Regulatory Requirements for Medical Devices and IVDs in India

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Lecture – L1
Medical Device and IVD: Introduction

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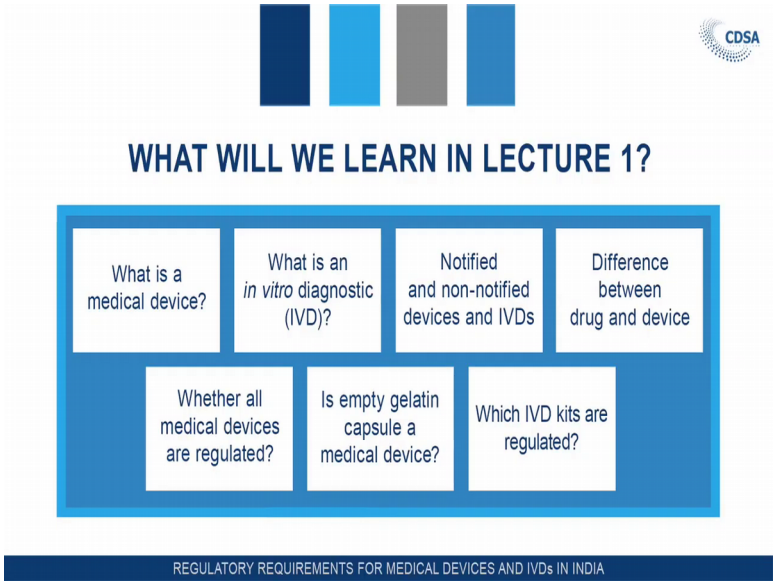

Welcome to Regulatory Requirement for Medical Devices and In Vitro Diagnostics in India. Lecture 1 that is Medical Devices and In Vitro Diagnostic Introduction what we will learn in this lecture? We will learn what is the medical devices? What is an in vitro diagnostics? Which law regulates medical devices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

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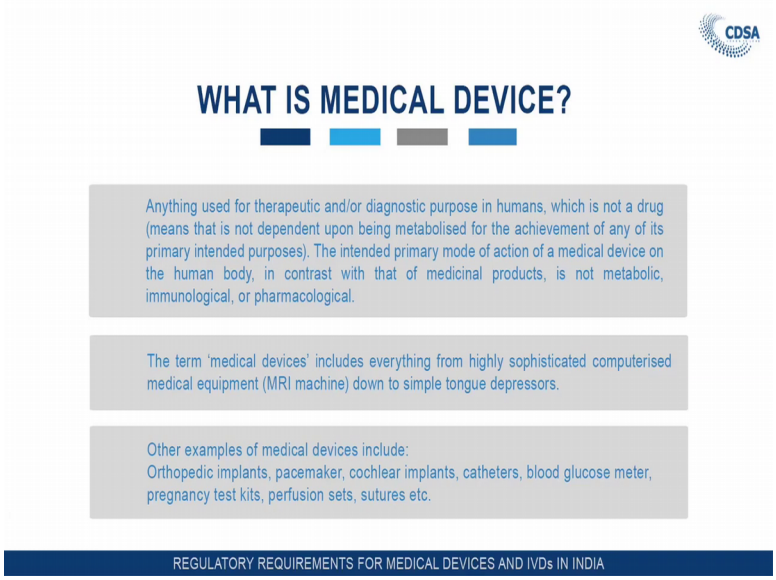

In general term medical devices means anything used for therapeutic and or diagnostic purpose in humans, which is not a drugs that we can say that is the medical devices. It means that it is not dependent upon being metabolised for the achievement of any of its primary intended purpose. The intended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

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

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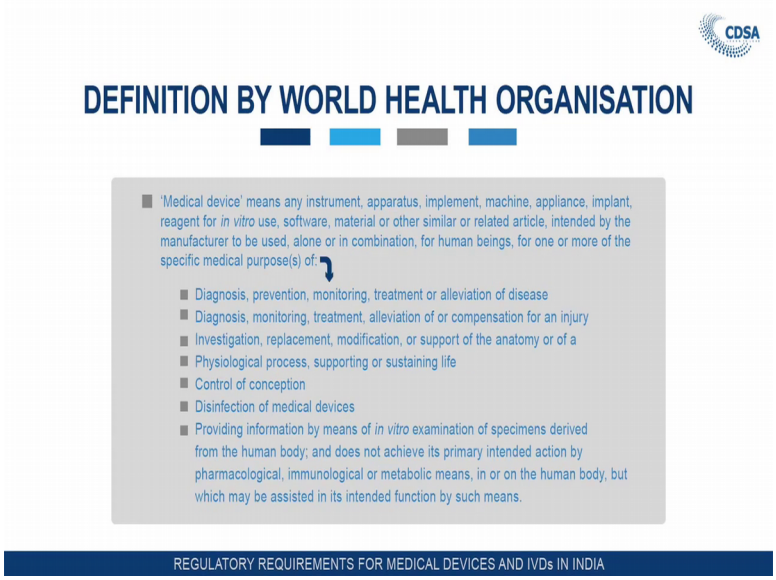

But the main content of the definition will be the same. Just have you look on the definition of the medical devices as per the WHO. WHO defines medical devices means any instrument, operators, implement, machine, appliances, implant, reagents, reagent for in vitro use, software, material or other similar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

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

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

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

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

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

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

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

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

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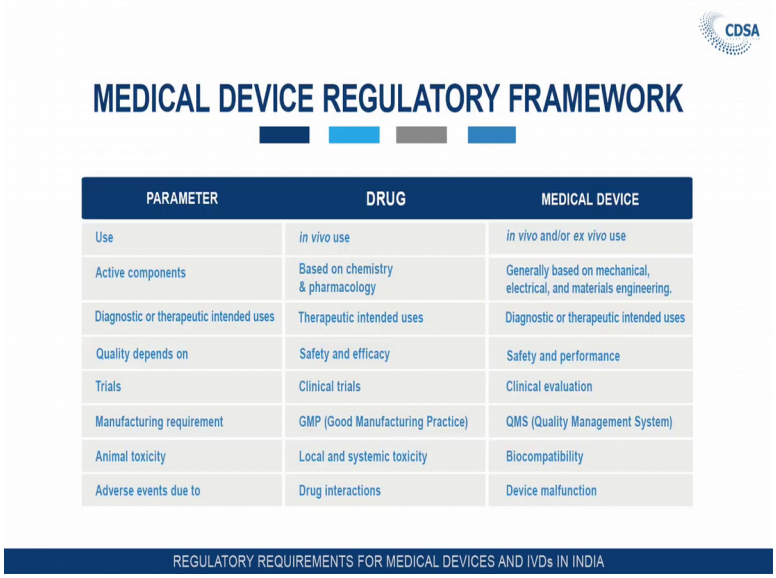

Now, the drugs and medical devices regulatory system, differs because of the because of their inherent and characteristic differences. And some of the example for this differences, we will discuss here. If you see the drug, in the drug generally drugs are used in vivo; however, the medical devices may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

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

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

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

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

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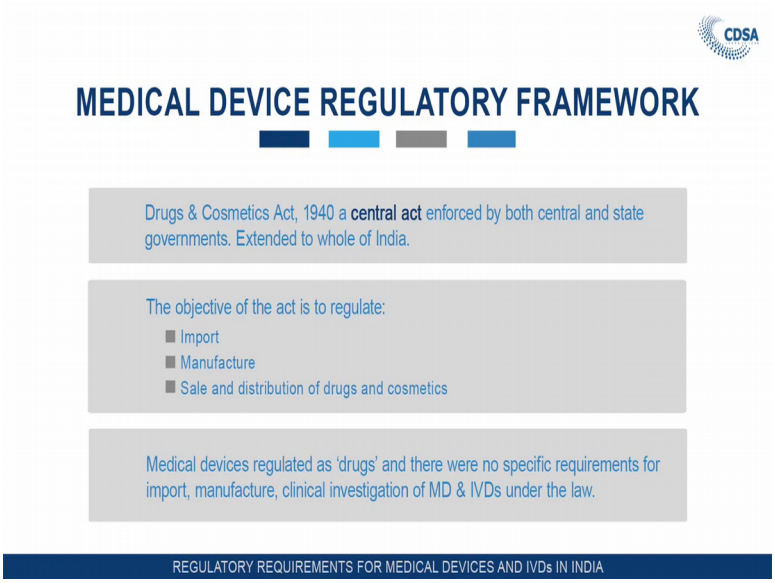

What is the medical device regulation in India? Presently the medical devices are regulated as a drug under the provisions of Drugs and Cosmetic Act 1940. This Act is just intellect enforced by both central as well as state the control department, the state governments and this act is extended to whole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

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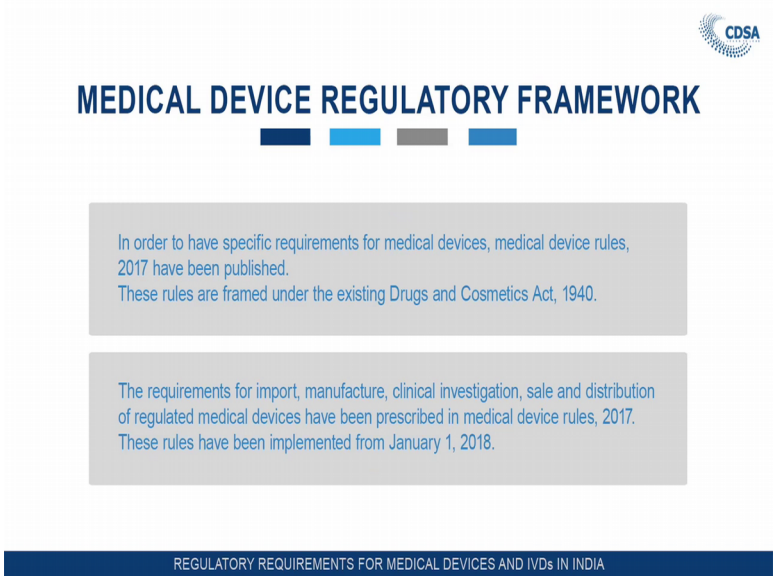

Therefore, in order to have the specific requirement for medical devices, the medical device rule, 2017 have been published. And these rules are frame under the existing Drugs and Cosmetic Act, 1940. The specific requirement for import, manufacture, clinical investigation, sale and distribution of the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

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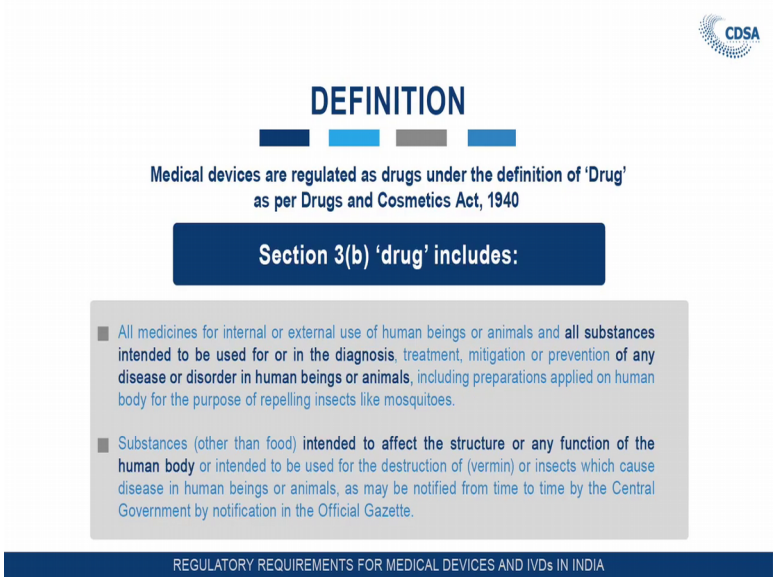

So, under this Drugs and Cosmetic Act; the medical devices are regulated as a drug. So, definition of the drugs covers the medical devices. The section 3 b of the Drugs and Cosmetic Act define the definition of the drugs.

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

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

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

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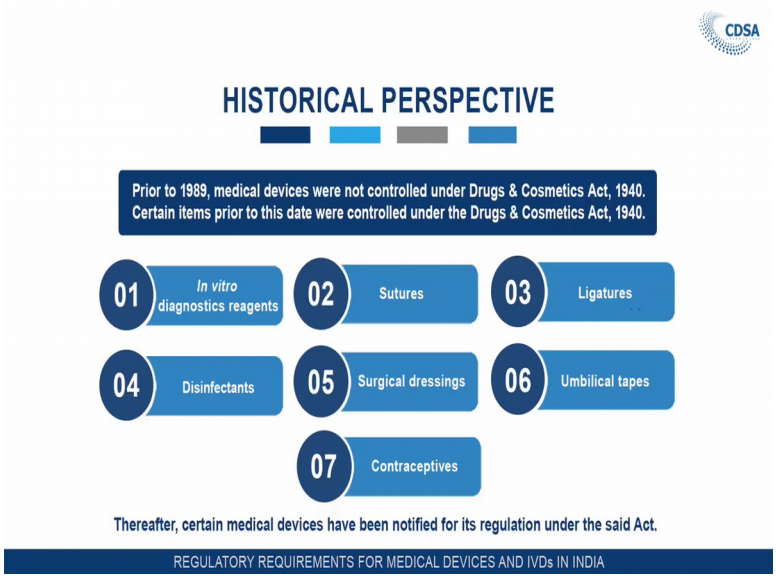

Now, historical perspective of the medical devices if you see, prior to 1989 the medical devices were not controlled under the Drugs and Cosmetics Act, 1940. However, the certain items prior to this date were controlled under the Drugs and Cosmetic Act, 1940. These are the in vitro diagnostic reagents,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

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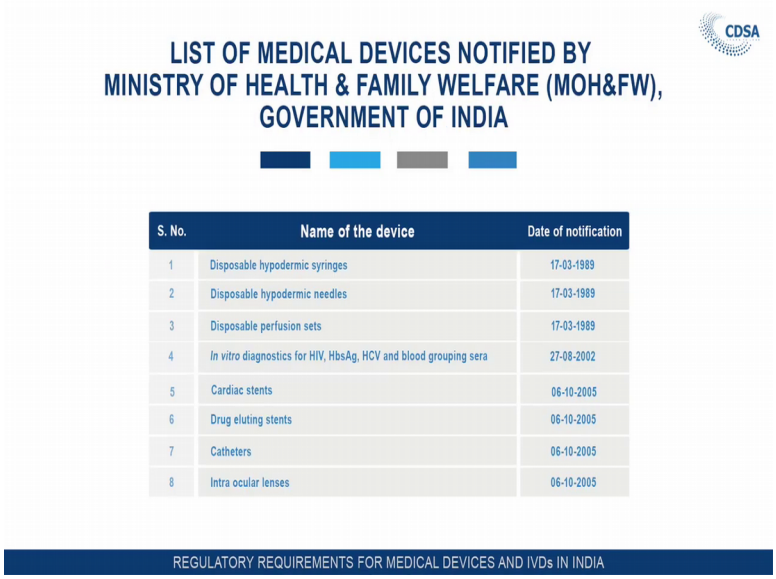

Now, in the year 1989 the Ministry of Health as notified three medical devices under section 3 b iv and those devices are disposable hypodermic syringes, disposable hypodermic needles, disposable perfusion sets. These three medical devices were notified in the year 1989 and regulated since then. Thereafter,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

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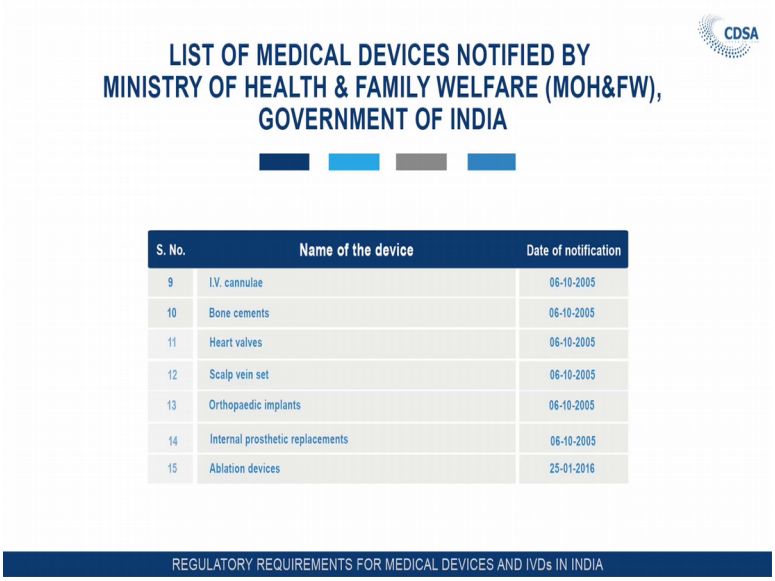

In 2005 the Ministry of Health and Family Welfare has notified 10 more additional medical devices under section 3 b iv. And these medical devices are cardiac stents, regulating stents, catheters, intraocular lenses, I.V. cannulae, bone cement, heart valves, scalp vein set, orthopedic implant, internal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

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

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

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

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

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

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

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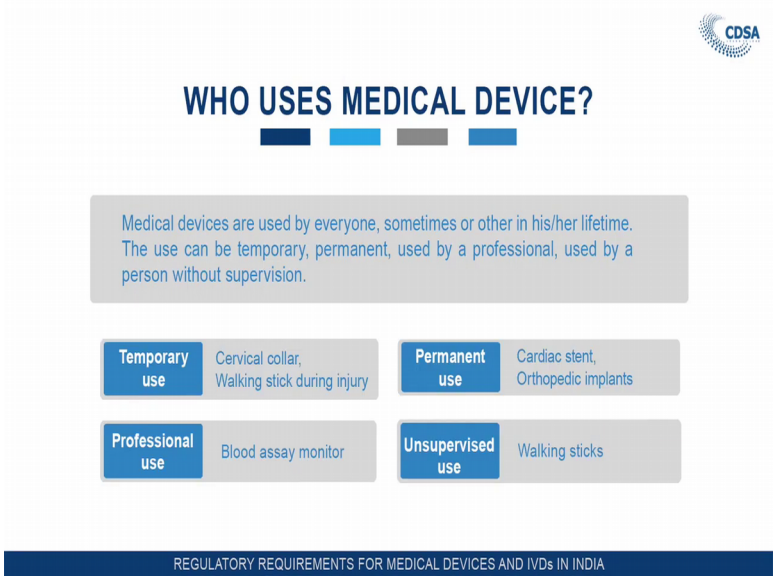

Now, who uses the medical devices? The medical devices are used by everyone in their day to day life. The use can be temporary, permanent, used by the professional or used by the person without supervision. The example of these medical devices are temporary use devices walking stick during the injury,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

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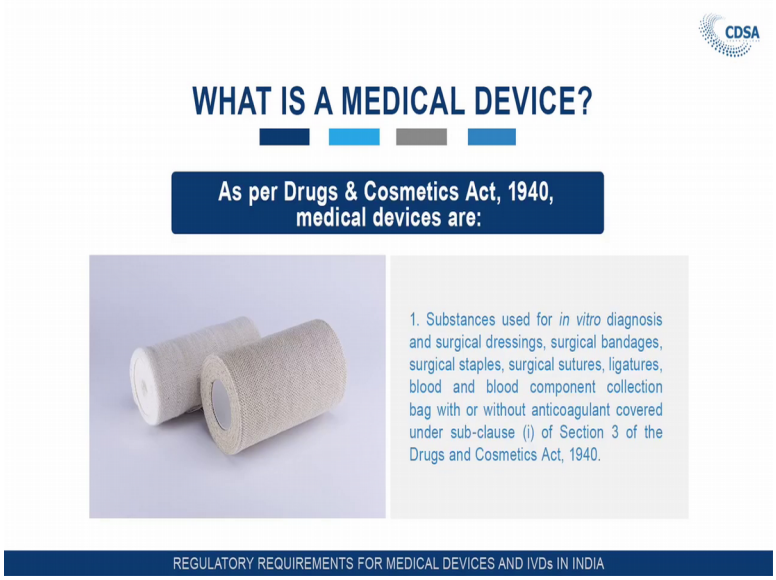

Now, we have already understand which medical devices are presently under regulation. So, we will again review the regulation of the medical devices in the line of the section 3 b of the medical devices. The section 3 b of the definition of the drugs, the substances used for in vitro diagnosis; in vitro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

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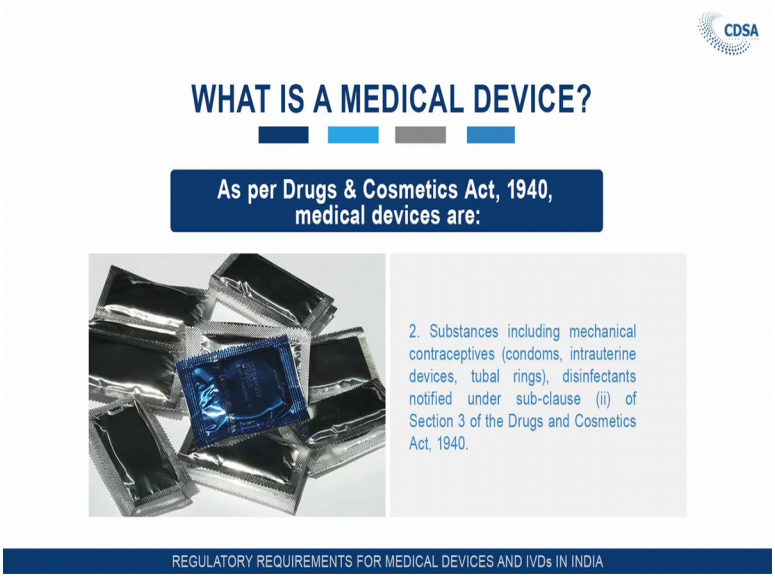

The other type of medical devices that is mechanical contraceptives like condoms, intrauterine devices, tubal rings and disinfectant solution, these devices are covered under the section 3 b ii of the definition of the drugs and regulated we have already discussed this in the previous slides.

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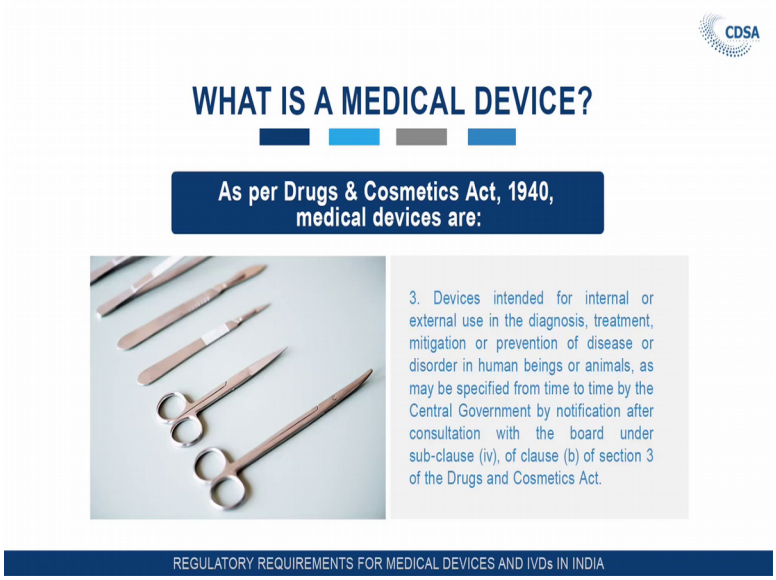

Now, certain notified medical devices that is I.V. cannulae, scalp vein set, heart valve, ablation devices, cardiac stent, bone cements, scalp vein sets, perfusion sets, surgical needles all these medical devices has been notified and regulated under section 3 b iv of the Drugs and Cosmetic Act.

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

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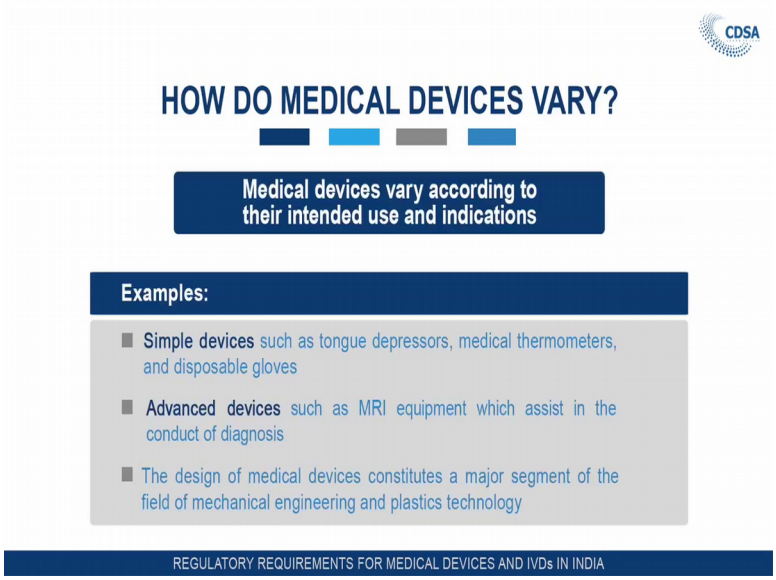

Now, how do medical device vary? The medical device vary according to their intended use and indications example, so simple devices such as tongue depressors, thermometers, medical thermometers and disposable gloves. These are simple devices and used differently as per the intended use of the medical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

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

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

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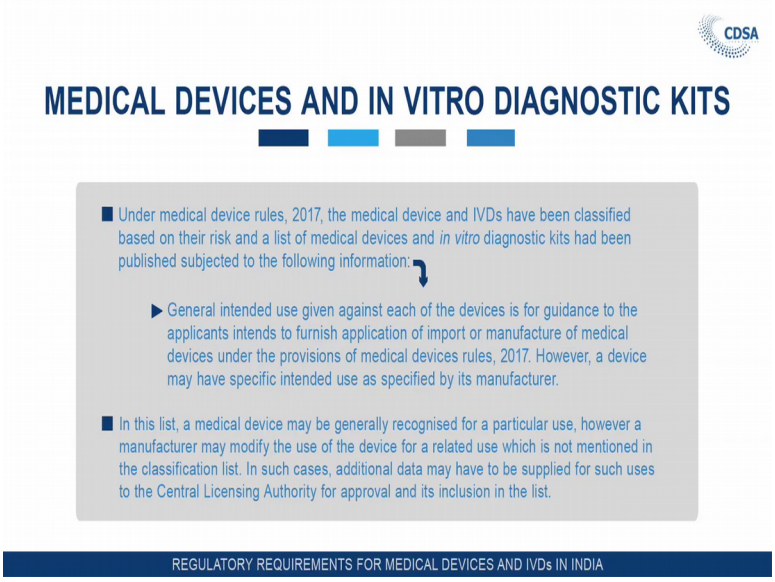

So, this initiative that Ministry of Health and Family Welfare has been has taken till we have the comprehensive regulation on the medical device in the country. Under this medical device rule 2017, the medical devices and in vitro diagnostics have been classified based on the risk as mentioned in the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

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

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

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

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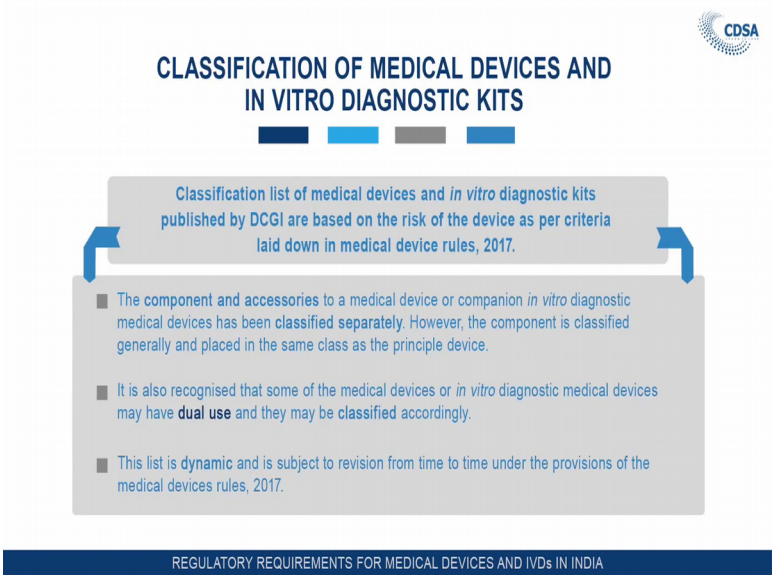

So, the classification list of the medical devices and in vitro diagnostic published by the Central Licensing Authority is based on the risk of the devices and the component as well as accessory of the medical devices or companion in the in vitro diagnostic medical devices has been classified separately.

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

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

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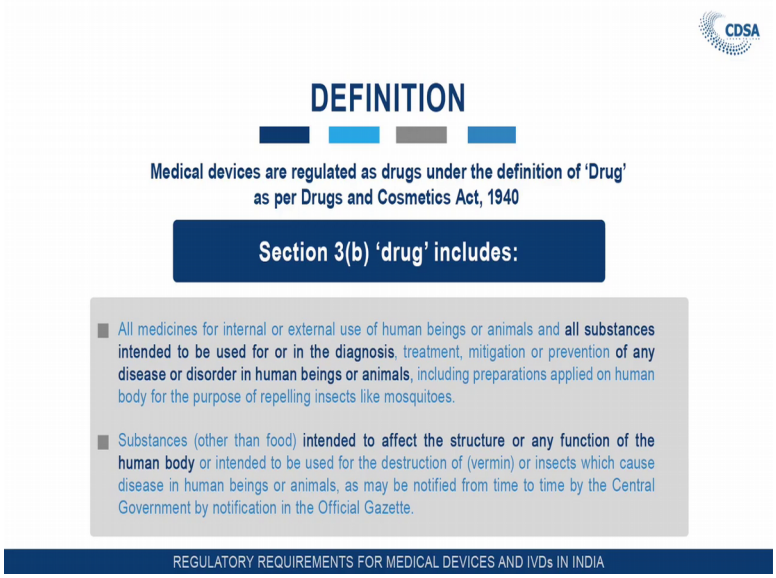

Now, we have understand what are the devices regulated under the Drugs and Cosmetic Act, 1940. So, we will have some exercise on those medical devices. You can see this medical devices and identify whether this medical devices is regulated or not regulated.

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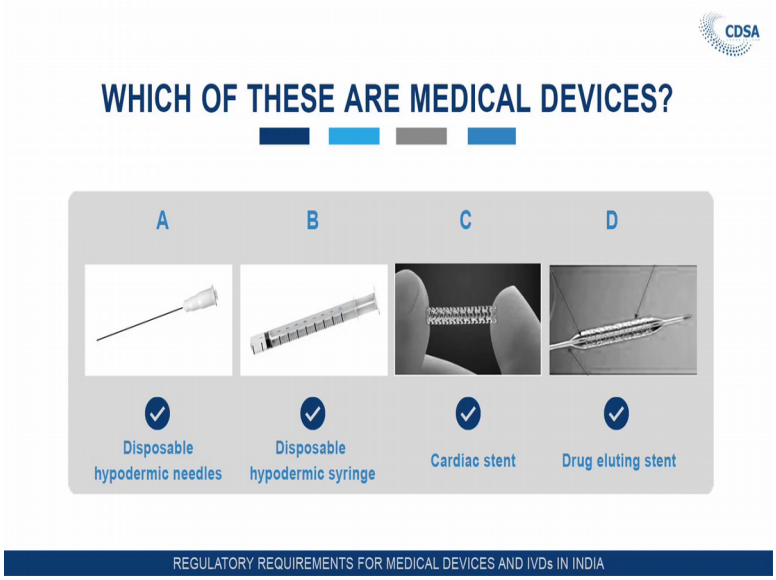

What is this medical devices? This is hypodermic disposable needles, this device is notified devices and regulated under Drugs and Cosmetic Act, 1940. This device what is

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

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

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

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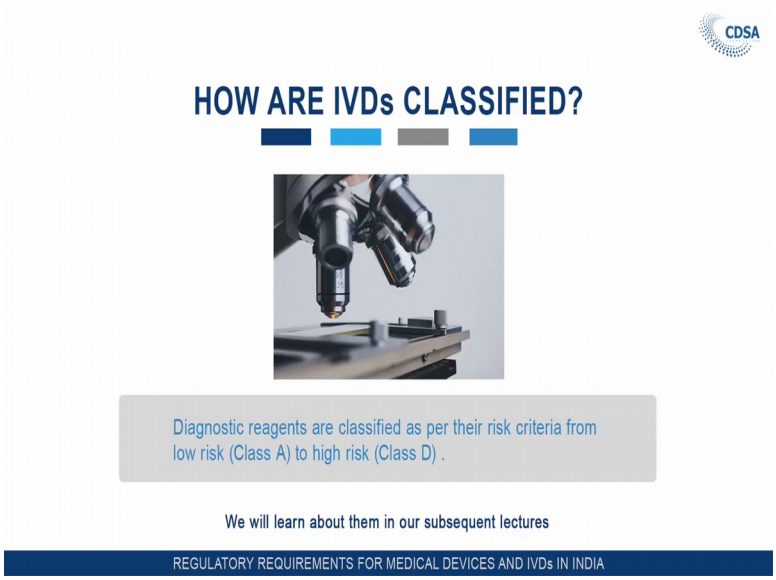

What are the classification for the in vitro diagnostic kits? The in vitro diagnostic kits are classified by the Central Licensing Authority as per the risk criteria from low risk to high risk that is class A to class D devices. We will discuss this classification in the subsequent lectures.

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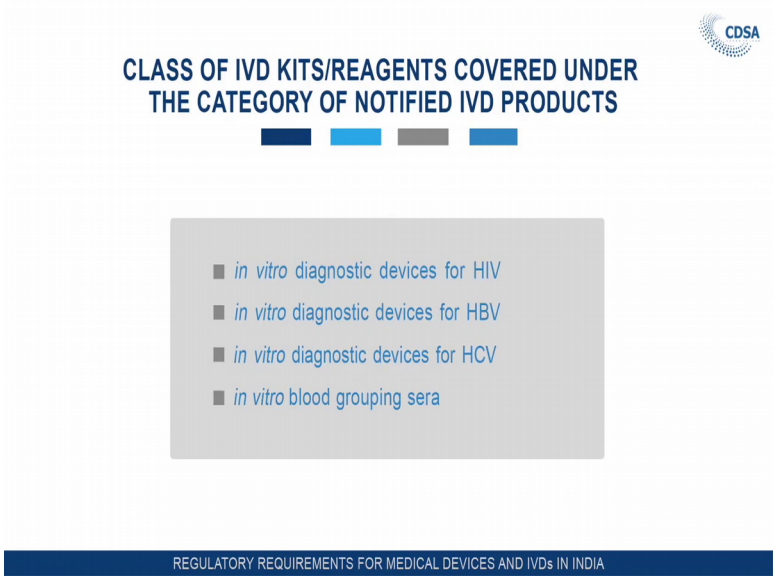

Now, what is the notified in vitro diagnostic products during the previous lectures we have discussed which in vitro diagnostic kits has been notified by the Central Government. So, the devices which have been notified under section 3 b I, 3 b iv of the

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

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

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

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

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

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

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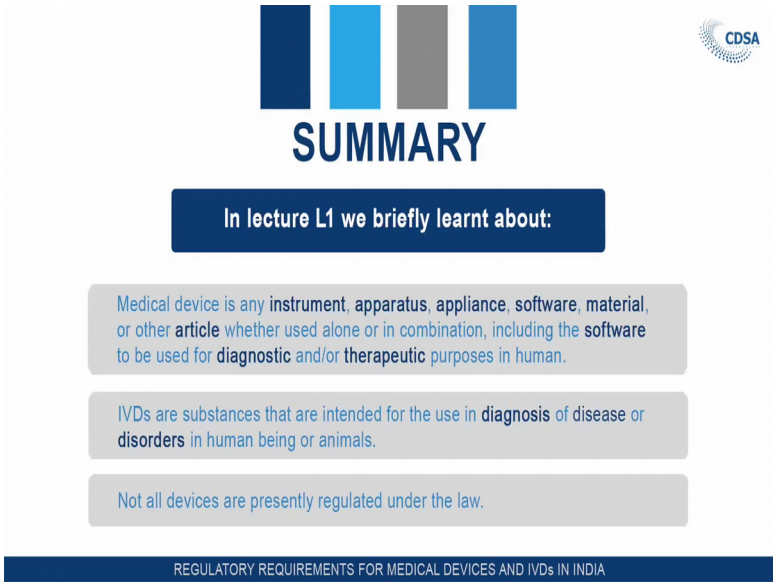

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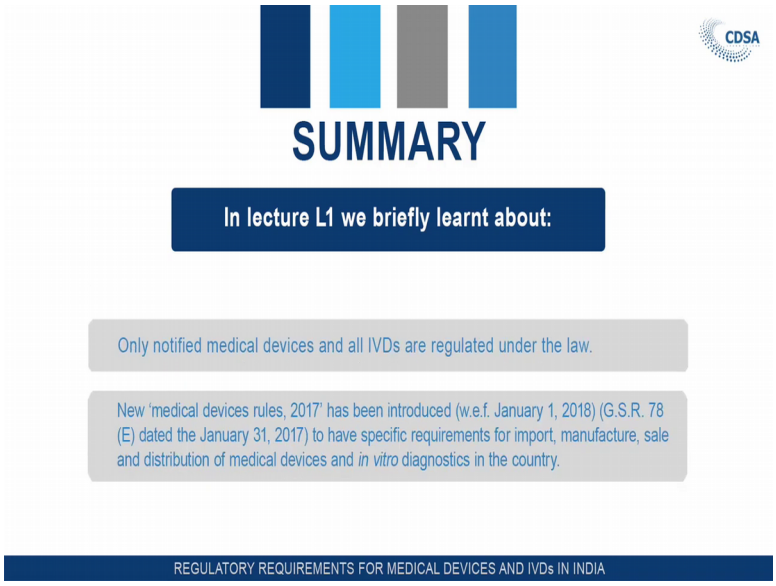

So, now we have the basic idea about the medical device regulation what are the medical devices which are regulated under the provisions of Drugs and Cosmetic Act, what are the devices category as non notified in vitro diagnostic devices? What are the devices categorized as notified in vitro diagnostic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

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

Thank you very much.