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

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Lecture – 03
Classification of Medical Devices

Hello, welcome to the training for training module Regulatory Requirements for Medical Devices and IVD in- Vitro Diagnostic kits in India.

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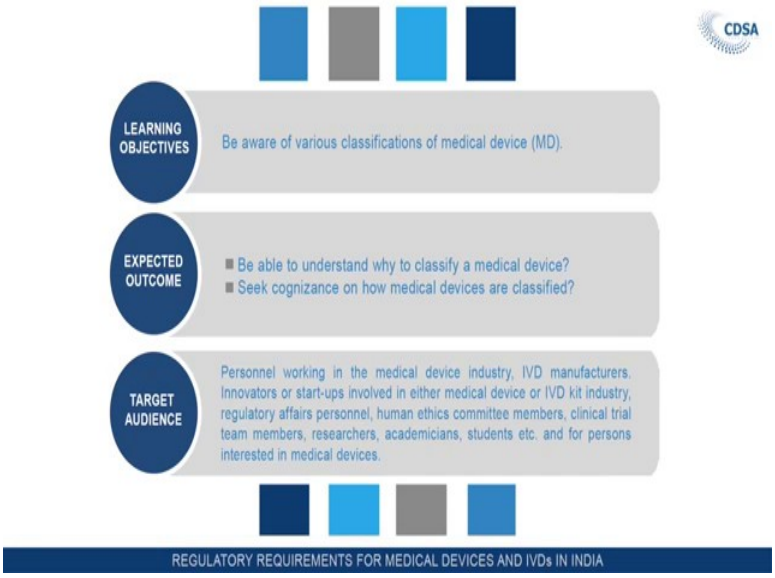

This presentation will actually give you how to classify a medical devices and what is classification of a medical device. This is a series of 10 lectures on medical devices and IVDs and we shall learn about classifications from this presentation. The objectives of this particular presentation is to be aware of various classification of medical devices. Outcome is able to understand why to classify medical device, seek cognizance on how medical devices are classifiedand, target audience is personnel working in the medical device industry IVD manufactures, innovators or start ups involved in either medical devices or IVD kit industry, regulatory affairs personnel, human ethics committee members, clinical trial team members, researchers etc. and for the persons generally

interested in medical devices. Anybody can go through this course and learn about classification of medical devices.

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What will we learn in this lecture? Why classify? Classification is the main heading, risk based classification, we shall learn about it. In-vitro diagnostics is part of the classification. How to classify? Helpful documents.

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Before we start the presentation on classification of medical devices, we have to understand the difference between drugs and medical devices. Before, we going for the

classification it is very very important to know why drugs and medical devices are different. If drugs and medical devices were not different we do not have gone in classification of medical devices.

But, rather used drugs in the sense that the drugs are categorized.Though both drugs and medical devices form an important component of health care and are used for humans and animals for bringing them to normal state, their basic action and composition are different. This is the basic reason why medical devices cannot be considered as drugs and must be classified. In the next slide we shall see how they are different in different parameters..

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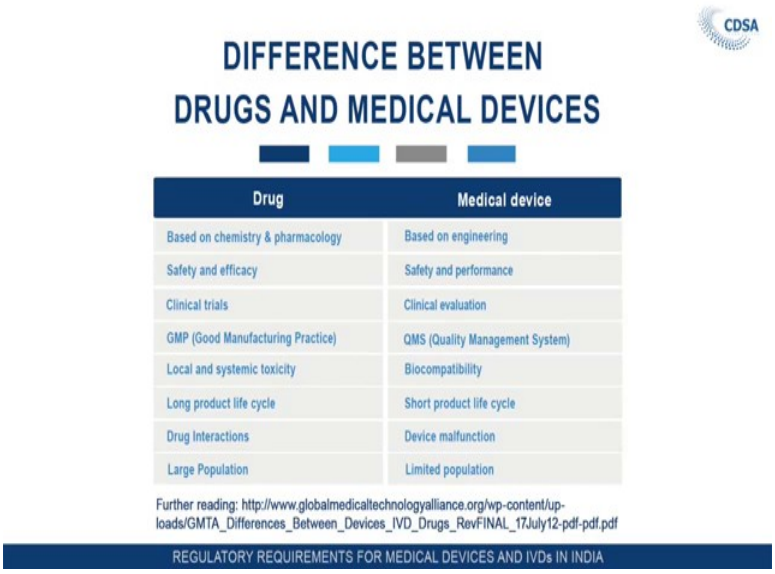

Difference between drugs and medical devices, on the left hand side you will see the parameters of drugs, on the right is parameters of devices. Drugs are based on chemistry and pharmacology, devices are based on engineering. They are solid engineering products of plastic, metal or wood or whatever. Drugs have safety and efficacy as their guiding criteria. They should be safe and efficacies, medical devices are safety and performance, how they perform as a device in the human body.

For drug its clinical trials, for device it is clinical evaluation, for drug it is GMP, for devices it is Quality Management System(QMS). For drugs local and systematic toxicity happens, for devices its biocompatibility whether the devices rejected by the human body or not or its compatible to the human scale. For devices its local systematic toxicity

which is which can be which are going to the systems and cost problems and sickness in the human body.

So, the drugs they have a very very long product life cycle, for devices a very short product life cycle and the device can changed within a year or 6 months. For drugs it is drug interactions, for device it is device malfunction. Drug it can interact with a human body, device can malfunction and cause problems. Drug is used in very very large number of pPopulation, devices are used in a limited population and, that is the reason why devices have a short life cycle also.

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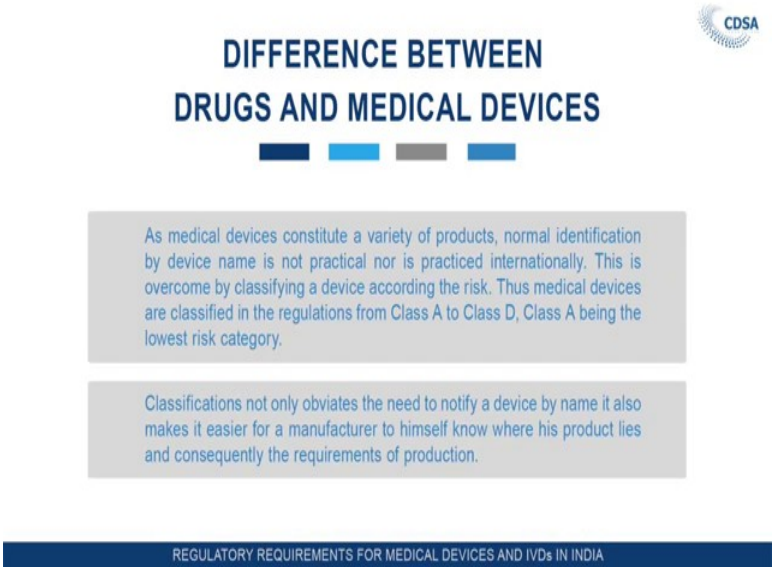

As medical device constitutes a variety of products, normal identification by device name is not practical nor is practiced internationally. This is overcome by classifying a device according to the risk. Thus, medical devices are classified in the regulations from class A to class D.

Class A being the lowest risk category, classification not only obviates the need to notify a device by name, it also makes easier for a manufacturer to himself know where his product lies and consequently the requirements of production. A medical device, a common medical device can have say a 100 variant. So, therefore, it is better to have a device class for that variant rather than naming each 100 device by name.

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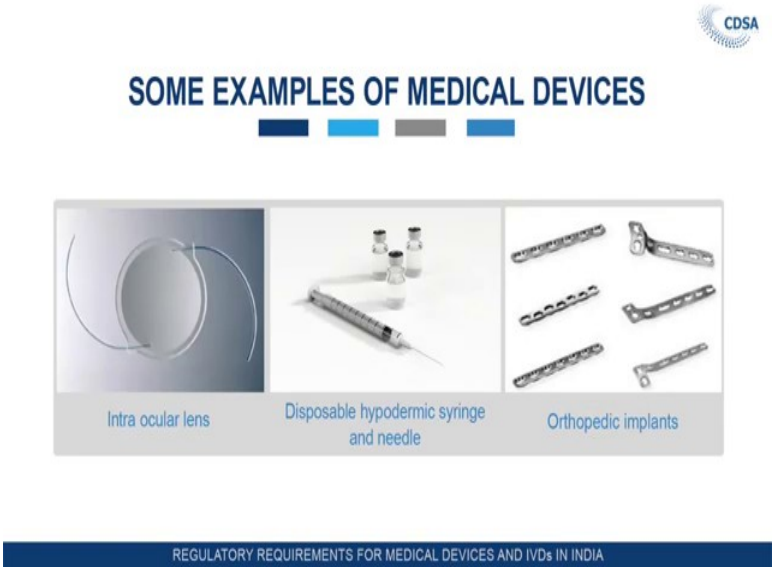

Some examples of medical devices to show that the range that the medical devices constitute as a group; we have intra ocular lens which is made of polymer, plastic or PVP. We have got disposable hypodermic needles and syringes part of it is metal, part of which is plastic. We have cardiac stent which is made of again metals. We have orthopedic implants which can be plastics or stainless steel or any other metal, suitable metal.

So, this is a small range of implantable medical device, apart from this you can have medical devices which are like instruments for blood chemistry, you can have devices which are actually in vitro diagnostic kits and various ranges. So, it is a huge complex complicated range of device. So, it is not easy to name them and use them, but have to classify them to show know what class they fall into. Why classify a medical device?

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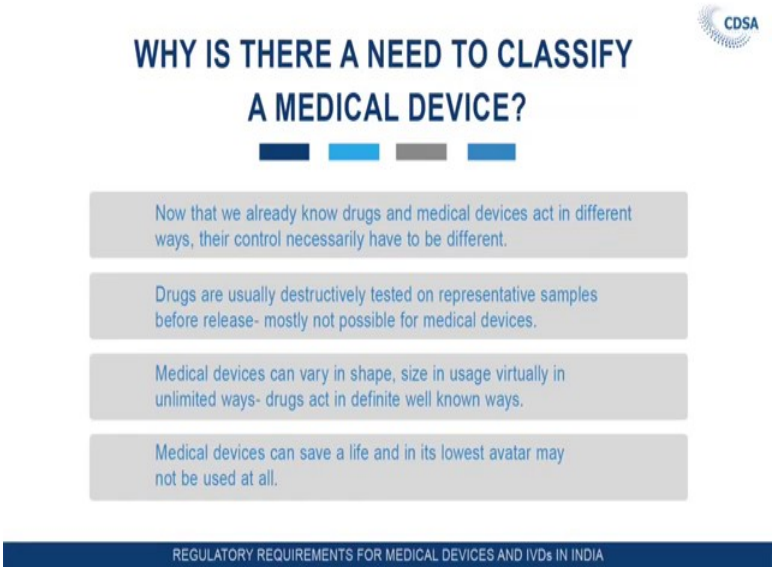

Now, that we already know drugs and medical devices are different are in different ways their control is also necessary to have to be different. Drugs are usually destructively tested in representative samples before release, mostly not possible for medical devices. Let us develop this one drugs are usually destructively tested; that means, if I take a common drug say as an example paracetamol tablet.

It is a batch of 1 lakh tablets, I usually takes a 100 tablets, send it to the lab, it is tested, destroyed powdered and it become unusable. But, in medical devices in most of the cases it is cannot be done, you cannot destroy a medical device and test it. So, therefore, it has to be it has to be actually put in a class of high risk or low risk to see and accordingly build the Quality Management System(QMS) for the device. So, that the product is actually representing that design of that device.

Medical device can vary in shape and size usually virtually in unlimited ways, drugs act in definite well known ways. Drugs for instance a tablet we know it what will be the shape, size, there are fixed parameters for testing of a tablet. In case of medical devices, a same device which is used say for in a plant can vary a shapes and sizes. So, we focus more on the material of construction of the medical device rather than what it is straight away. Medical device can save a life and in its lowest avatar may not be used at all.

So, very simple medical devices for instance for cardiac stents can save a life whereas, in the lowest possible class A you may not use a medical device at all in case you require it.

So, its optional whether use it or not in the lowest case of medical device; so, it'shuge range.

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Basic principle of classification of medical devices risk based we know earlier low risk to high risk. Lowest risk medical devices are simple items like a walking stick, spectacles or for instance say hospital bed or a bed panel whatever. And the high risk of coursewe know it can be IVDs for HIV etc.and cardiac stents and brain implants.

All medical devices are not placed in the same basket of risks, over here may I mention the classification that a same medical device class it is dependent on the usage of the medical devices. Same medical device can be used in high risk class Also and a low risk class Also.

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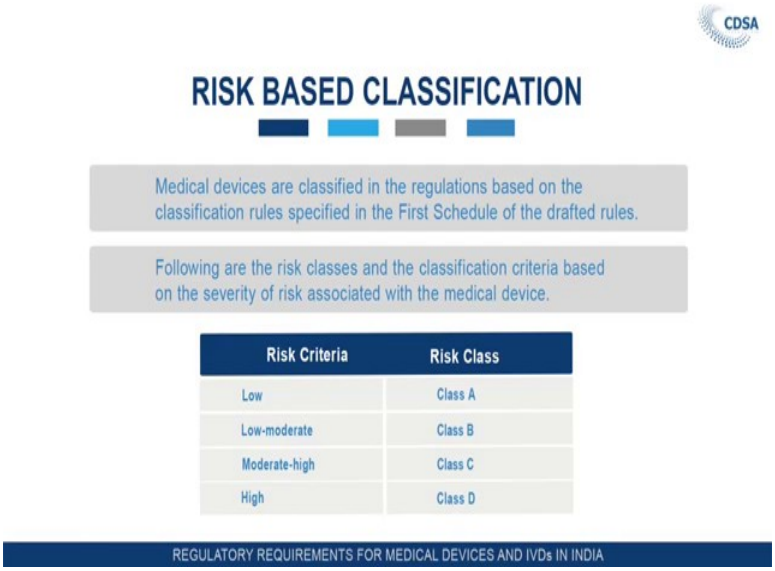

Risk based classification: medical devices are classified by the regulations based on classification rules divide in the First Schedule of the drafted rules. I will not say drafted over here because the rules already been published. Following at the risk classes and the classification criteria based on the severity of risk associated with the medical device. Risk criteria low is class A, low moderate is class B, moderate high is class C and very high risk medical devices are class D.

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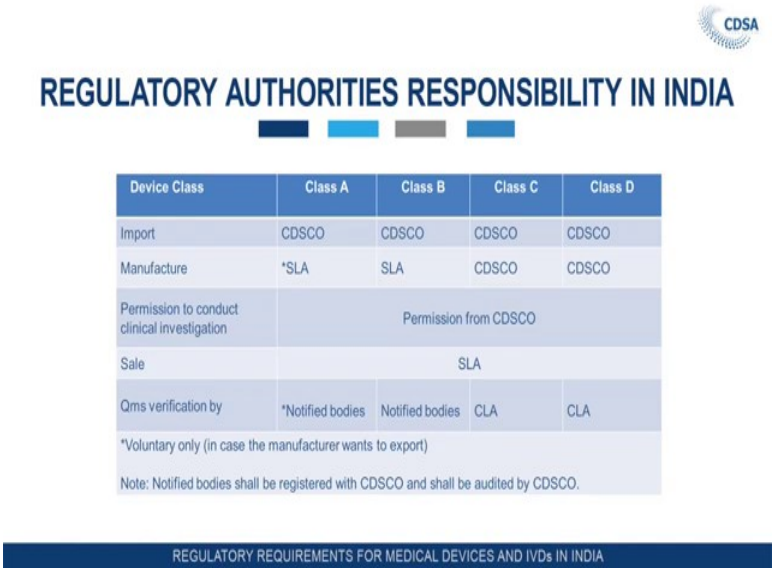

Regulatory authorities is responsible in India. Now, we have got in this particular slide the device classification and the regulatory authority who are responsible for certain actions on those medical devices. Now, for import all classes class A, B, C and D import is the CDSCO of the regulatory authority that is a central government Central Drugs Standard Control Organization. For manufacturer class A and class B are controlled by the State Licensing Authorities (SLA), class C and class D are controlled by the CDSCO.

Permission to conduct clinical investigation is Central Government again, sale is controlled by the State Government, QMS verification is done for class A and B by notified bodies, class C and D by the Central Government. Now, whether you need a license or not for class A medical device depends, whether you want to export that medical device or not? You may get a license, but notified you may carry out your own classification and own QMS if you want to, if you do not want to export it.

But, if you want to export it you have to carry out QMS verification by a notified body. Notified bodies shall be registered with CDSCO and shall be audited by the National Notification Authority(NNA).

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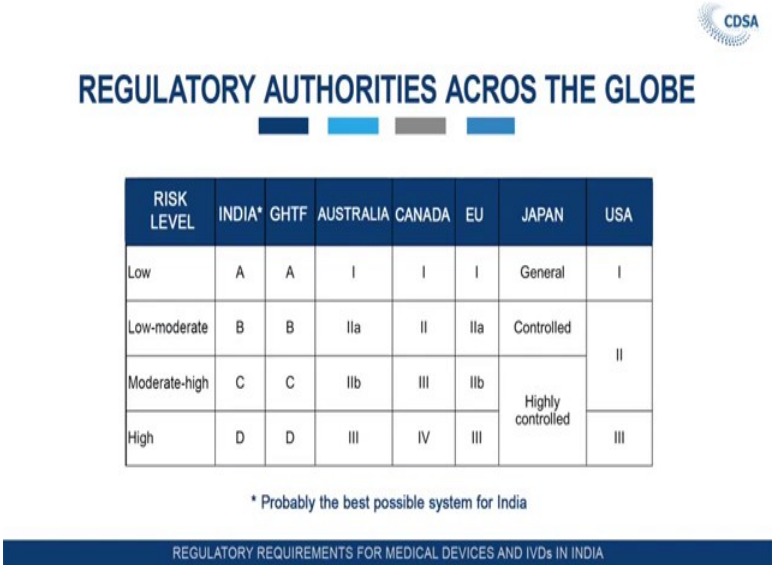

This is a chart just to give an example of how classification is done worldwide. We have got India and GHTF in the first two columns A B C D is the classification done by the GHTF that the Global Harmonization Task Force. And, we have adopted that in India and notified our medical device just as A B C and D. In Australia it is class I, class IIa,

class IIb, class III corresponding to each of the classes of GHTF. In Canada it is I, II, III and IV, similarly with GHTF in the EU it is same as Australia as I, IIa, IIb, III.

In Japan of course, now this is different a bit different, in Japan low risk are general medical devices, low moderate risk are controlled medical devices and moderate high and high are put in to a similar category of highly controlled devices. In the US again there is a difference, the low risk devices are class I, GHTF class I is the lower risk devices class I, class II devices constitute low moderate and high mod part of high moderate medical devices and class III are high highly risky medical devices.

So, this in general there is a there is a difference in Japan and US, but still we have the same low high and low, low, moderate high and very high risk medical devices categorized in each of the countries. We have to mention here that in case a manufacturer India wants to export a medical device to say USA, in spite of its classification done in India, he has to get its classification as and the manufacturing QMS as per the class II of the USA.

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How classification is done? It is for the manufacturer to decide on the classification of device. The regulator will not tell a manufacturer what is his class, he can guide him to the class, but the manufacturer has to first decide what is his class. Regulator does not play role in the classification at the time of submission. The regulator examines the

device and decides and allows the product to be permitted to be manufactured or sold. The classification can go up in case of the regulators field it deserves to be so.

So, in case a manufacturer applies for a class B device manufacture and the regulator feels that class C device. The regulator can tell the manufacturer that your devices class C according to our assessment and it should not be placed in class B. So, initial assessment has to be done on the manufacturer, the final decision with the regulators who can agree with a manufacturer's classification or put a more stringent classification.

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A system has been devised to decide on a devices classification to avoid any discrepancy, classification rule is the decision tree basically. So, yes no correct type of decision tree which the GHFT has formulated very nicely and through the tree you can find out where you have medical device falls in the risk class. It has been agreed by the industry and the regulators for a smooth and effective implementation. Decision is based on the way a device is used basically.

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Now, let us come down to our regulation reference to classification of Medical Devices Rule 2017. First schedule rule 4: parameters of classification of medical devices and in vitro diagnostic medical devices. I shall give it to headings of these which give a description in the actual rule. If you go through the actual rules you will find out the small description of that heading.

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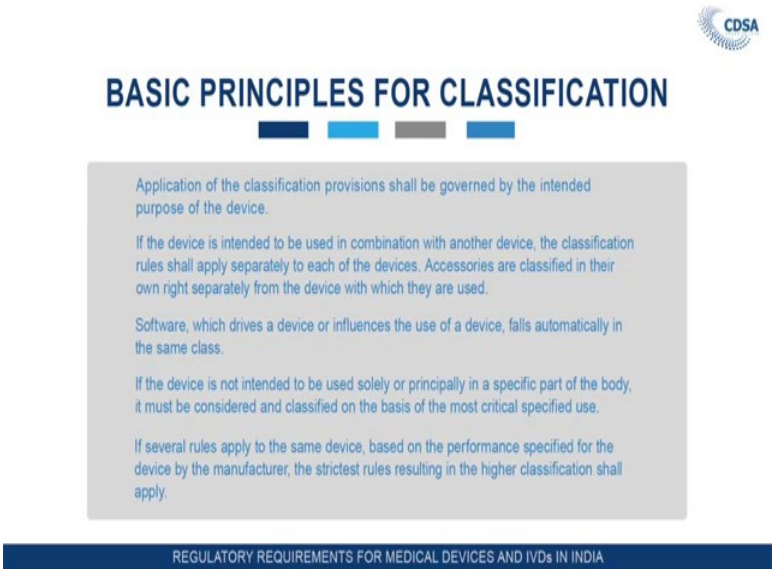

Basic principle of classification: application of the classification provisions shall be governed by the intended purpose of the device. The device is to be used for a risky

procedure in the human body, accordingly the risk classification will decide the device classification. 2, if the device is intended to be used in combination with another device, the classification rules shall apply again. So, if two medical devices are mixed together, added together you have to go for the classification rule and decide. We have to come to the classification rule later on.

However, accessories are classified in their own rights separately from the device with which they are used. So, if there are two medical device, one major medical device along with an accessory. The accessory shall be classified in their own right compared to the main medical device which is used. At the end of the day; however, if they are used together in the human body then the higher risk class will apply to both of them. If the class of device which is the main device is class C and the accessories class B then both of them will treated as class C in case it is used together.

Software which drives a device or influence the use of a device falls automatically in the same class as the major device, that is very simple. If the device is not intended to be used solely or principally in this specific part of the body, it must be considered and classified on the basis of the most critical specific use.

If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply. This is very simple, if we if a device is falls in this separate different categories low to high risk, the highest risk will apply to the device not the low risk.

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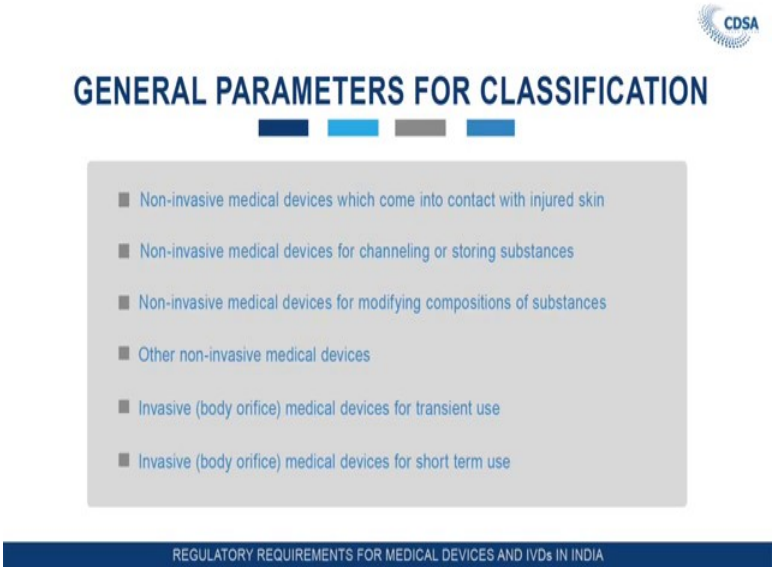

Now, how do you classify? These are the parameters of classification in a medical device. And, each of this parameters are described in short detail in the drug and cosmetic regulations which you can go through. And, if there are quarries regarding those you can get back to us a little bit apply to ah. Now what are the parameters? Number 1 is non-invasive medical devices which come into contact with the injured skin. So, these are medical devices which do which are non-invasive.

In the sense they do not enter the human body, but come into contact with a surface of the skin which is injured. Number 2 is non-invasive medical devices for channeling or storing substances. Number 3 is non-invasive medical device for modifying composition of substances. Number 4 is other non-invasive medical devices which are usually class A devices. Number 5 is invasive body orifice medical devices for transient use, next is your short term use, third is your long term use.

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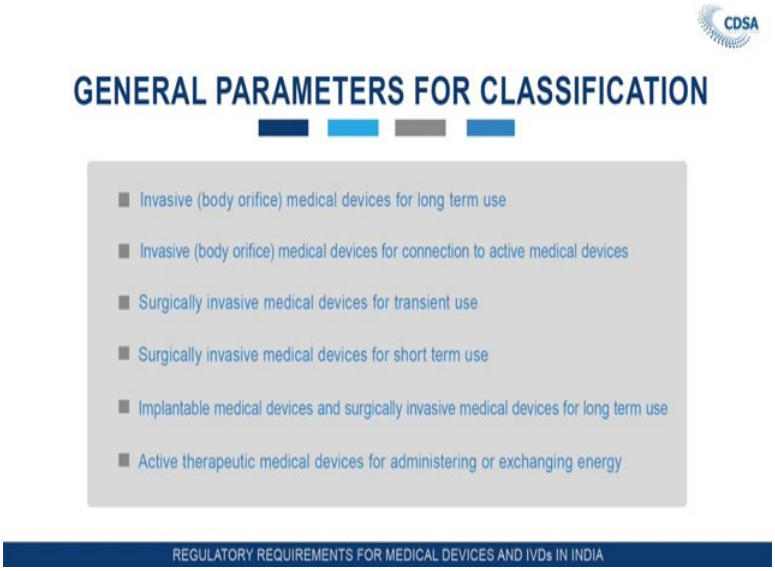

We can explain this very clearly with the help of an example. Invasive body use for transient use short, not actually short term a medium term used. For instance a catheters is inserted in the human body for say 2 hours or 3 hours that is the transitive medical device, in which in the body orifice. The body orifice is invasive in the body orifice means it's punctures the body orifice. A needle for short term use is your injection that will be which injures enters the body and remains in the human body for a few seconds.

And, for long term use it can be used for 15 days to 1 month or even more than that which goes it to human body. So, these all three are defined separately in the classification table, 8 is invasive body orifice medical device for connecting connection to an active medical device. Now, we have an active medical device which can be instrument which uses a electricity and is active and that is connected to a human body through a body orifice. So, that becomes actually a invasive medical device for its different classification.

Surgically invasive medical devices for transient use, short term use, they both are the surgically invasive means they are put into the human body for short term use and all long term use. Number 11 is a implantable medical devices are surgically invasive medical device for long term use. These are also for long term use, you can see these medical devices being used in a continuous manner in ICUs, in hospitals where a lot of devices going into the human body and remain there for long time. So, those are long

term uses medical devices. Number 12 is an active medical device for administering or exchanging energy.

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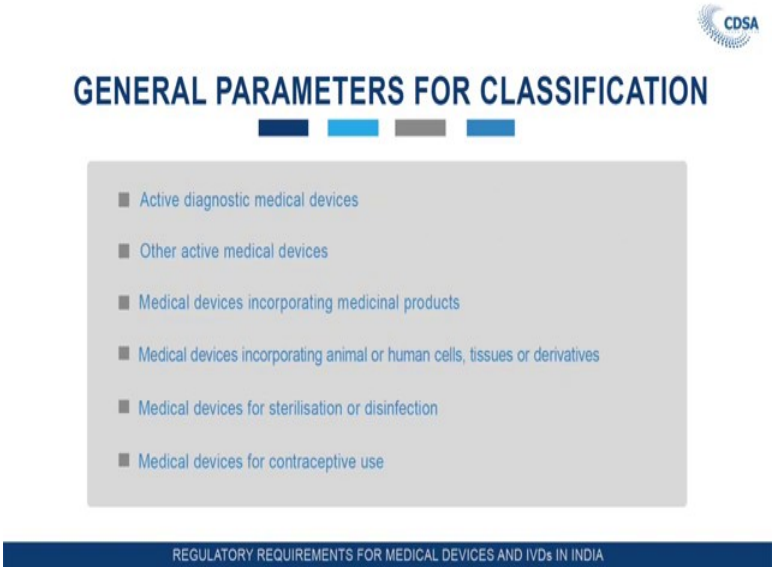

Number 13 is active diagnostic medical devices, this is the diagnostic part were coming over here which are also controlled another classification rules. Other active medical devices, medical device incorporating medicinal products which are combinational devices, there is separate presentation on that. Medical devices incorporating animal or human cells, tissues or derivates, this is also combination medical device help them separately.

Medical devices for sterilization or disinfection, this is a bit odd man out over here because in India till recently we used to consider sterilization or disinfection material to be drugs. For instance when a common parlance we can say Dettol or Savlon were drugs, but in the new regulations they are medical devices of course, internationally they are medical devices.

So, they fall in different category altogether and the next one is the medical devices for contraceptive use, that is may be condoms, copper T and all those things.

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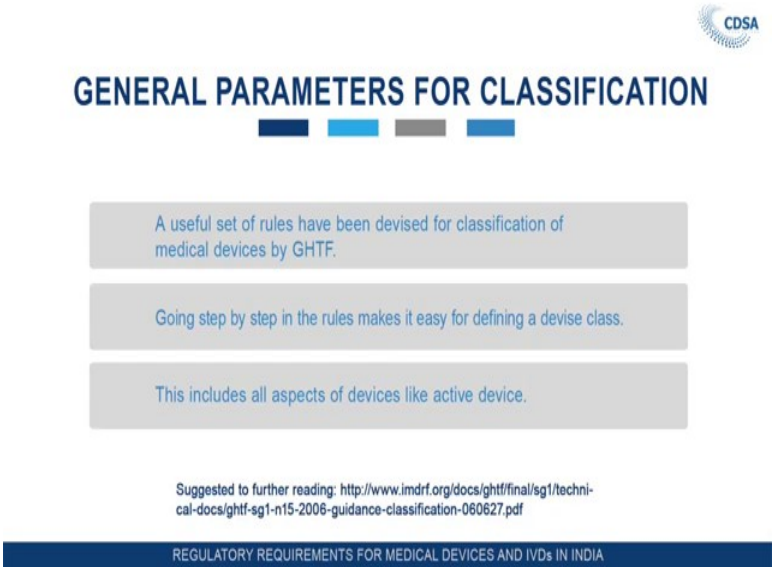

A useful set of rules have been devised for classification of medical devices by GHTF, you can go through GHTF website and find that out. It is very simple, very easy, it gives step by step, how to make it easy for defining a device class. This includes all aspects of such devices like active devices etc. and I have get a link at the bottom which is for suggested to further GHTF pdf for that.

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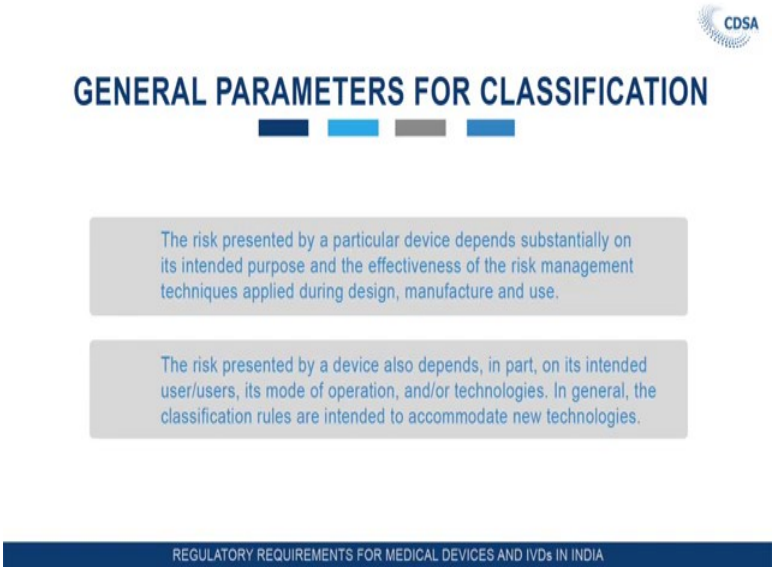

The risk presented by a particular device depends substantially on its intended purpose and the effectives of the risk management techniques applied during design manufacture

and use. So, the risk presented by device also depends in part on its intended users, its mode of operation and our technologies. In general the classification rule are intended to accommodate new technologies.

So, classification rules are extremely essential and useful for classifying a device and without the classification rules you cannot classify a medical device at all. So, I suggest that you go through the classification rules in details to understand how they are classified.

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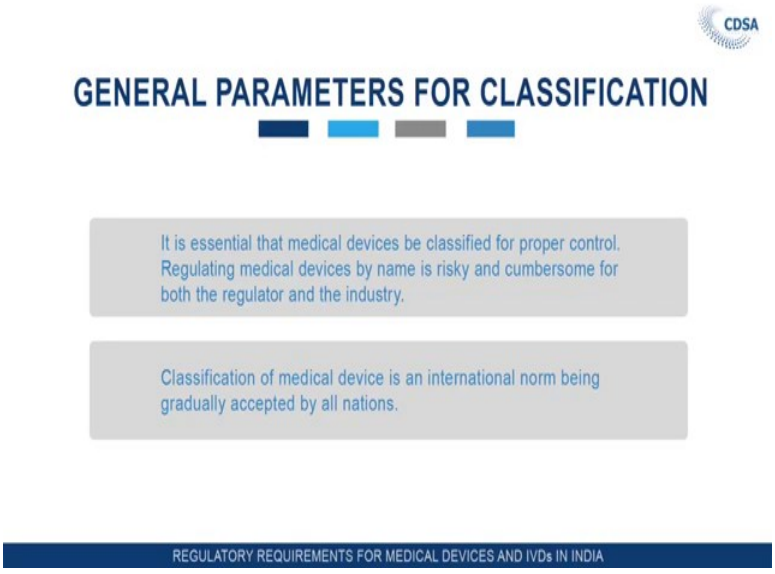

It is essential the medical devices be classified for proper control. Regulating medical devices by name is risky and cumbersome for both the regulator and the industry. Classification of medical device is an international norm being gradually accepted by all nations. So, classification of medical devices is not country specific, its internationally accepted.

So, any medical device which is a class C medical device, D medical device sold in one country; we know what class it is, what is the risk associated with that in any other country also. So, instead of having a name of the medical device and its use, its classification gives the general picture of the type of medical device it is.

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Now, I here at the end I would like you to I suggest you to go through this particular document or other documents available in the world also, in other regulatory agency Australia has got also, where Health Canada has certain documents which is very very useful for the industry. And, anybody who likes to know what classification classified medical devices, as a as a starting point you can use this and can merge with existing guideline if you wish to.

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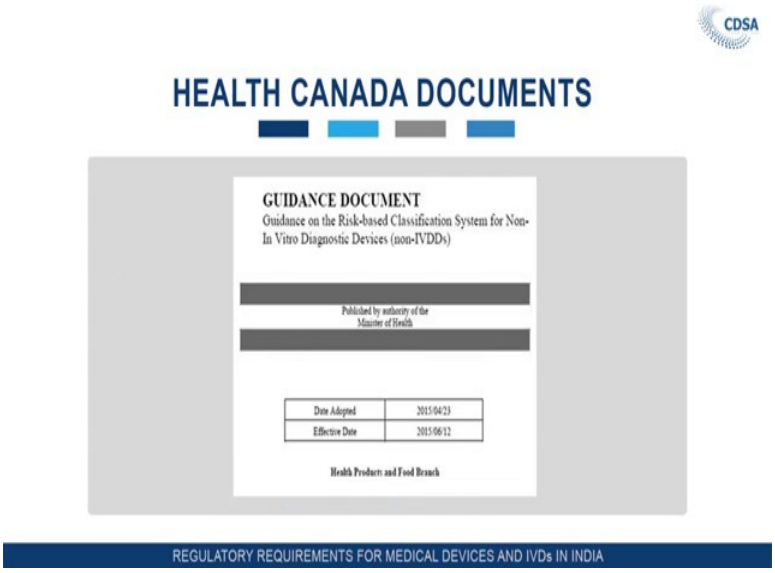

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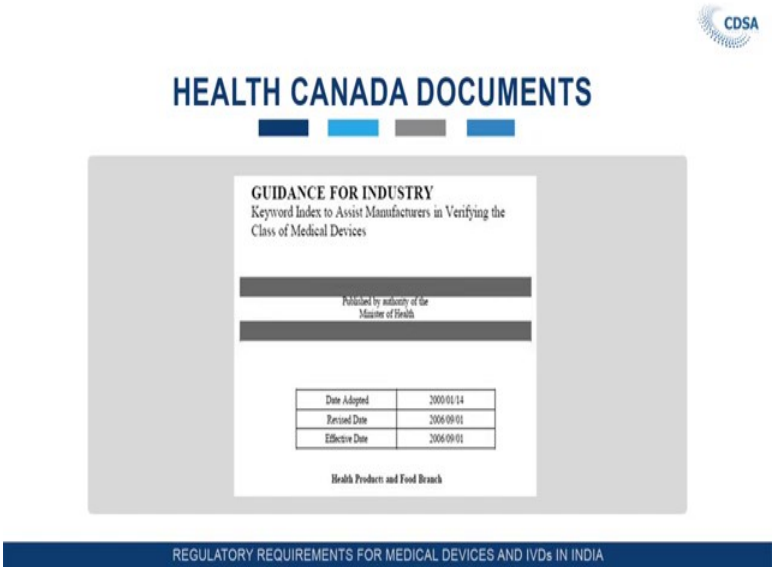

Now, what is this? This guidelines document of Health Canada gives you a list, a comprehensive list of medical devices with their class.

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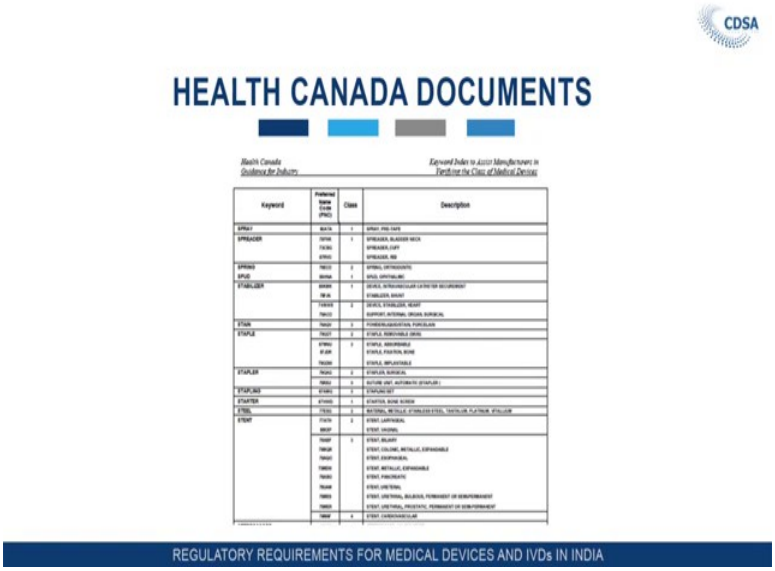

It is a very very long comprehensive lists of a few 8 to 900 medical devices. So, you can as a starting point you can take this document and decide which is the nearest match with your medical device and classify it according to that. And, do your QMS and everything according to that and then submit an application for manufacture or export or whatever. In case a regulator agrees to that your things become easy, otherwise you have to go

through the classification rules and then fall into the particular bracket which make them cumbersome.

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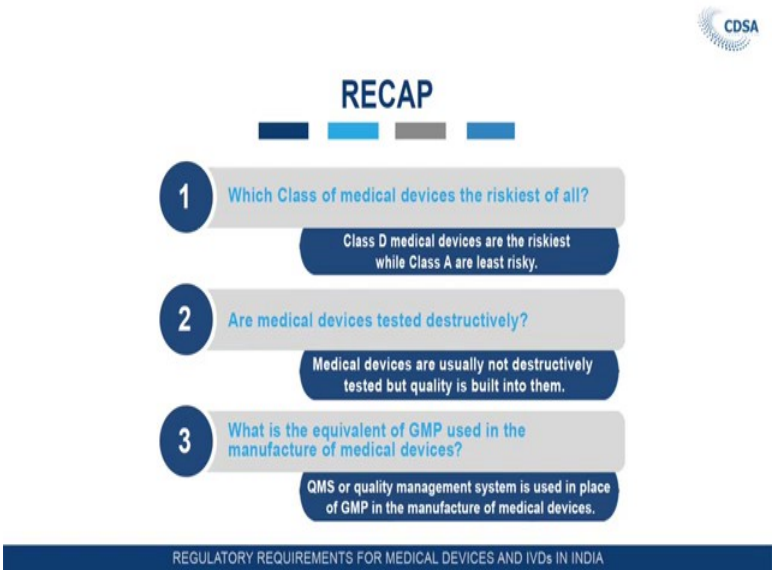

Now, some of the question and answer over are over here very simple one; however, you will be getting much more question and answers, you have to submit later on for assessment.

Thank you very much. This is the end of that.

Yeah. Welcome to Regulatory Requirement for Medical Devices and In Vitro Diagnostics in India. This is addon lecture to 3, that is the classification of the medical devices. This lecture already we have discussed in detail previously. So, this is continuation to the earlier lecture which we have discussed in detail.

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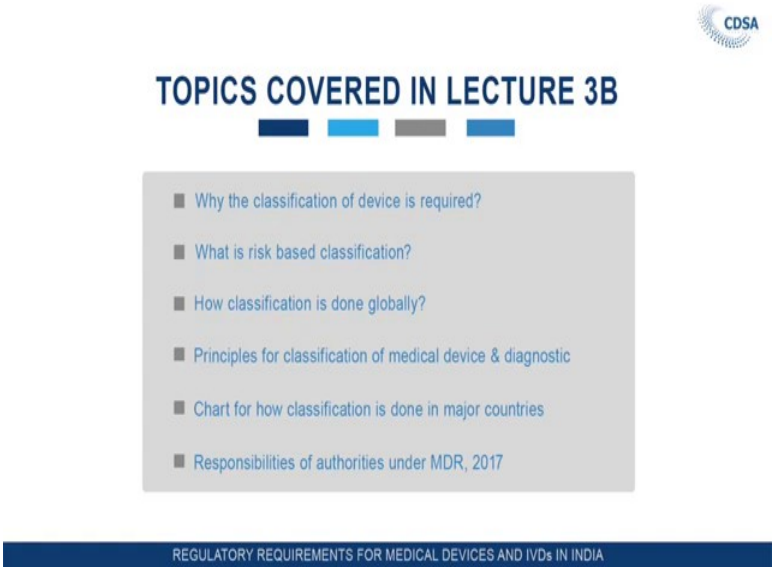

In this lecture we have discussed that why the classification of the devices is required. We have also discussed that what is the risk based classification, how the classification is done globally, what criteria for classification of the medical devices in different countries? The principles for classification of medical devices and diagnostics. We have also discussed that, also we have discussed the classification of the major country, what classification they have made and how they have done that classification.

We have discussed that classification of the GHTF, classification of health Canada, we have discussed the classification of PMDA that is Japan, we have also discussed the classification of the Australia TG Australia. We have also discussed the classification of the US FDA and also in our country what classification we have made that we have discussed in the earlier lecture 3; classification of the medical devices. Also in that lecture we have covered the responsibility of the authorities under the Medical Device Rules 2017.

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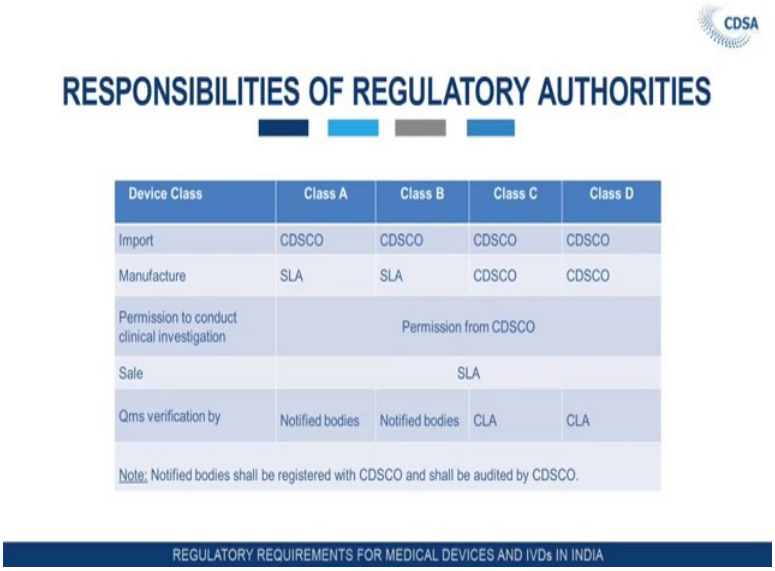

The responsibility of the authorities that is given in the Medical Device Rule based on the risk of the classes, we discussed that class A and class B devices that is the low risk devices. The responsibility for different activity have been prescribed in the Medical Device Rule 2017. We have discussed earlier that import responsibility lies with the Central Licensing Authority(CLA) that is CDSCO, manufacture for grant of manufacturing license, the responsibility has been given to a State Licensing Authority(SLA) for class A and class B devices, for Central Licensing Authority(CLA) class C and class D.

The permission to conduct the clinical investigation, permission from CDSCO is required, CDSCO is the Central Licensing Authority(CLA). So, permission for all classes of the devices, if clinical investigation or clinical evaluation is required to be obtained the licenses the permission is issued by the Central Licensing Authority(CLA). Responsibility of the sale and distribution of the medical devices and in vitro diagnostic, responsibility is given to the State Licensing Authority(SLA)..

QMS verification for class A and class B devices, the provisions for audit of notified body has been made. Notified body will audit the premises of the class A and class B medical devices. They will confirm the Quality Management System(QMS) as prescribed in the 5th schedule of the Medical Device Rule. It is mandatory for all type all

class A and class B devices, QMS compliance by notified body is mandatory. However, for class A devices the prior audit or inspection by the notified body has not required.

Once the license is submitted to the State Licensing Authority(SLA), the State Licensing Authority is responsible for grant of manufacturing license. However, the QMS audit and verification will be carried out by the notified body. So, for class A medical devices, the QMS verification will be done after issuance of the manufacturing license.

And, class B devices prior audit is required before grant of the license QMS audit is to be carried out. Timeline has been clearly prescribed in the rules, the satisfactory compliance of the QMS requirement and other relevant document as we have discussed in the previous lectures. These State Licensing Authority shall grant manufacturing license to the manufacturer for manufacturing of class A and class B devices.

So, the QMS verification is mandatory for class A and class B devices, it is not a optional. For class C and class D QMS verification will be done by the Central Licensing Authority(CLA) and based on the satisfactory report and other required other requisite information review by the Central Licensing Authority(CLA) found satisfactory then license will be granted. So, this is the responsibility given in the Medical Device Rule 2017 for State Licensing Authority(SLA) and for the Central Licensing Authority(CLA).

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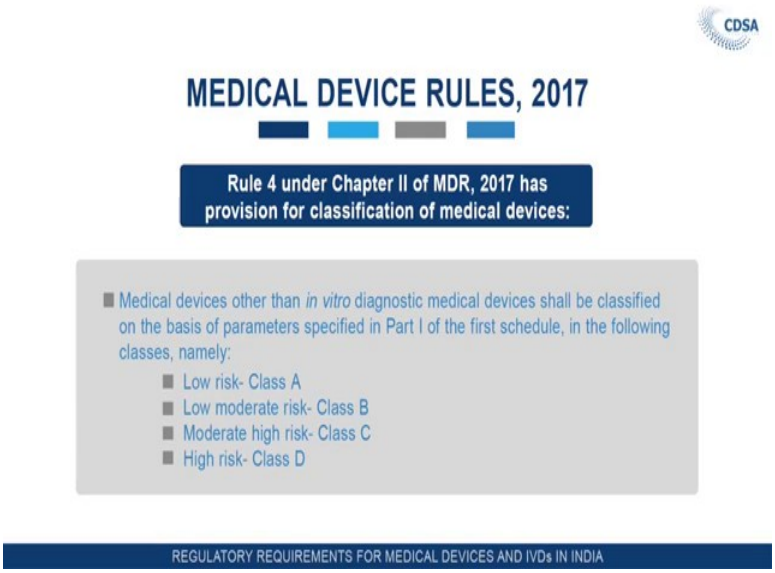

Now, in the classification of the medical devices although this part we have discussed in earlier lecture, but under Medical Device Rule 2017 the provision for classification of the medical devices has been made in chapter II. We have also discussed in the previous slides and previous lecture also the Medical Device Rules have 12 chapters and 8 schedules. Out of 12 the chapter II which gives the provision for classification of the medical devices. Under chapter II rule 4 that gives the provision for classification.

Under this rule medical devices other than in vitro diagnostic shall be classified on the basis of parameter specified in part I of the first schedule, the classification shall be done based on the risk. And, following classes that is low risk to high risk classes devices has to be done by the Central Licensing Authority(CLA). Where, the low risk devices that is class A devices, low to moderate risk devices that is classified as a class B devices, moderate to high risk class C, high risk devices will be classified as a class D devices.

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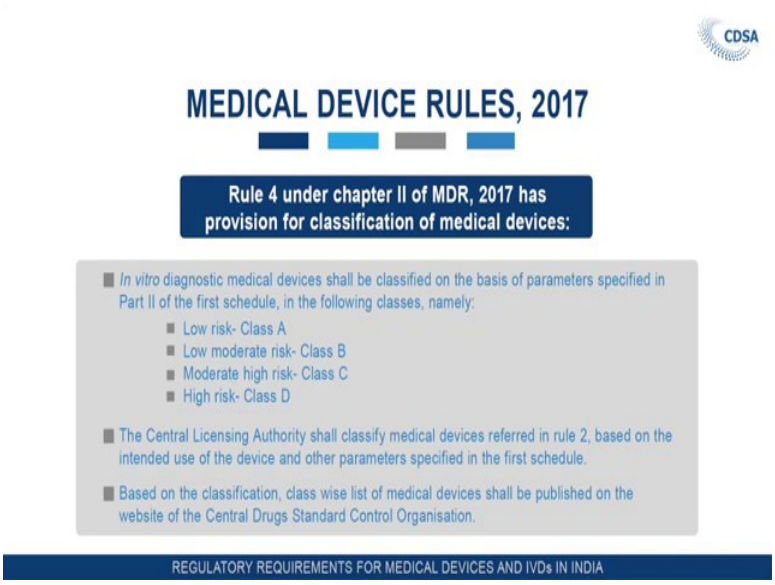

Likewise in vitro diagnostic kits shall also be classified on the basis of parameter specified in part II of the first schedule, in the following classes low risk to high risk classes low risk class A devices, low to moderate class B devices, moderate to high risk class C, high risk devices class D devices. So, this provision have been made in the Medical Device Rule 2017. And, the Central Licensing Authority(CLA) shall classify the medical devices refer to in rule 2, rule 2 where the medical devices which are regulated under the Medical Device Rule 2017 has been given.

So, the medical devices which are presently regulated under the Medical Device Rule 2017 shall be classified by the Central Licensing Authority(CLA) based on the intended use of the devices, their potential risk and other parameters as specified in the first schedule. also we have discussed in the earlier lectures, first schedule gives the details, criteria, parameters, principles of the classification.

Part I of the first schedule gives the detail parameter and criteria for classification of the medical devices, part II of the first schedule gives the principles and criteria for classification of the in vitro diagnostic kits. Based on the classification as per the first schedule of the Medical Device Rule Central Licensing Authority(CLA) shall publish the classification list for the manufacturers, for the importers.

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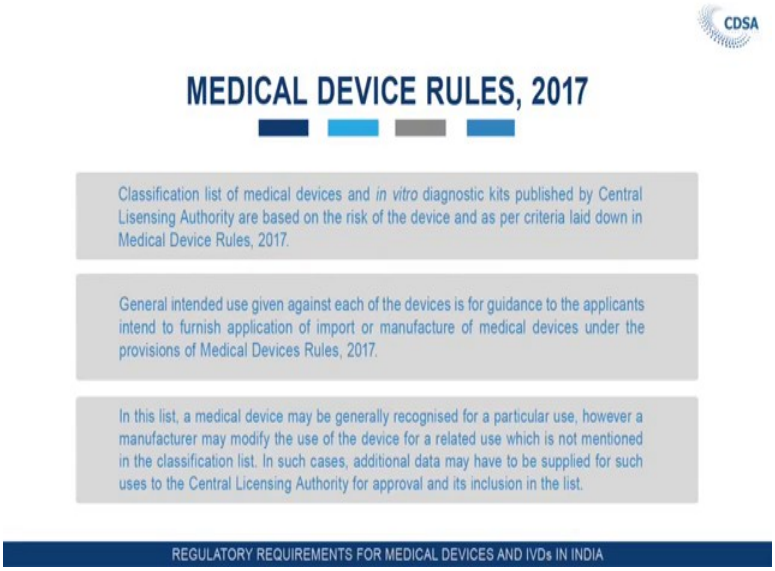

And, based on the classification the importer or manufacturer shall submit their application to the authority for grant of import or manufacturing license for marketing their product into the country. We have also discussed that classification list of the medical devices and in vitro diagnostic kits have been published and it is uploaded on the website of Central Licensing Authority (CLA), that is CDSCO. This classification list has been published based on the risk of the devices.

This classification list is for guidance to the applicant intend to furnish the application to the Central Licensing Authority (CLA) or the State Licensing Authority (SLA) for import or manufacture of the medical devices under the provisions of Medical Device

Rule 2017. In this list devices may be generally recognized for a particular use; however, the manufacturer may modify the use of the devices for the related use which is not mentioned in the classification list.

In such cases additional data may have to be submitted to the Central Licensing Authority for consideration and approval. And, once it is approved by the Central Licensing Authority, it is included in the said classification list. So, this classification list whatever that Central Licensing Authority(CLA) that classification list is only applicable for the devices which has been classified under the classification list. And, based on the classification of the medical devices, the applicant shall be submitted application to the concerned authority for grant of import or manufacturing license.

So, here in India it is not the case the manufacture can classify their devices based on the criteria mentioned in the Medical Device Rules. To have the uniformity in throughout the country this decision has been made by the Ministry of Health and Family Welfare (MoHFW). And, to have the harmonized classification for the medical devices in the country throughout the country this classification list has been published.

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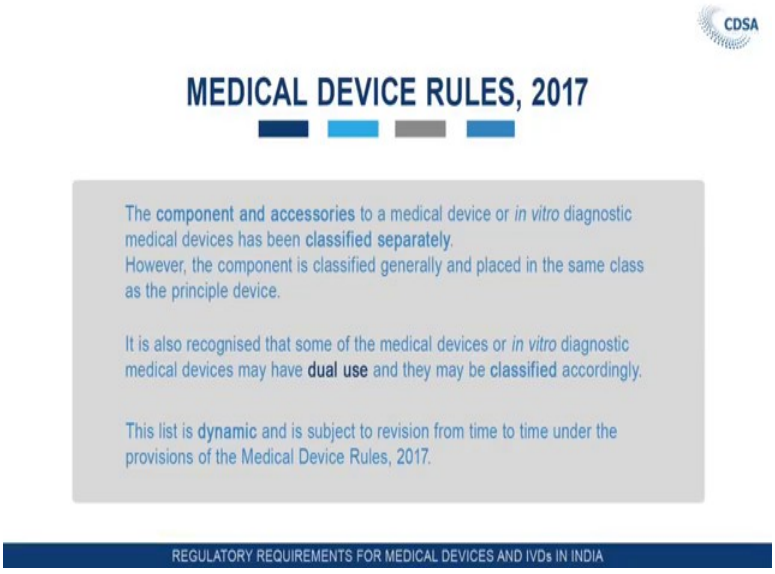

In this classification list also we have discussed the component and accessory to the medical devices or in vitro diagnostic kits have been classified separately. However, the component is classified generally and placed in the same class as the principal devices. It

is also recognized that some of the medical devices and in vitro diagnostics may have dual use and they may be classified accordingly.

This list is dynamic so, from time to time this based on the review of the documents the Central Licensing Authority (CLA) may review the classification list and make certain changes based on the documents, based on the evidence. And, they can again publish, they can again update the classification list.

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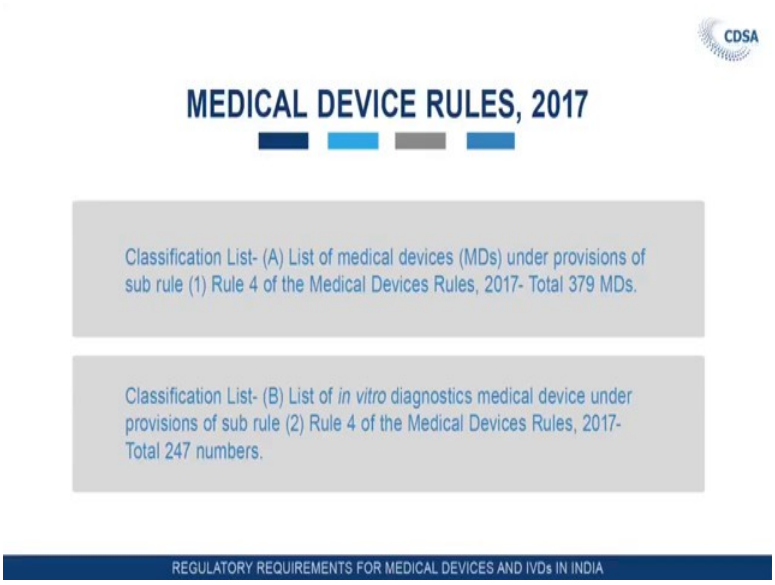

In the classification list published by the Central Licensing Authority (CLA) part I that is the classification of the medical devices have been made under this classification. So, for 379 different medical devices has been classified, 379 medical devices which are presently regulated under the Medical Device Rule 2017. These includes all the categories of the medical devices which are presently under regulation. Detail list we have discussed in the previous lecture, classification list for in vitro diagnostic kits.

The part B of the classification list gives the details about the classification of in vitro diagnostics and total 247 types of the in vitro diagnostic kits have been classified. So, this is all about the classification. So, in the classification of the earlier lecture and this adon lecture we have discussed why the classification of the device is required.

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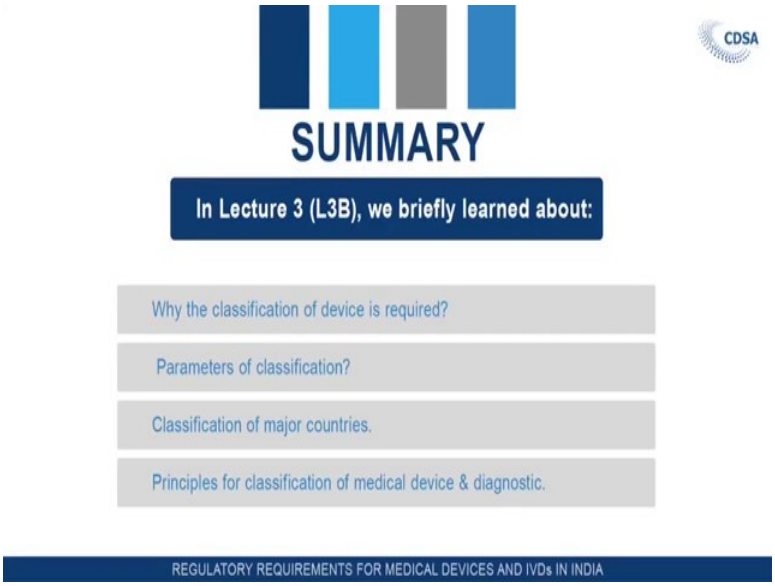

Parameter for the classification, what classification have applicable in the major country, the principles of the classification in medical devices.

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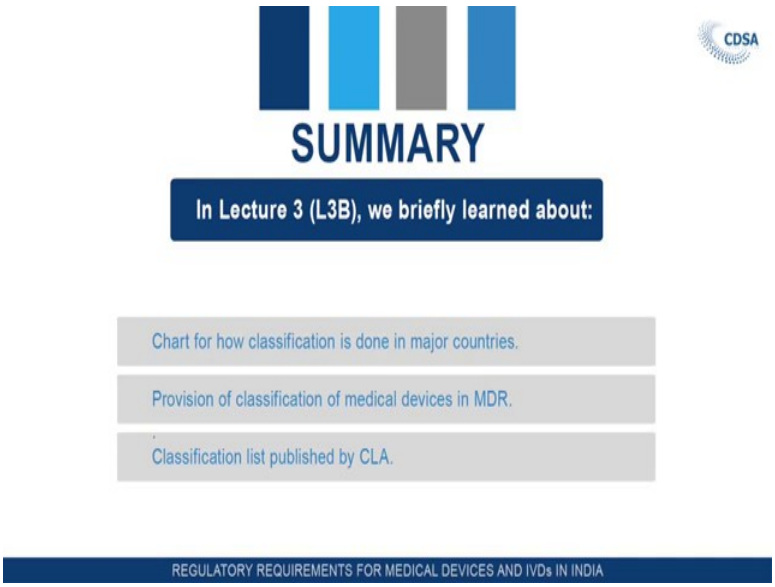

How classification is done in other countries, provisions of the classification of the medical devices in Medical Device Rule 2017 and the classification list published by the Central Licensing Authority (CLA).

So, by this way we have come to the conclusion this classification based on the risk of the medical devices, their intended use have been done in India also. This classification

criteria is in the line of the globally accepted criteria for classification of the medical devices and in vitro diagnostics. So, other chapter of the medical devices regulation, we will cover in the next lecture. With this I would conclude this lecture.

Thank you very much.