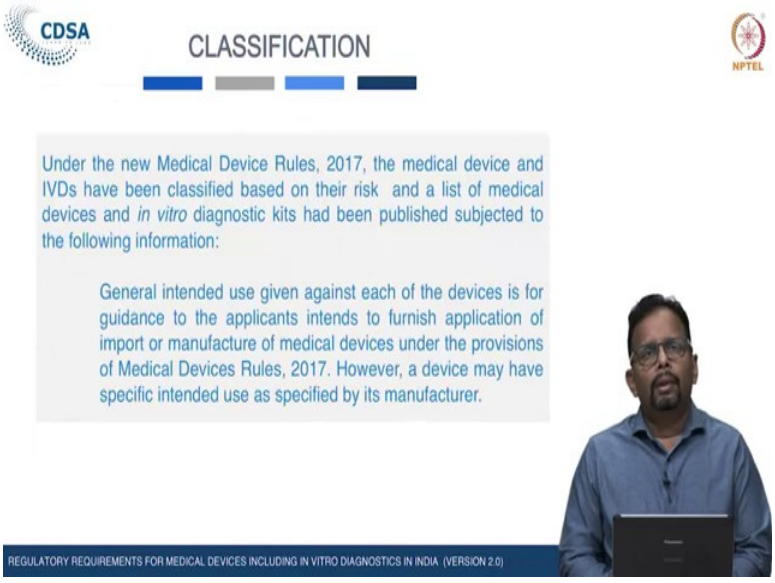

And, the responsibility for classification is lies with the Central Licensing Authority(CLA) that is Drugs Controller General India, who is the center licensing authority, also heading the Central Drug Standard Controller Organization that is the central government bodies for regulation of the Medical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

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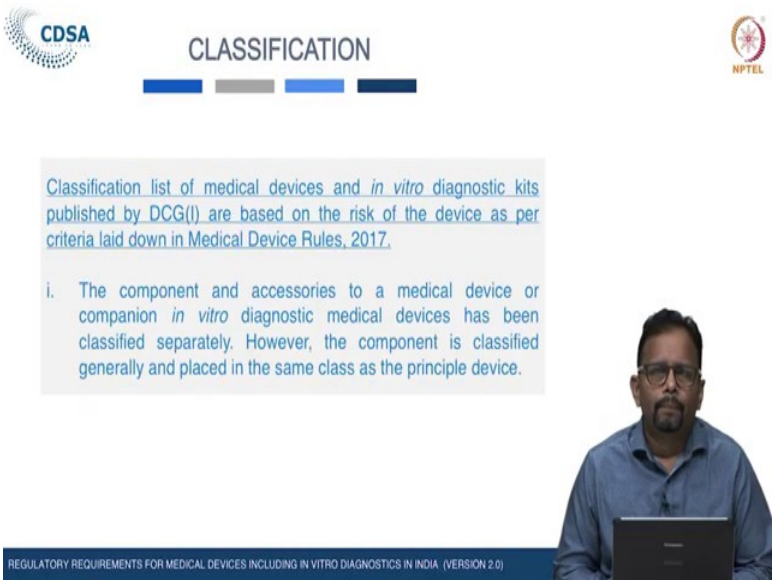

And, based on the criteria laid down in the MDR rule 2017, the center licensing authority has classified the devices and in vitro diagnostics. And, these classification list has been uploaded in the website for the stakeholder which includes the manufacturers or importers. And, based on the classification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

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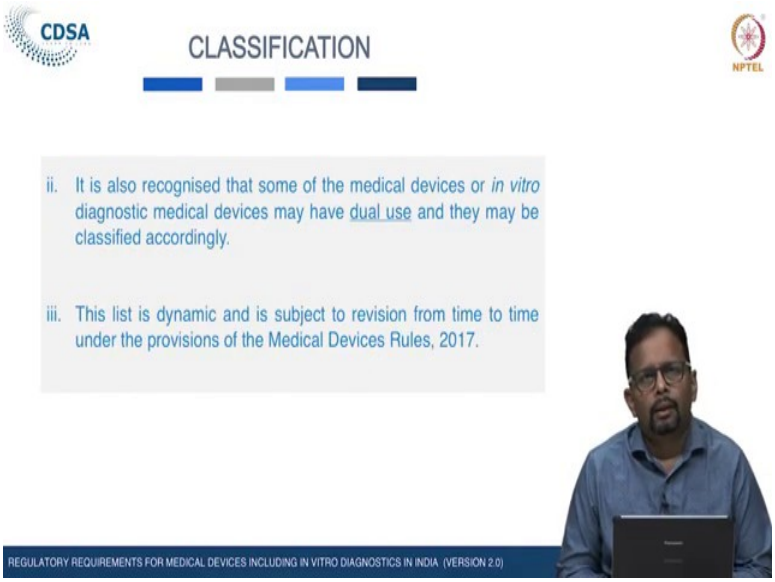

This classification list, it is a dynamic classification list. If certain devices or in vitro diagnostic kits is classified in a particular class, the classification of that particular

medical devices or in vitro diagnostics will varies 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.

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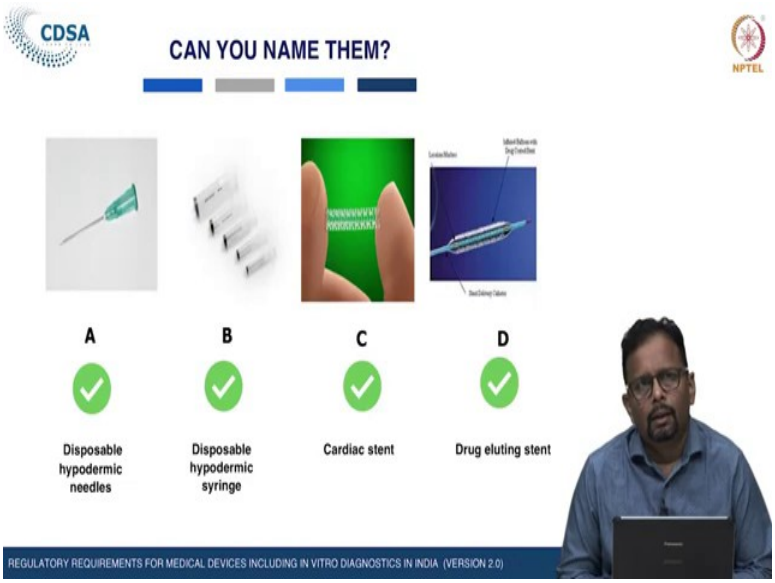

The components and accessories of the medical devices also classified under these categories. Now, categories of the medical devices.

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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.

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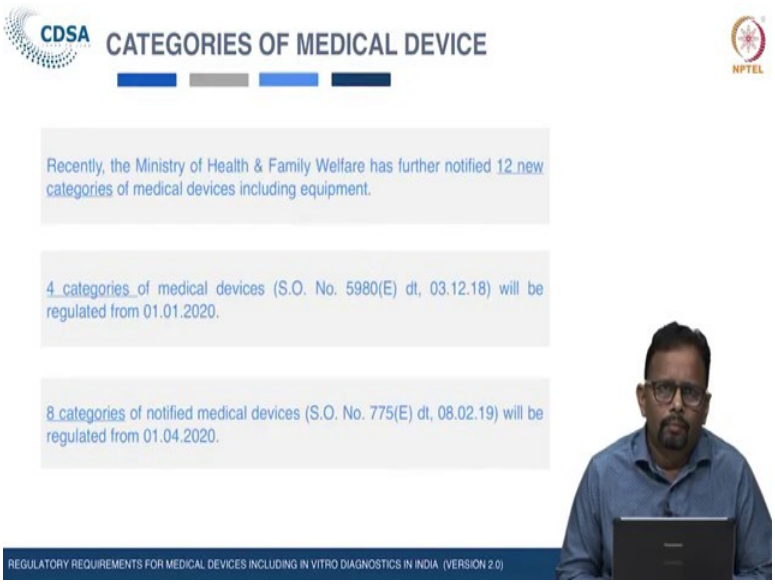

And, these different categories based on the notification of the Government of India, Ministry of Health and Family Welfare; these different categories of the medical devices has been classified based on the risk associated with the devices or in vitro diagnostics as well as its intended use. And, under 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.

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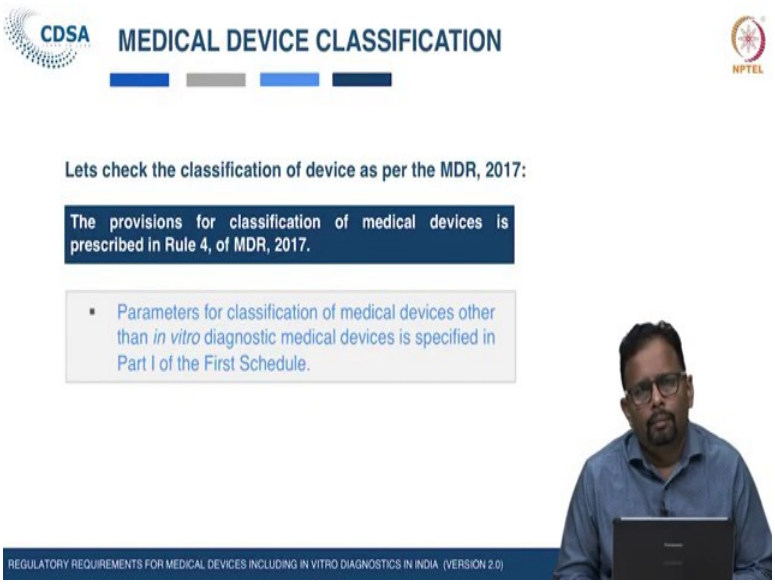

Medical device classification we have also discussed, the provision have already been made in the Medical Device Rule 2017 under rule iv which gives the power to the Central Licensing Authority for notification of the medical, notification of the classification list for the stakeholders. And, the parameter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

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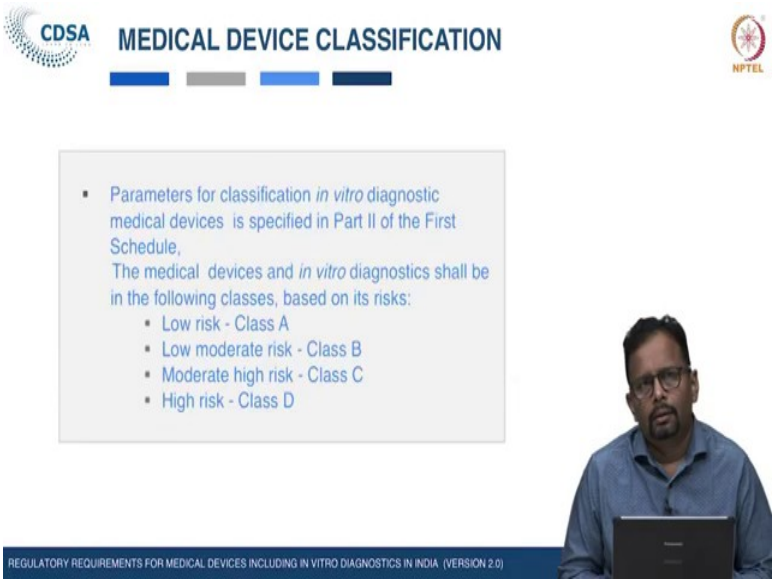

Part I wherein the criteria and parameter for classification of the medical devices and part II of this schedule includes the parameter and classification of the in vitro diagnostic kits. As already we have discussed the based on the risk of the classes, low risk devices will be classified as a class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

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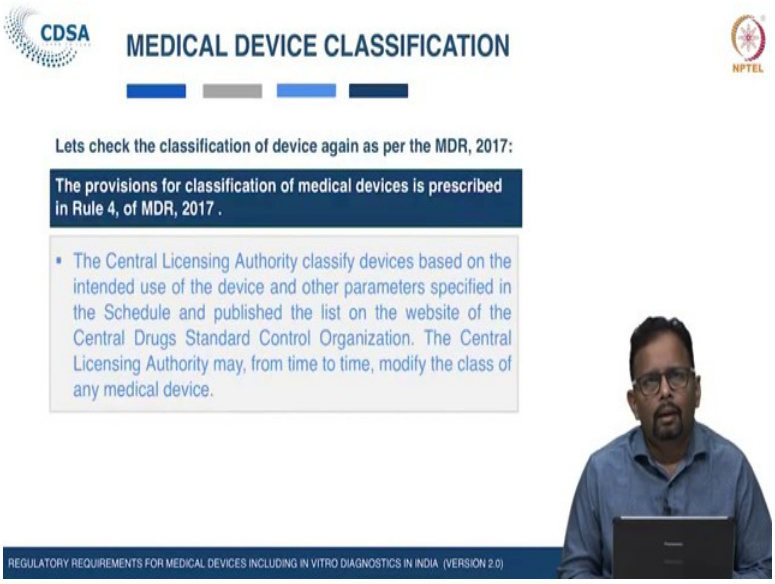

In the Medical Device Rules though the definition of the medical device has been defined, but that definition is only w.r.t the definitions of the drugs as defined in section 3 b of Drugs and Cosmetic Act, 1940.

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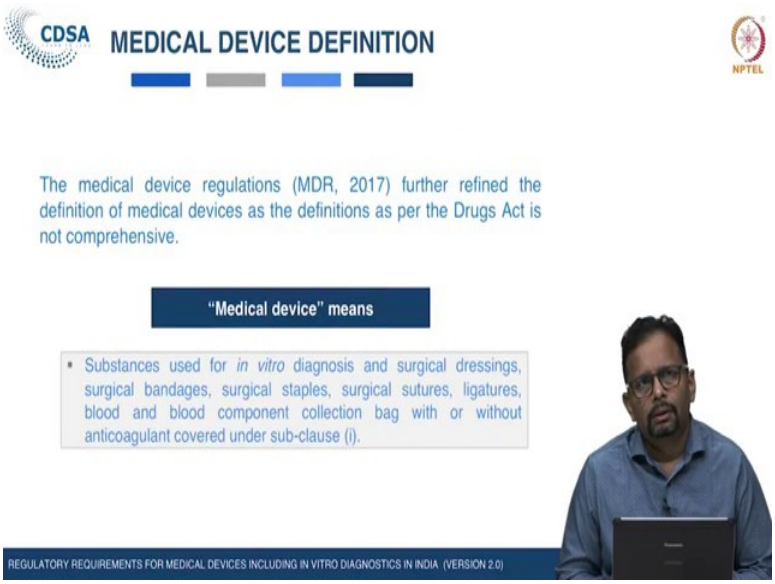

So, this Medical Device Rules all the devices which are notified and covered under the definition of the drugs are only regulated.

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

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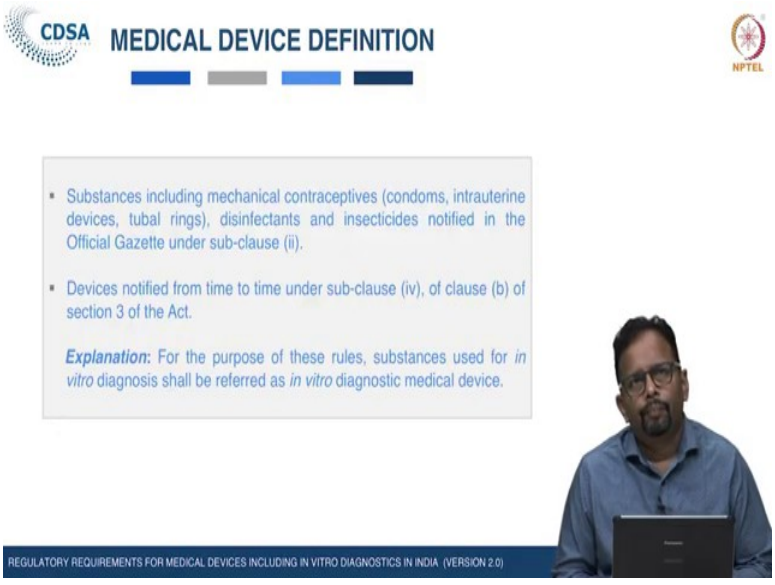

We have discussed the classification of the devices, now various types of the devices. The medical devices it is a very complex devices.

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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.

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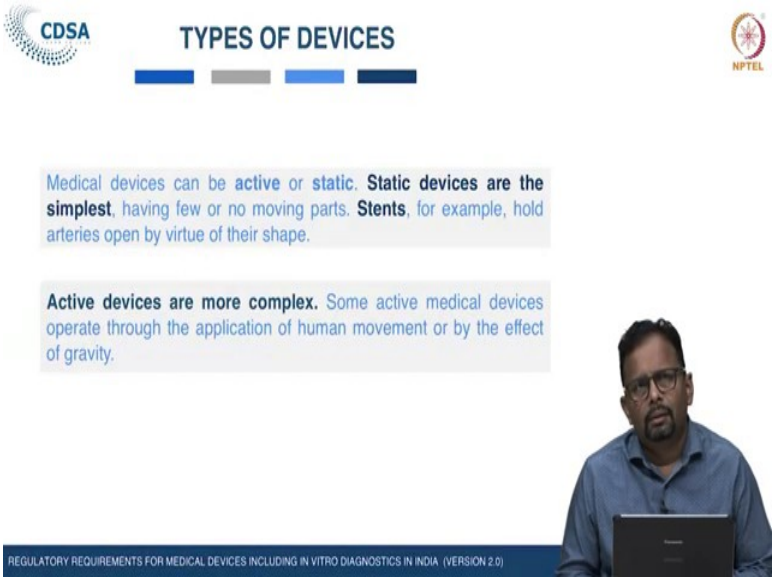

The active devices that operate through the applications of the human movement or effect defect of the gravity. If you see the example of the active devices, if you see the syringes, syringes is powered by the force applied by the patient or the medical professionals.

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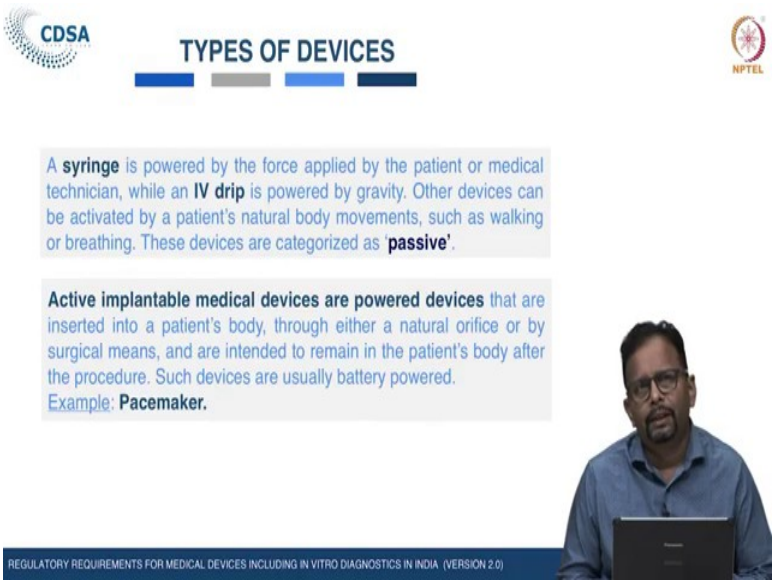

While, in I V drip it is powered by the gravity, other devices can activated by the patient natural movement such as walking or the breathing. These devices are categorized as a passive devices, other types of the devices that is known as active implantable medical devices. These are the power devices, 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.

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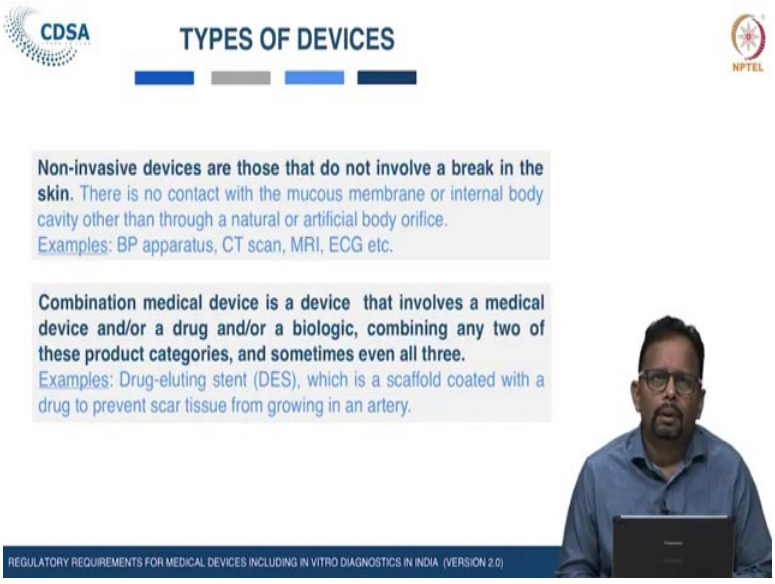

Other types of the devices, non-invasive medical devices that devices there is a no contact with the mucous membrane or the internal body cavity. The example of non-invasive devices are BP apparatus, CT scan, ECG machines, MRI machines. Another types of the medical devices, the combination medical devices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

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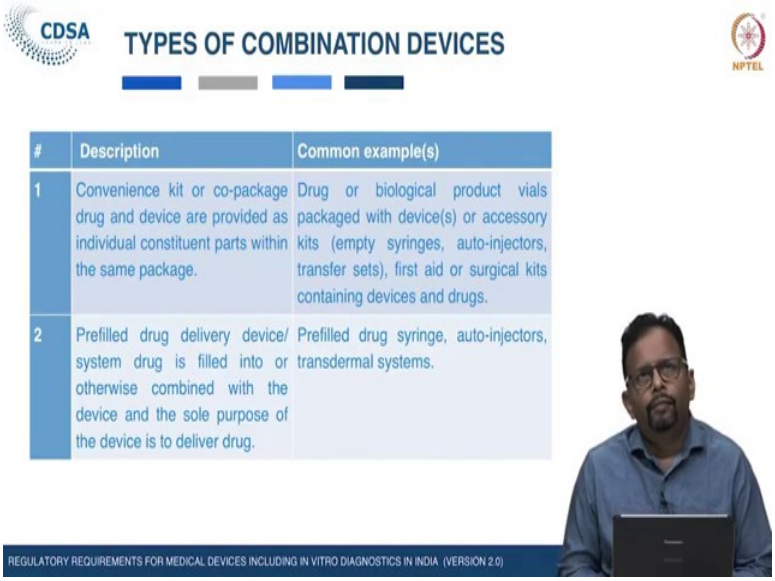

If you see the Medical Device Rule 2017, the Medical Device Rule 2017 we have also discussed that certain definitions related to the medical devices and in vitro diagnostic kits have been incorporated in the Medical Device Rule 2017.

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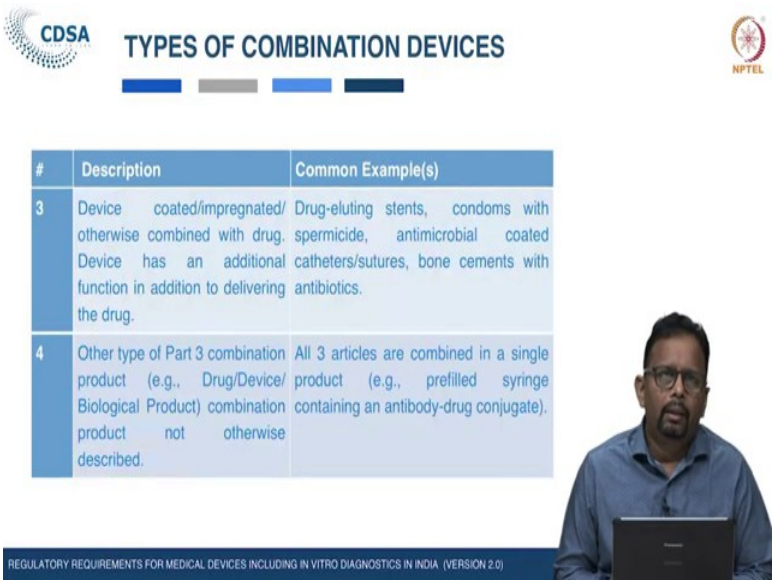

So, certain definitions of various types of the medical devices which we have discussed just now is also prescribed in the Medical Device Rule 2017.

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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.

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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.

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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.

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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.

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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.

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

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

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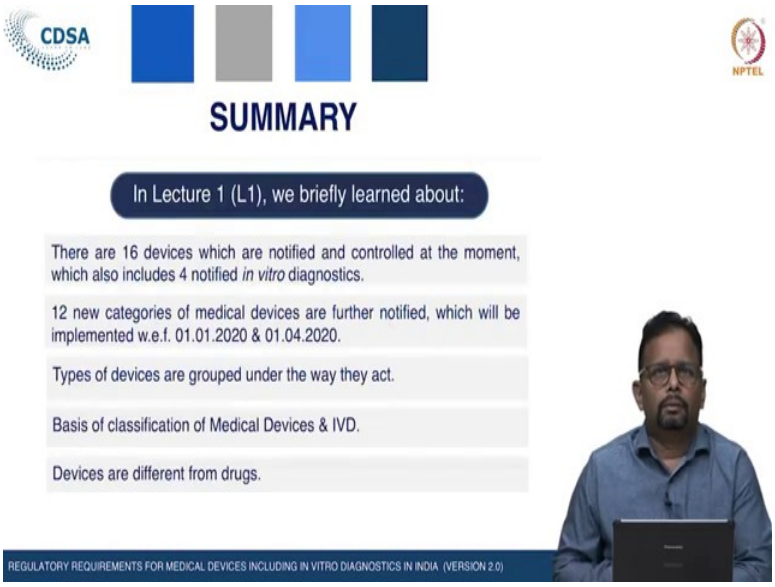

In this lecture we have covered the general definition of the medical devices, we have covered what is the devices regulated under the Medical Device Rule 2017; so, Drugs and Cosmetic Act 1940, what are the different types of the devices, what are the devices

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..

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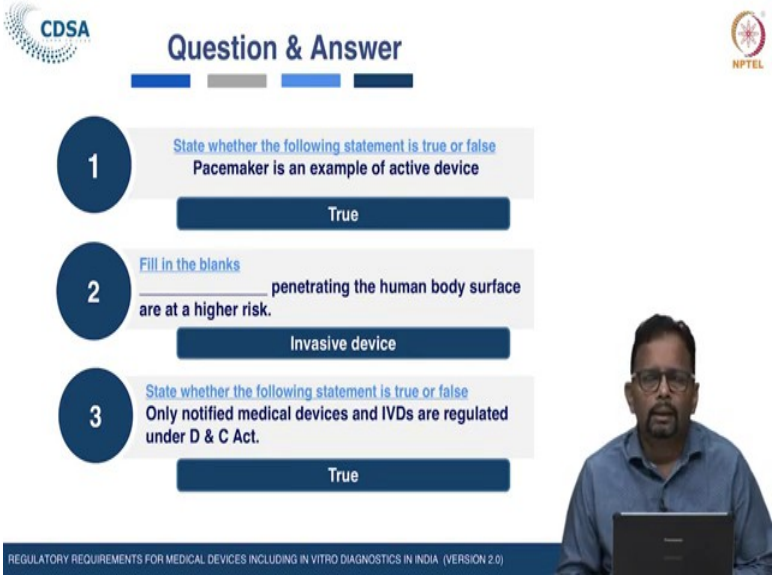

So, tell me whether the state which is mentioned here is correct or not. The devices pacemaker is the example of the active devices, whether it is true or false can anybody tell? It is true.. Now, which devices penetrating the human body surface are at higher risk, the category of the devices can anybody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