Regulatory Requirements for Medical Devices and IVDs in India

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Lecture – 04
Types of Devices
Types of Devices Including Combination Devices

Friends, again welcome to Regulatory Requirement for Medical Devices and In Vitro Diagnostics in India lecture 4 that is Type of Medical Devices including combination devices. In this lecture before we further continue I want to brief you in the previous lecture we have discussed what is the regulation for the medical devices? What type of medical devices are under regulation? It is not the all the type of medical devices are presently under regulation in India.

So, only certain medical devices which falls under the definition of section 3 b i, section 3 b ii and section 3 b iv. Section 3 b iv that is the notified medical devices and we have also understand how many devices, how many categories of the devices so far the Ministry of Health and Family Welfare has been notified. And what are the new medical devices which have been notified recently by the Ministry of Health and Family Welfare.

So, we understand [FL] how many devices total notified to which are under regulation, also we discussed in detail classification of the devices. The classification of the devices that criteria has already been in prescribing the first schedule of the medical device till in 2017. And in that classification, the classification is made based on the intended use of the medical devices as well as the risk associated with the medical devices.

So, based on the risk and their intended use the devices is classified and risk based classification, criteria, parameter have already been given based on that the Central Licensing Authority has classified various medical devices under the category of regulated medical devices.

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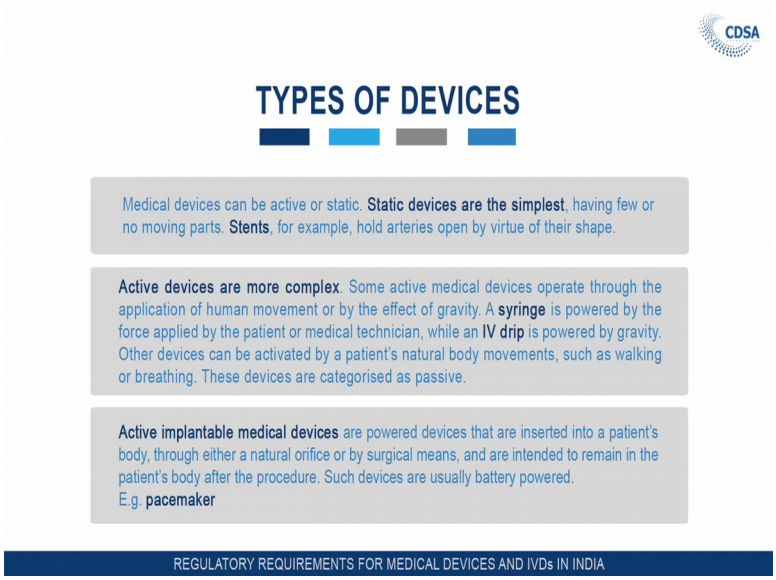

In general, the medical devices can be active or statics. The static devices are the simplest devices having few or no moving parts. Example of the static devices are cardiac stent, it holds the tree open by virtue of their shape. The active devices are more complex. Some active medical devices operates throughout the application of human movement or by the effect of the gravity, The example a syringes which is a powered by the force applied by the patient or the medical professionals, while an in while an IV drip is powered by the gravity.

Other devices can be activated by a patient's natural body movements, such as walking or breathing. The active implantable medical devices are powered devices that are inserted into the 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 usually operated usually powered by the battery it is a battery powered. Example like pacemakers is one of the example for active implantable medical devices.

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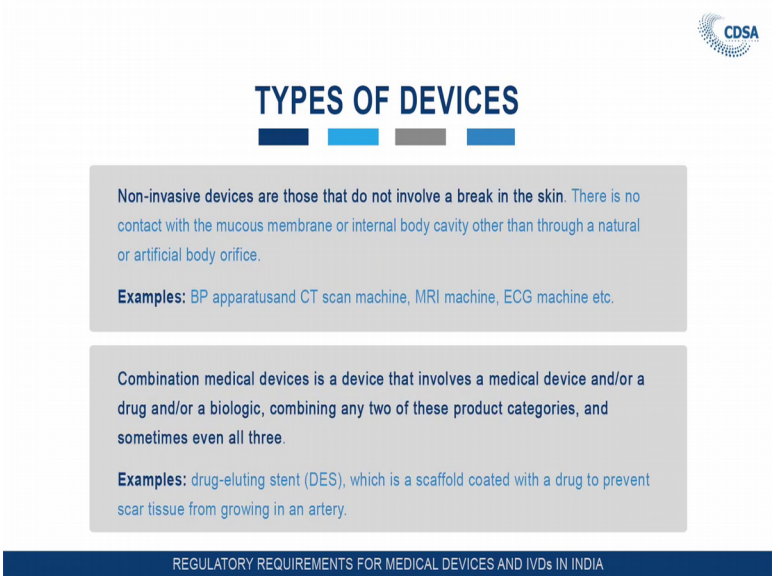

Non invasive devices are those devices that do not involve a break in the skin. There is no contact with the mucous membrane or internal body cavity other than through a natural or artificial body orifice. The example of non invasive medical devices are the BP apparatus, CT scan, ECG, MRI etcetera. The combination medical devices; combination medical devices is a devices that involve a medical devices and or a drugs and or a biologics, combining any two of these product categories and sometimes even all the three.

These types of the devices will be consider as a combination medical devices. The example of the combination medical devices that is one of the example is drug eluting stent, where is a scaffold coated with the drugs to prevent the scar tissue from growing in an artery. Although in the medical device rule, the combination devices have not been clearly defined, but in general the devices like drug eluting stent, wherein the drug is coated with the stent platform, stent platform that is meant for stainless steel or cobalt chromium will be example of the combination medical devices.

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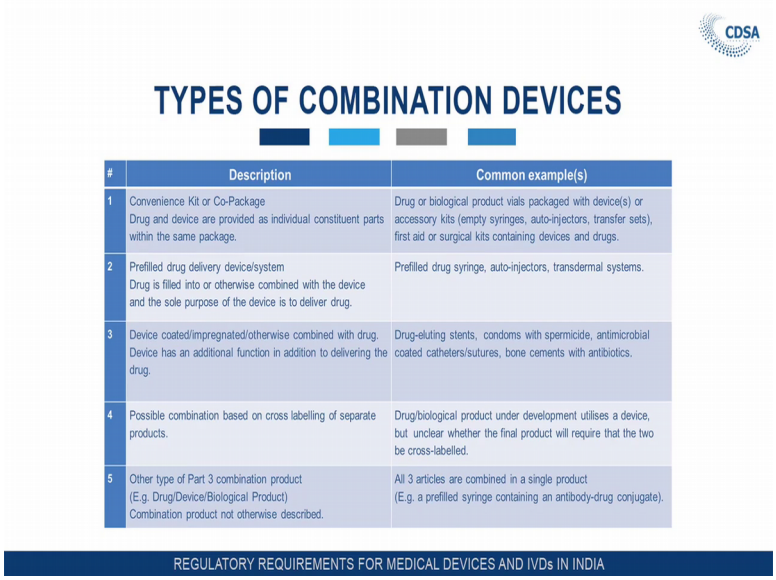

In other regulatory systems like USFDA they have to define the types of the combination product. And what types of the combination devices are there they have categorized. Some of the example like convenience kit or co package where in drug and devices are provided as individual constituent part within the same package. The prefilled drug delivery devices or system where in drug is filled into or otherwise combined with the device and the sole purpose of this device is to deliver the drugs.

Prefilled drug syringes, transdermal systems the example of such devices. The devices coated impregnated otherwise combined with the drugs. The device as an additional functions in addition to the delivering the drugs. Example of such combination devices are the drug eluting stent, condom with spermicide, antimicrobial coating catheters, sutures, bone cements with that antibiotics. The possible combination based on cross labelled of separate products. That is dug biological products under development utilize a devices, but unclear whether the final product will require that the two be cross labelled.

Other type of combination products where in drug, device and biological product. Combination product or not otherwise describes all the three articles are combined in a single product. The example are the prefilled syringes containing an antibody drug conjugates, so these are the various types of the combination devices. Though other reliability authority have defined were but in and in the medical device around 2017 this combination device has not been defined.

Although the medical device rule 2017 includes certain definitions of active diagnostic medical devices, active medical devices, active therapeutic medical devices. So, in the definition of the chapter 1 these devices has been clearly defined.

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The active diagnostic medical devices define the medical device rule 2017; that means, 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, state of health, illness or congenital deformity. The example in the hepatitis or HIV tests, clinical chemistry, coagulation test systems, urine test strip test. Another definition for the active medical devices have been included in the medical device rule.

Active medical devices means a devices, the operation of which depends on the source of electrical energy or any other source of energy other than the energy generated by human or animal body or gravity. The example of this type of active medical devices are cardiac pacemakers, defibrillators, cochlear implants.

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also in the medical device rule 2017, active therapeutic medical devices has been defined which prescribe that, active therapeutic medical devices means any active medical devices used either alone or in combination with any other medical devices to support, modify, replace or restore biological function or a structure with a view to the treatment or alleviation of any illness, injury or handicap.

The example of such type of medical devices are incentive care monitoring system, blood gas analyser used in the open heart surgery. But in the medical device rule only the definition has been defined, but the medical devices based on the category notified by the Ministry of Health and Family Welfare Government of India. The products are classified based on the risk and the parameter as prescribed in medical first schedule of medical device rule 2017.

Also the medical device rule 2017 includes definition of invasive medical devices, which state that invasive devices means a devices which in whole or part penetrates inside the body either through a body orifice or throughout the surface of the body. Example of this type of invasive devices are sutures, hypodermic needles and syringes.

Active implantable medical devices also defined in the medical device rule 2017, active medical devices which is intended to be totally or partially introduced, surgically or medically into the human body or animal body or by the medical intervention into a natural orifice and which is intended to remain after the procedure. Active implantable

medical devices examples are cardiac pacemaker and defibrillators people discuss in the previous slides.

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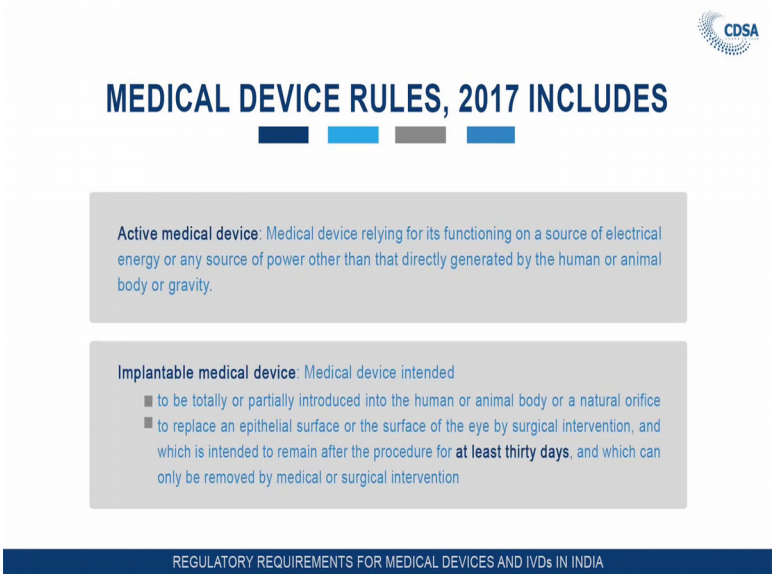

Active medical devices also defined in the medical device rule in 2017 which state that medical devices, relying for its functioning on a source of electrical energy or any source of power other than that directly generated by human or animal body or gravity.

Also then medical device rule 2017 define implantable medical devices which means, it is intended for the medical devices intended for 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 a at least thirty days and which can only be removed by the medical or surgical intervention.

What type of devices are regulated under which category and what will be the classification of the that medical devices? So, concentrate on the lecture which will be given again by Mister Malay Mitra former the deputy drug controller. He will explain all those thing and concentrate on the lecture and also enjoy the lecture thank you very much.

Hi, today we will talk about different types of medical devices including combination devices. We whenever we go to the market or we decide to select a medical device to

manufacture or design we find that there are hundreds of hundreds of different types of medical devices available in the market. And we are we are actually confused as to what kind of medical device that is whether its combination device, it is a single use device or how do you go about it. So, this short presentation will give you a general idea of the types of medical devices moving in the market including combination devices.

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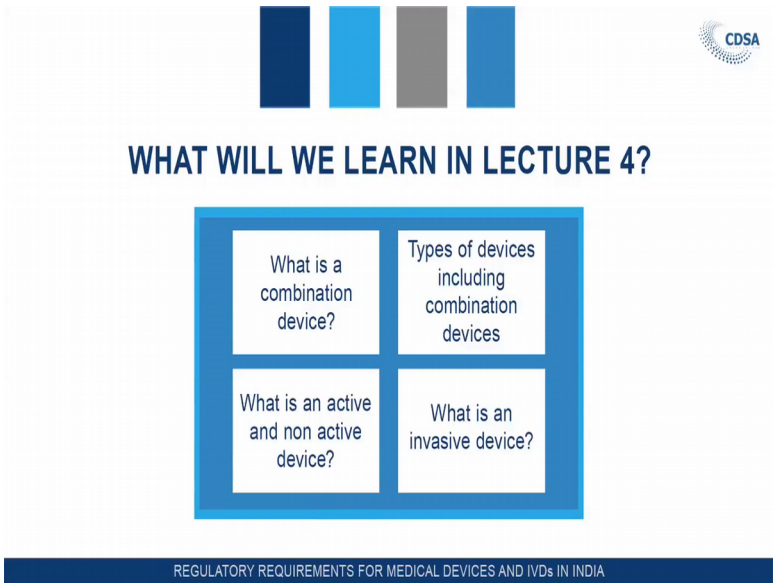

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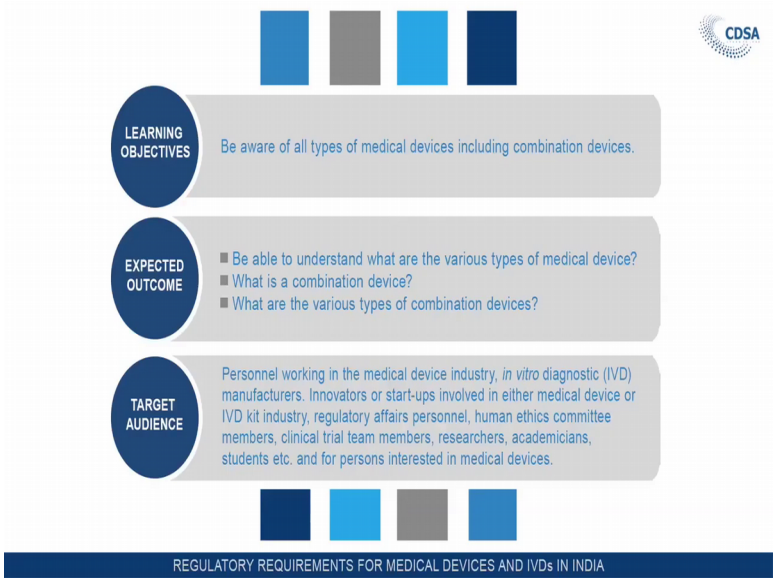

A device you must understand the definition of a device actually to get into focus of combination devices. What is the device? The device according to the definition can be

anything from as simple as a walking stick to an ultrasound machine. So, you can understand the huge range a medical device has got. It can be a simple device it can be very very complicated device which is not a accessible and usable for a common man.

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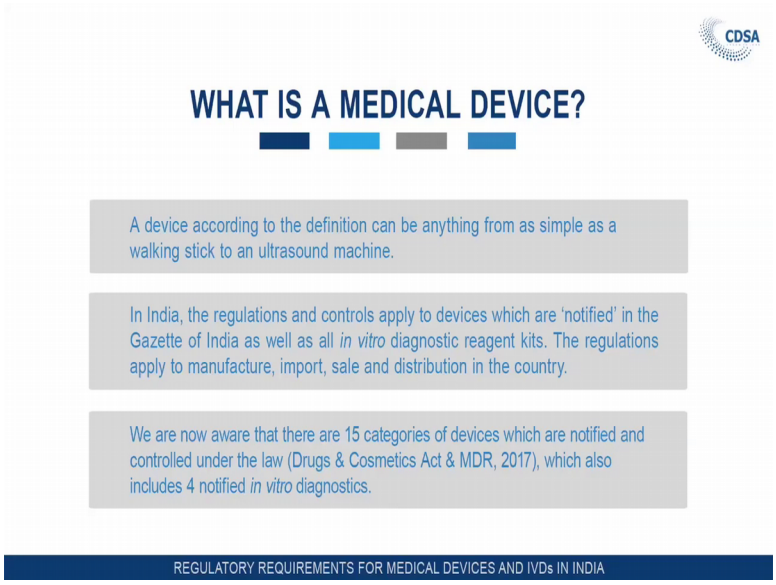

However, regulations and controls apply to devices which are notified in the Gazette of India. The regulations applied to manufacture sale and import of for obvious reasons. In India the devices which are controlled are actually notified in the Gazette of India and the whole range of a manufacture, testing, sale etcetera are controlled under the government

And there are 15 types of devices and about three or four more devices are going to be incorporated from twenty twenty and these 15 devices which are actual medical devices are controlled under the law and this also includes 4 in vitro medical devices. In vitro medical devices the road medical devices in which are used outside the human body for detecting or finding out a disease in the human body and these 4 in vitro medical devices are basically used for testing of human blood.

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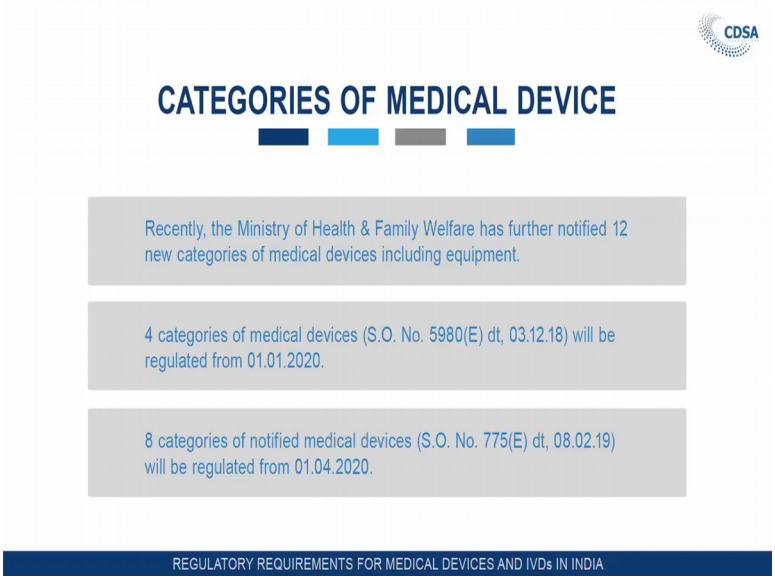

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Let us check the definition of device again as per the Drug and Cosmetics Act, in 1940. This will be useful because we must remember that as long as we deal with anything concerning the control substandard under the Drug and Cosmetics Act we should keep the definition in mind always, this will give a perspective to the product that we are dealing with.

In part b drug includes all medicines for internal or external use of human beings and 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 preparation applied on human body for the purpose of repelling insects like mosquitoes.

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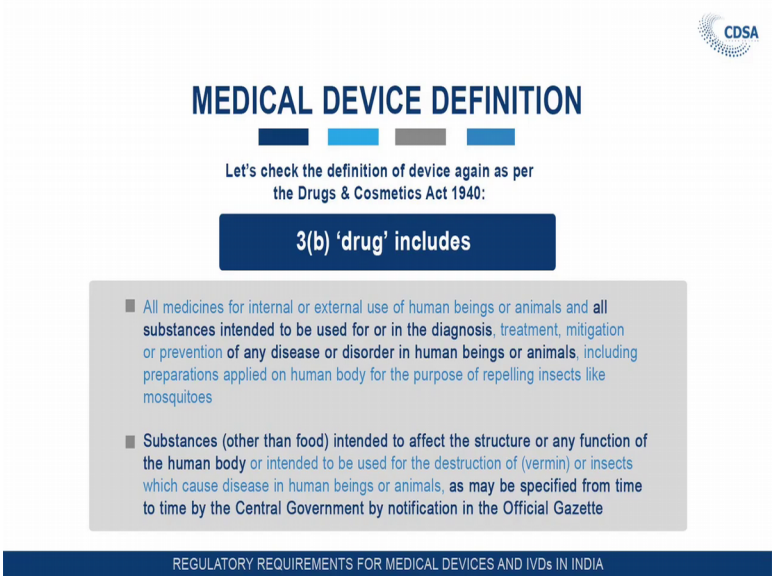

This particular definition is actually completely applied on drugs, medicines which we call them tablet, liquid, capsules etcetera. The part 2 of the definition say such substances other than food, intended to affect the structure or function of the human body or intended to be used in the destruction of vermin or insect which cause disease in human beings or animals or as may be specified from time to time by central government by notification in the official gazette.

So, in this case the part mark red that is intended to affect the structure of function of the human body. Actually refers to a device in a way, if you see the function of a device they are there is sometime affect the structure of function of the human body. All substances the next parts is all substances integrated for use of the components of a drug including empty gelatine capsules etcetera this is also applicable to drugs pure drugs.

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Forth one is such devices intended for internal or external use in diagnosis, treatment, mitigation or prevention of diseases 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. This portion is completely on medical devices as we know it. Ah This definition per se is not a comprehensive definition of a medical device, but this particular portion actually refers to medical devices that we actually know.

Now, this is actually the gazette replica of the gazette which actually just for the information to tell you that this is what a gazette looks like. The medical in the medical device regulations which came out in 2017 the 17 regulation there are definitions again given for medical devices. These are a bit more comprehensive to and there are definitions also which give a focus on the medical device as they exist.

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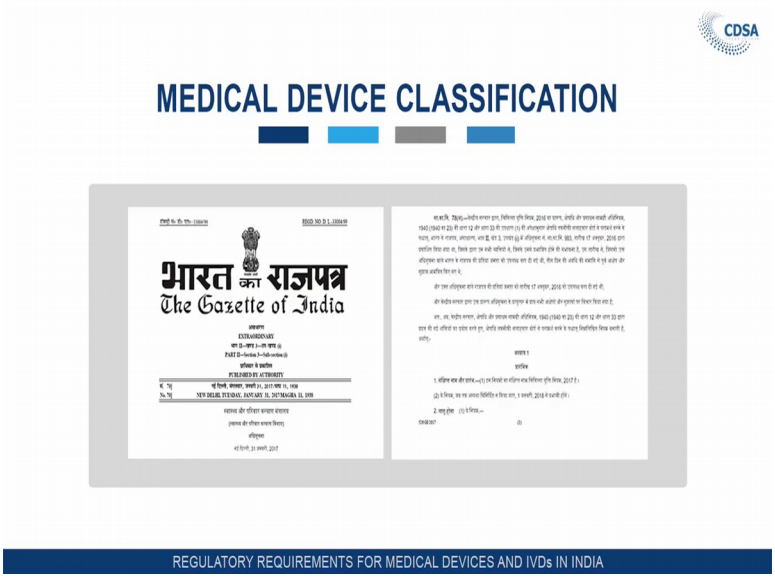

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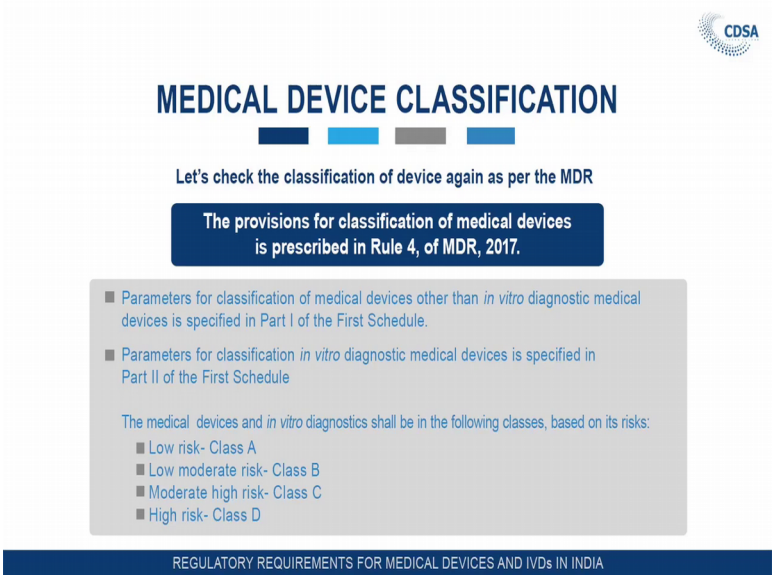

It says medical device means rule 3 definition ZB medical device means, substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, surgical ligatures, blood and blood components, collection bag with or without anticoagulant covered under sub clause i.

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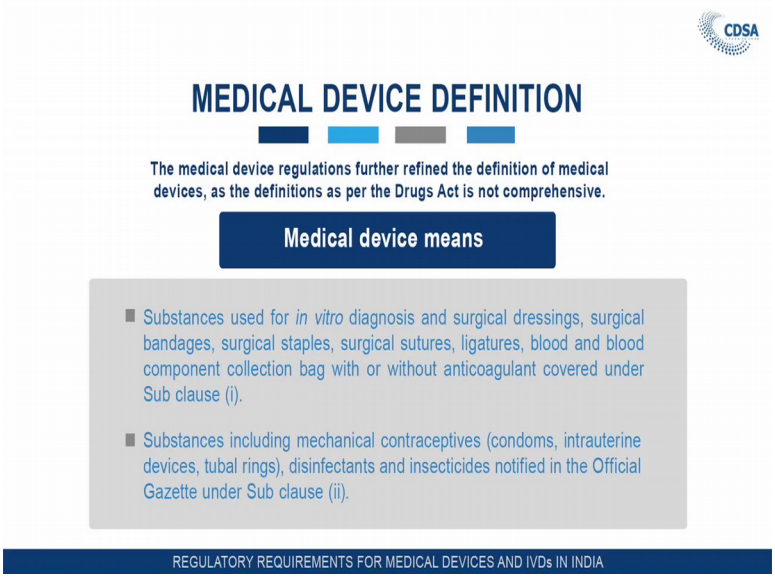

Now, let us look at this one very carefully substance used in vitro diagnosis and surgical dressing, surgical bandage, surgical staples. It says surgical dressings and surgical bandages we must remember one thing these two items, were also covered in the Indian pharmacopoeia as drugs earlier. Now this has been brought clearly under the medical device definition.

Similarly, blood collection bag earlier was not a device, but this has been brought under a device. Earlier it was just a container for collection of whole human blood or components or with a coagulant or an empty bag. These were not medical devices earlier, but this has been clearly covered under the medical device definition now.

B says substances including mechanical contraceptives condoms, intrauterine, tuber rings and disinfectant these four items were earlier covered under the definition of drug and are controlled as drug under the Drug and Cosmetics Act. This is very clearly brought under the medical devices by the new regulations. Devices notified from time to time under sub clause iv sub of clause b of the section 3 of the act. Now this particular definition c is the is the defining definition which enables the government of India to notify medical devices as an when required.

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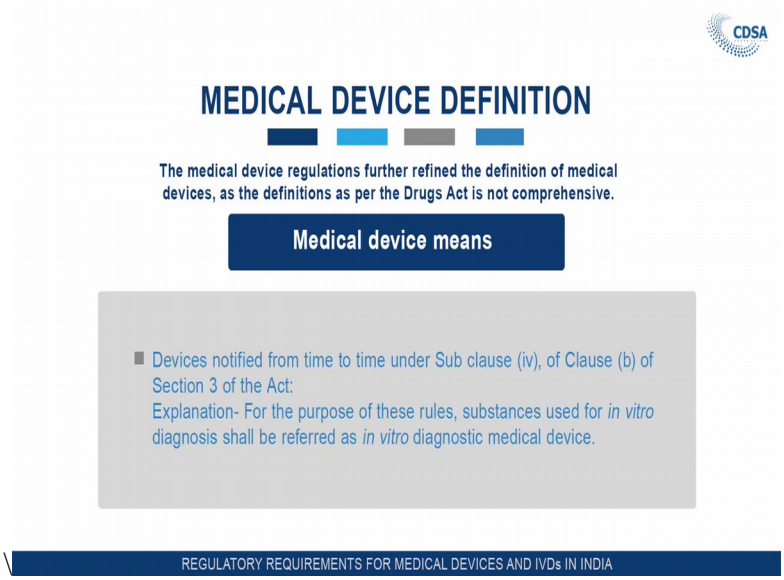

So, as I discussed earlier there are 15 medical devices covered under the act they have notified under this section. Explanation for these rules substances used for in vitro diagnostic shall be referred to as in vitro diagnostic medical device. So, medical device when it is in vitro which is which is basically a chemical entity or a biological entity for testing of human body outside the human body are in vitro medical devices they are also medical devices, but known as in vitro medical devices.

It is therefore, apparent that devices constitute a huge variety of items, devices can be as simple as a walking strip to a compressor items that the MRI is software even software used for analyzing data is a medical device.

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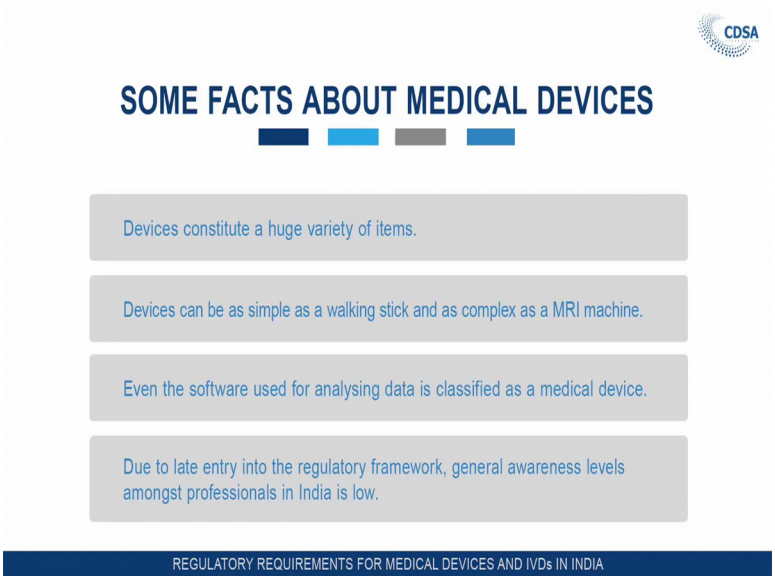

So, if you have got a MRI machine having a software installed in it and a computer system attached to it they are all part of a medical device. Due to late entry of into the regulatory framework, general awareness amongst professionals in the country is low. This is a fact that the definition of medical device amongst professionals and a common people are very very low because it has not been invoke legally in our country all these years. There has been some sort of control, but not regular comprehensive control.

This is been rectified by the government as an ongoing process by law. What is now we come back to combination device. The medical device regulations in our country, as on they do not to defined combination devices, but it is essential that we know about it. USFDA however, has an effective and useful regulation in CFR 3.2 e which is reproduced. It says a product comprised of two or more regulated component that is drug or device or biologic a device, drug or biologic or drug device biology.

That are physically chemically or otherwise combined or mixed and produced as a single entity. That means, a drug or a device, a biological substance or a device, a drug and a biological substance and a drug, a biological substance and a medical device, if they combined together constitute a medical device combination device. Two or more separate products package together in a single package or a unit and comprised of a drug and device products device and biological products or biological entire product. That is a packaged kit is also a combination device as for the USFDA definitions.

This is not available in our definitions; however, there are aspects in the regulations which covers this separately. A drug or device or a biological product packaged separately that according to its investigational plan or proposed labelling is intended for use, only with an approved indigenous specified drug, device or biological product where both are required to achieve the intended use indication of effect.

And where upon approval of the proposed product, the labelling of the approved product would need to be changed that is reflected change in the intended use those just form strength router registration on significant change in those, this is also a medical device.

That means, we packet separately drug, device or biological product which are packed separately and intended for use with an approved individually specified drug for biological product is also a combination device. You cannot use it without a individual product which is required to be used with that device.

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Now, some of the question and answers about the are over here with the simple one; however, you will be getting much more question and answers we have to submit later on for assessment. So, that is over all.

Thank you very much.