Regulatory Requirements for Medical Devices and IVDs in India
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Lecture - 04
C2L02

Welcome to Regulatory Requirement for Medical Devices and in vitro diagnostics in India; lecture 2 that is Medical Device Rules 2017 implication on medical devices.

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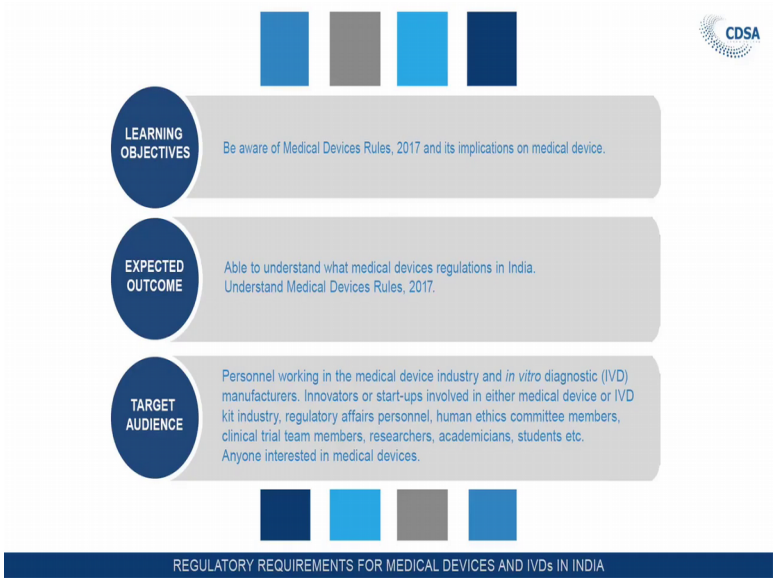

This lecture we will discuss about the Medical Device Rule which is the new rules that is rules is applicable for medical devices and in vitro diagnostics. The learning objective of this lecture is understanding of Medical Device Rule 2017 and its implication on the medical devices.

Now, what is the expected outcome? The expected outcome could be we will able to understand what is medical device regulation in India, we will able to understand Medical Device Rule 2017, target audience, personnel working in the medical device industry and in vitro diagnostics manufacturers, innovators or a start-up involved in either medical devices or in vitro diagnostic industry, regulatory affairs personnel, human ethics committee, members, clinical trial team members, researchers, academicians, students and the person generally interested in medical devices.

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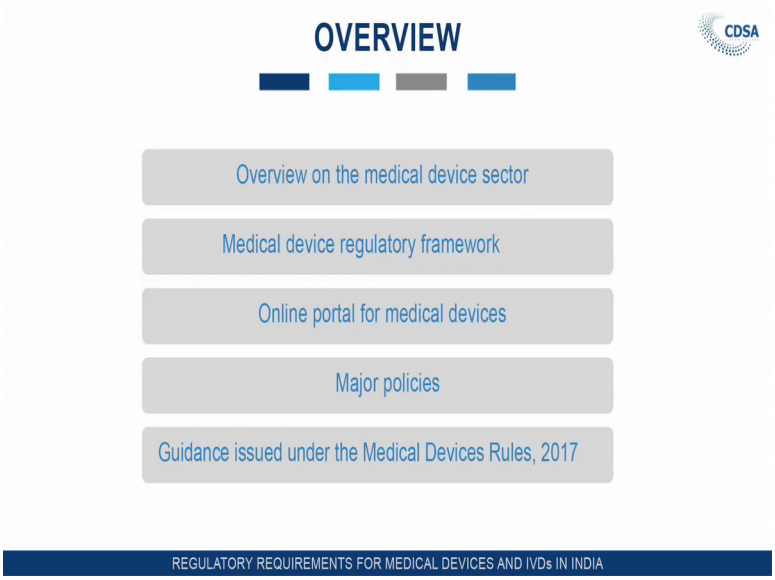

Now, the topics; topics of this lecture. What is the topic we will in cover in this Medical Device Rule 2017? The topics are medical device sector; what is the sector, what is the size of the sector, where this sector stand in India, the medical device regulatory framework, what are the regulatory requirement presently for the medical devices, which law is applicable for medical devices, under which rules the medical devices are regulated, online portal for medical devices, the major policies which the Ministry of Health and Family Welfare has taken in the Medical Device Rule 2017.

And the guidance document which have been issued by the Central Licensing Authority after publication of the Medical Device Rule 2017 for effective implementation of these Medical Device Rules. Now, come to the medical device sector; this sector in India is very small by size as compared to rest of the manufacturing industry.

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If you compare this with the pharma industry; we understand that [FL] pharma industry is much much bigger industry as compared to this sector. In India the pharma industry they are exporting their medical their pharma products to more than 200 countries and in the generic medicines the other pharmaceuticals products which we are exporting we are covering more than 50 percent of the global market in the pharma sector.

If you see the medical device sector India is one of the top 20 market for medical devices in the world; not very good position and if you see in the Asia it is 4th largest market after China, Japan and South Korea. This industry is valued at approximate US Dollar 6.5 billion. If you compare this with the pharma sector, the pharma sector valued approximate US Dollar more than 35 billion. This sector is growing at the rate of CAGR of approximate 15 percent, showing that India is one of the fastest growing market in the world; very growth very good growth factor as far as this sector is concerned.

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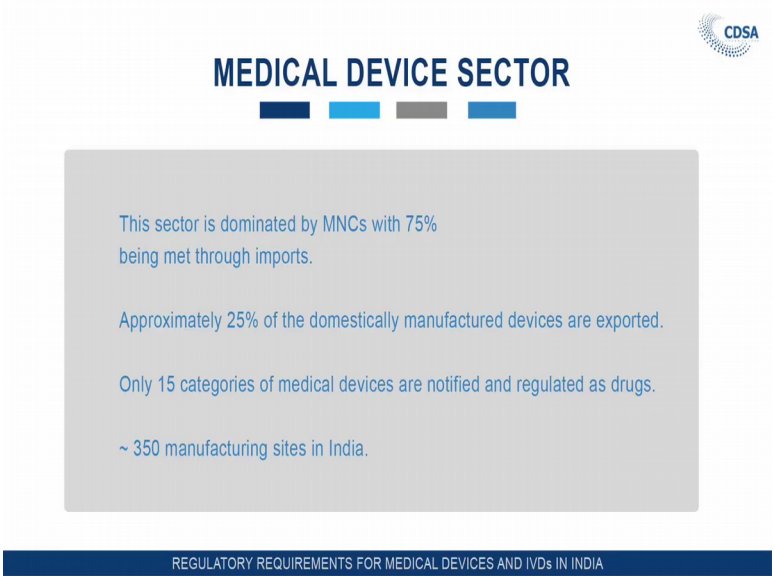

In this sector this sector is mainly dominated by the multinational companies with the 75 percent being met through the import; we do not have much indigenous capacity capability to met the requirement of Indian population; our population. Approximate 25 percent of the domestic manufactured devices are exported and the devices which mainly exported from India are disposable low in devices not the high in medical devices.

The medical devices only 15 categories or the medical devices are notified and presently being regulated under the law and under the law; the law is Drugs and Cosmetic Act. Under the definition of the drugs these medical devices are regulated. Approximate 350 manufacturing site in India so far have been approved by the licensing authority under the provisions of the present existing law and all these manufacturers they are manufacturing only regulated medical devices.

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The challenges; what challenges this sector has faced so far. As we know and we have discussed in the previous lecture also this medical device regulation it is not the comprehension regulation in India; only the certain limited number of medical devices are presently regulated. Which are those devices; in the previous lecture we have discussed that devices in details, in the subsequent lecture also we will again repeat that slides. Only certain notified medical devices and in vitro diagnostic kits are being regulated.

Not all the medical devices or the medical equipment; these devices are regulated as a drug, no separate distinct sector for medical devices. The requirement for the import, manufacture, clinical investigation of the medical devices are same as drugs in the previous rules.

So, the lack of the proper regulatory systems that is the main factor; harmonised standards, accreditation, legal requirements, proper guidance on the quality and best practices are affecting the medical device industry adversely. The Ministry of Health and Family Welfare have taken these major steps for this sectors and various measures that Ministry of Health Family Welfare and Government of India they have initiated.

New Medical Device Rule 2017 also one of the major initiative in this medical device sector where the Ministry of Health and Family Welfare has made separate requirement

specific requirement for medical devices and in vitro diagnostics for its regulation in India.

So, rules the Ministry of Health and Family Welfare has amended and separated from the Drugs and Cosmetic Rules that is the actually that Drugs and Cosmetic Rules mainly have the requirement for the drugs and cosmetics but for medical devices there were no specific requirement in the Drugs and Cosmetic Rules 2000 rules 1945.

Therefore this new law separating the rules from the Drugs and Cosmetic Rules for medical devices and in vitro diagnostics the Ministry of Health and Family Welfare has set up and published in the year 2017 January2017. To ensure that this medical device sector is considered as a significant as the other sectors are and to show the distinct sector against the drugs this new rule Ministry of Health and Family Welfare has published. This new rules is now presently effective from January2018.

This new rules aim to address the problems of this sector and to harmonise the regulatory requirement of the medical devices and in vitro diagnostics at par with the globally accepted regulation. So, this is one of the major that steps Ministry of Health and Family Welfare has taken as far as regulation of the medical devices and in vitro diagnostic is considered.

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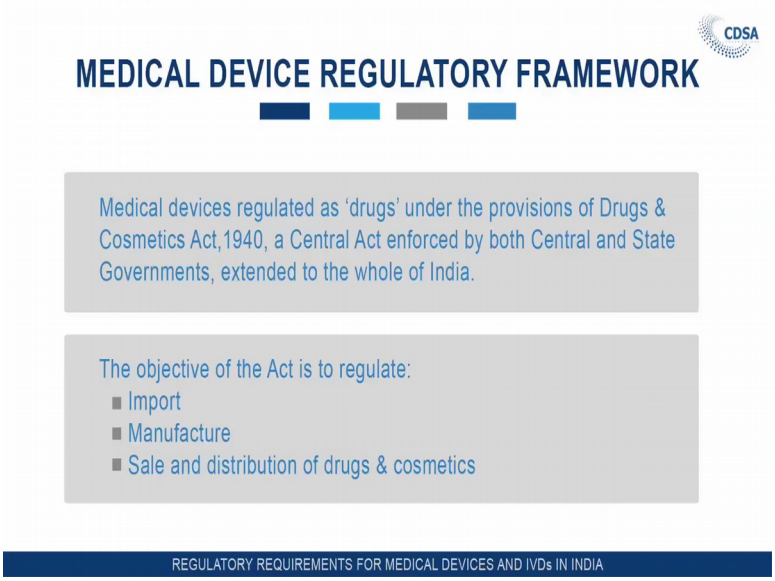

Now, come to the medical device regulatory framework. We have discussed so many times, again that medical devices regulated under the Drugs and Cosmetic Act 1940. This act is just Central Act enforced by both Central as well as State Drug Control Department. This act is extended to whole of the India and under this act medical devices are regulated as a drug.

Presently in the act there is a no separate definition for the drugs. The definition of the drugs include the medical devices; we do not have the separate definition is specific for the medical devices. So, under the Section 3b that is the definition of the drugs. This Section 3b of the act covers the medical devices and in vitro diagnostics and since it is under the drugs definition of the drugs; the earlier rules whatever the rules applicable for the drugs the same rule is has been applicable for the medical devices and in vitro diagnostics and because of that limitations, because of that challenges the Ministry of Health and Family Welfare has come up with the new Medical Device Rules 2017 for having specific requirement for import, manufacture, clinical investigation, sale and distribution of the medical devices and in vitro diagnostics.

The objective of the Drugs and Cosmetic Act is to regulate, import, manufacture, sale and distribution of the drugs and cosmetics. In order to have the specific requirement as already we have discussed this Medical Device Rule have been framed it is a separate rule for the medical devices published under the existing Drugs and Cosmetic Act. No other acts for the medical devices.

However, under the Drugs and Cosmetic Act this Medical Device Rule have been incorporated, this new Medical Device Rules replaced the earlier Drugs and Cosmetic Rules for medical devices and the requirement for import, manufacture, clinical investigation, sale distribution of the medical devices and in vitro diagnostic has have been prescribed in this Medical Device Rules.

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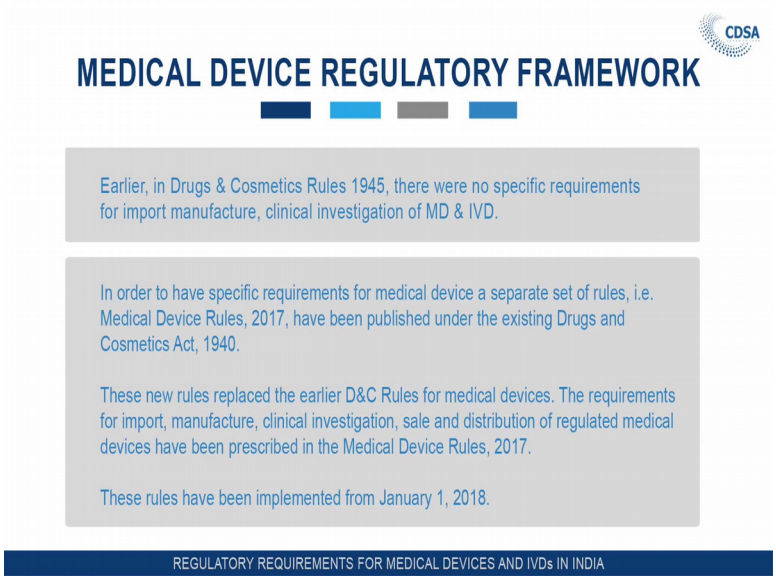

The requirements made under the Medical Device Rules for import, for manufacture, for clinical investigation that rules are in the line of the globally accepted requirements for medical devices and this new Medical Device Rule have been affective from the January 2018.

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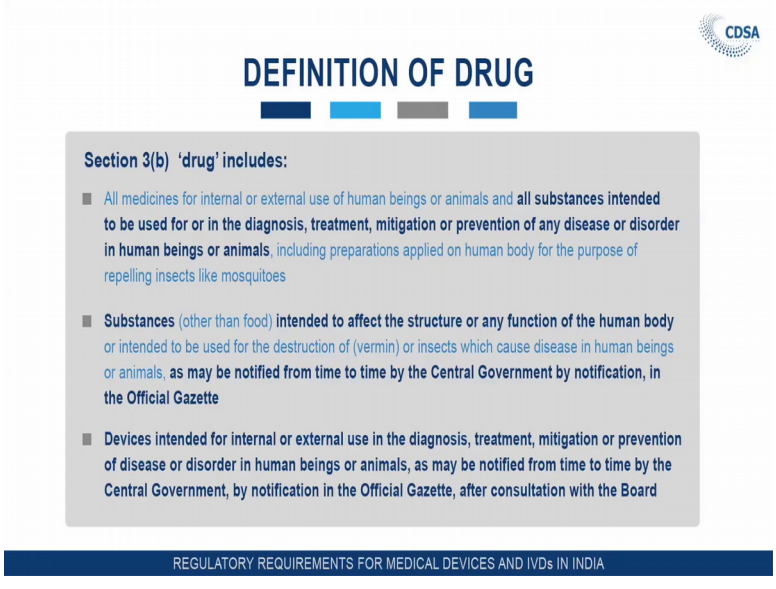

Again this we will further discuss that definition why that required again and again deliberation. We have to understand what is the medical devices, which medical devices

are covered under the definition of the drugs and are regulated because under the Drugs and Cosmetic Act. There is a no separate definition for the medical devices.

So, to have (Refer Time: 14:04) on the regulation of the medical devices which devices are regulated, which in vitro diagnostics are regulated; we have to understand what is the definition, in which definition which class of the definition the medical devices and in vitro diagnostics are regulated. If you see the Section 3b that is the definition of the drugs which includes 4 parts are there, 4 sub-clause are there. Under sub-clause i if you the highlighted portion here all the substances intended to used for or in the diagnosis, statement, mitigation or prevention of any disease or disorder in human being or animals.

Under these sub-clause of the drug definition all the in vitro diagnostic kits used for diagnosis of disease or disorder in human beings or animals are covered. So, Section 3b sub-clause i covers all the in vitro diagnostics. Other than in vitro diagnostics the surgical dressings all the surgical dressings, blood bags and blood component bags with or without anticoagulants; these categories of the medical devices are regulated. If you see the sub-clause ii of the Section (Refer Time: 15:58); sorry we describe such substances intended to affect the structure of any function of human body as may be notified this is the important one.

As may be notified from time to time by the central government by notification in the Official Gazette; means whatever the substances intended to affect the structure or any of the human body which have been notified by the central government Ministry of Health and Family Welfare through notification; will cover under this sub-clause of the drug definition and those devices are regulated.

So, under this sub-clause section certain disinfectant solutions which is intended to be disinfectant the medical devices and equipments that disinfectants are regulated, that disinfectant are covered; the mechanical contraceptives (Refer Time: 17:10) condoms, tubal rings. So, these mechanical contraceptives which have notified by the Ministry of Health and Family Welfare covered under this definition of the drugs.

Now, come to the sub-clause iv of Section 3b of the definition of the drugs that is the main devices which covered under this section.

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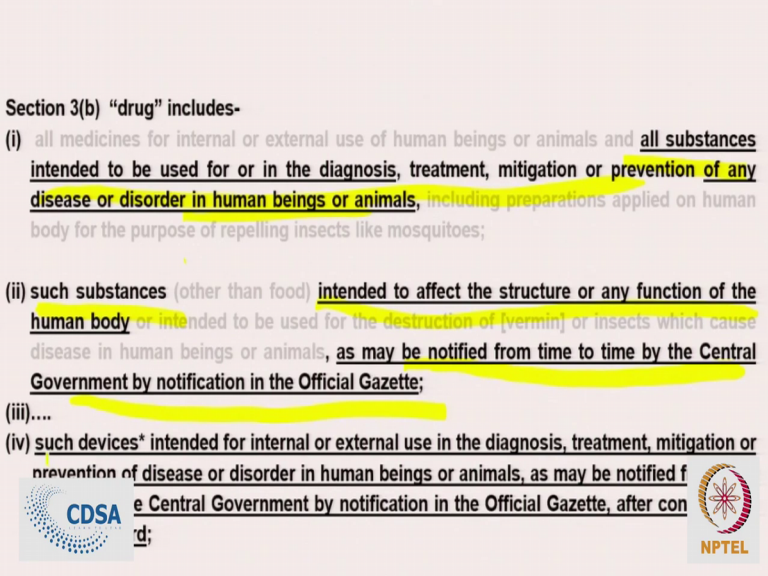

Such devices intended for internal or external use in the diagnosis, treatment, mitigation, prevention of the disease or disorder in human being or animals as may be notified by the central government through notification from time to time after consultation with the board. Board means the (Refer Time: 18:17) board under the Drugs and Cosmetic Act is Drug Technical Advisory Board. After recommendation from the board the central government that is the Ministry of Health and Family Welfare central government they will publish the; they will notify the more and more medical devices to come under the regulation and this Section 3b iv various medical devices have been notified by the Ministry of Health And Family Welfare. So, far we will discuss in the subsequent slides.

So, if you see the definition of the drugs and we have discussed that Section 3b i, Section 3b ii and Section 3b iv of the definition covers the definition of the medical devices. So, all these medical devices which covered under this definition is now regulated presently under the Drugs and Cosmetic Act and rules their under and for regulation of these medical devices the new rule which as published in the month in the year 2017 that is the Medical Device Rule 2017; the requirement prescribed in this Medical Device Rule is applicable for all those medical devices and in vitro diagnostic which falls under the definition of Section 3b i.

I hope you understand that if you see the definition of the drug the which types of the medical devices and which types of the in vitro diagnostics are presently regulated.

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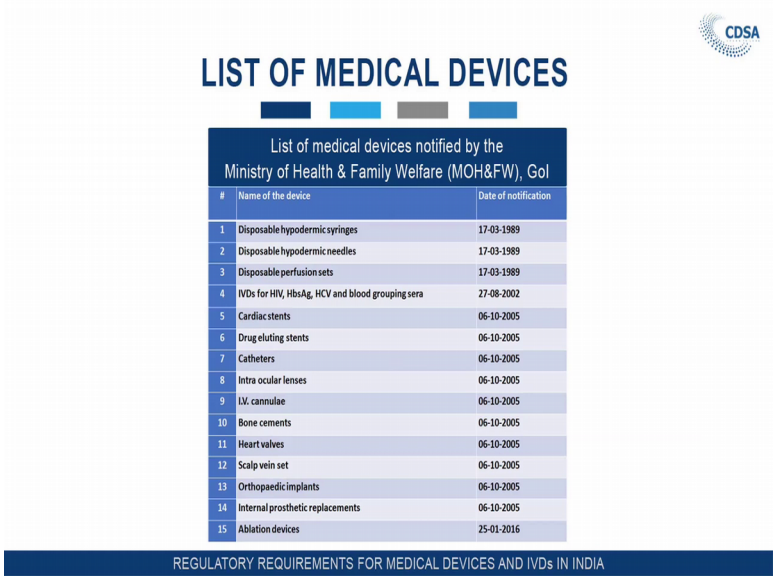

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Now, the notified medical devices; if you see the notification of the medical devices under Section 3b iv of drug definition. Presently they have 15 medical devices have been notified so far by the Ministry of Health and Family Welfare and these 15 medical devices are presently under regulation; also the additional categories of the medical device have also been notified by the Ministry of Health And Family Welfare.

However, a certain timeline has been given for implementation of that new medical devices which are recently notified. We will discuss that medical notified medical

devices in the subsequent slides. If you see the this list of the notified medical devices; the first three medical devices that is hypodermic syringes, hypodermic needle, perfusion sets these three medical devices were notified in the year 1989 and since 1989 these three devices have been regulated under Section 3b iv.

The IVD kits for HIV, HBSAG, HCV and blood grouping sera these four in vitro diagnostic kits have been notified in the year 20, 2002 27th August 2002; actual date and these four in vitro diagnostic kits are considered as a notified diagnostic kits and regulated as a notified in vitro diagnostic kits since 2002.

Although these in vitro diagnostic kits were already covered under Section 3b i and regulated, but as a notified in vitro diagnostic kit from 27th August 2002 it is notified and regulated. The remaining 10 medical devices that is from serial number 5 to serial number 14; these 10 medical devices have been notified by the Ministry of Health and Family Welfare on August 6th, 2005 and these are the cardiac stent, drug eluting stent, catheters, ocular intra ocular lenses, bone cements, heart valves, scalp vein set, orthopaedic implant, internal prosthetic replacement. And since 2005 this 10 more medic category of the medical devices have been notified and regulated.

In the year 2016 on 5th January 2016 one additional category that is ablation devices that was notified and regulated since 2016 with immediately effect. Thus regulation this notification has come. So, these 15 categories of the medical devices presently regulated under the Section 3b iv as a notified medical devices and the rules; the new rules is applicable for regulation of these 15 categories of medical devices.

Also the other medical devices which comes under Section 3b i that is all in vitro diagnostics other than these notified in vitro diagnostics, mechanical contraceptives, disinfectants, surgical dressings; all these have been regulated presently.

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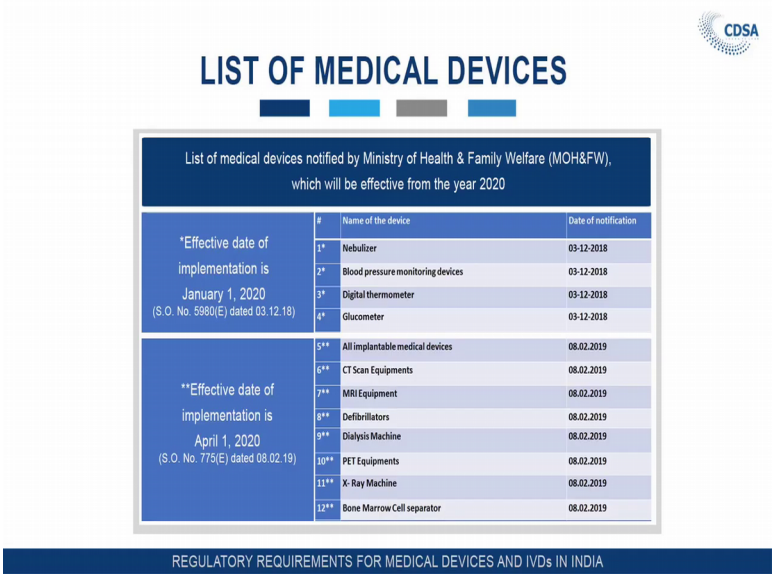

Now, come to the new notification recent notification has been published by the Ministry of Health and Family Welfare to have more medical devices under the regulation and December 3rd December 2018; these four nebulizer, blood pressure monitoring devices, digital thermometer, glucometer. This new; these are basically equipments and these new categories of the medical devices has been notified and the effective date for implementation, this notification is 1st January 2020 almost 12 month transition time has been given to the stakeholder.

The gazette notification wide as SO Number 5980E 3, 3rd December 2018 this notification was published. Thereafter in the recent week recent past week on 8th February 2019, 8 more; 8 additional devices have been notified again and these new medical devices are all implantable medical devices, CT scan equipments, MRI equipments, defibrillator, dialysis machine, PET equipment, X-ray machines, bone marrow cell separators.

These new 8 categories of the new medical devices has been notified and the effective date of implementation of these new notified medical devices is 1st April 2020. The notification gazette notification published by Ministry of Health and Family Welfare is SO Number 775E dated 8th February 2019. So, this is all about the notified medical devices.

Although total 27 categories of the medical devices has been notified so far by the Ministry of Health and Family Welfare under Section 3b iv; out of 27 medical devices; 27 categories of the medical devices, 15 categories first 15 which we have discussed in the previous slide is presently under is regulated under the act and these new 12 medical devices which also includes the equipments will be regulated with effect from January 2020 and April 2020.

So that more than 1 year of the transition time has been given up to publication of the notification of these new category of the medical devices. Now come to the Medical Device Rule 2017 as we have already discussed that this is the new rule; the genesis of this rule we have discussed; what is the constraint in the sector, in the medical device. sector

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So, these Medical Device Rule that Ministry of Health and Family Welfare has been has published the notification number GSR 78E 31st January2017 and the implementation date of the Medical Device Rule 2000 was 1st January2018.

If you see the publication and the date of implementation of this act almost 1 year time has been given to the stakeholder for implementation of this Medical Device Rule. Not only that 1 year to the stakeholders; the existing license holder because the (Refer Time: 28:00) it is not [FL] the medical device are regulated this and Medical Device Rules are applicable for the devices which are regulated under the Medical Device Rule 2017.

But the earlier in the Drugs and Cosmetic Rules all these regulated devices are covered and the rules drugs and cosmetic whatever the requirement given in the Drugs and Cosmetic Rules 1945; the rules the Drugs and Cosmetic Rules were applicable for these medical devices. So, all the licenses, permissions, NOCs granted to the regulated medical devices under the Drugs and Cosmetic Rules. So, whatever the licenses and permissions issued under the Drugs and Cosmetic Act and rules the existing license holder they will be given 18 month time for implementation of this new rules; 18 month time from the publication of this Medical Device Rules 2017.

Means [FL] if the license holder having the license issued under the Drugs and Cosmetic Rules; they will implement the law will be implemented till Jan July 20 2018; that 18 month time has been given if their or the validity of their existing manufacturing license or import license means [FL] if the manufacturer have validity of their license beyond 18 month of the date of the publication of the Medical Device Rule that much minimum time has been given to the manufacturers or importers to implement these Medical Device Rules.

Under these rules we understand and also discussed that [FL] requirement for import, manufacture, clinical investigation and sale and distribution of the medical devices have been clearly prescribed. The requirements are in the line of the globally accepted requirement. This Medical Device Rules shall overwrite all the previous notification issued under the Drugs and Cosmetic Rule 1940 related to the regulation of the medical devices.

I have already discussed and explained that. The Drugs and Cosmetic Rules 1945 that is the earlier rules which is under this rules the medical devices the requirement has been prescribed on medical devices although there is you a (Refer Time: 30:51) specific requirement, but whatever the requirement is there that these applicable for the medical devices. So, the previous notification under issued under the Drugs and Cosmetic Rules for the regulated medical devices this Medical Device Rule have overriding effect. So, this new Medical Device Rule will be applicable.

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The scope of this regulation; this new regulation scope you just go through the scope that is the scope prescribe mentioned in the Drugs and Cosmetic Rules. The substances used for in vitro diagnostics, surgical dressing bandages, surgical staples, sutures, ligature, blood component with or without anticoagulants are covered; we have discussed in the definition of the drugs.

The second the substances including the mechanical contraceptives and disinfectant notified under sub-clause 3b we have discussed in the drug definitions and third one is the medical devices notified from time to time under sub-clause iv of the class b of Section iii. So, in the this Medical Device Rule is applicable for all these medical devices which are regulated under this sub sections.

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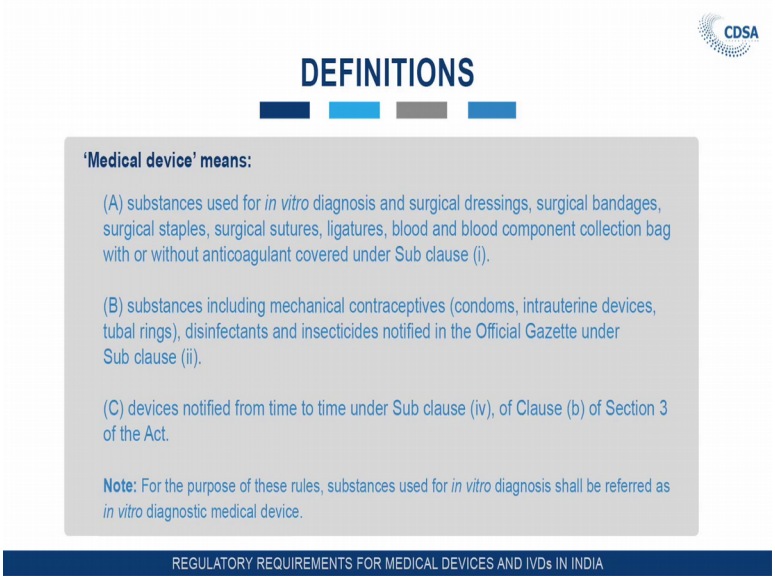

In the Medical Device Rule because the definition of the drugs very very confusings to have the (Refer Time: 32:28) on the definition to have the (Refer Time: 32:33) on the applicability of this Medical Device Rules; medical device has again redefined in the Medical Device Rules under the Medical Device Rules. In the definition of the Medical Device Rules as defined in the Medical Device Rules the substances used for in vitro diagnostic of the surgical dressing same thing which we have discussed earlier that has been again redefined to have the (Refer Time: 33:06) on the issue.

The stakeholder will clear [FL] what type of the medical devices are regulated, where these Medical Device Rule is applicable. In the expression portion of the definition defined in the Medical Device Rule 2017 it is stated that for the purpose of this rule the substances used for in vitro diagnosis shall refer as in vitro diagnostic medical devices.

So, the in vitro diagnostic kits, reagents which are regulated that will be considered as the in vitro diagnostic medical devices under this redefined medical device definition in the as per the Medical Device Rule 2017.

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Also in the Medical Device Rules various new definitions; this is the new definitions that have been included with respect to the medical devices. What are those definitions; so many other (Refer Time: 34:13) are like change in the constitution, if there is a change in the constitution of the manufacturers; how we define the change in the constitution?

What is clinical investigation? Clinical performance evolution means conformity assessment, also the definition define the custom made medical devices, intended use, in investigational medical devices, predicate devices, substantial equivalence devices, long term use, medical device testing laboratory, medical device testing officer, medical device officers, notified body, performance evaluation post marketing surveillance, quality management system and so many other definitions have been incorporated in the Medical Device Rule 2017.

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Now, the content of the Medical Device Rule 2017; if you see the content of the Medical Device Rule 2017 this rule have total 96 rules, 12 chapters, 8 schedules and 40 forms have been included in this new Medical Device Rule 2017. This forms related to submission of the application to the licensing authority, registration of the labs, permission or the license issued. So, various forms covers all those activities.

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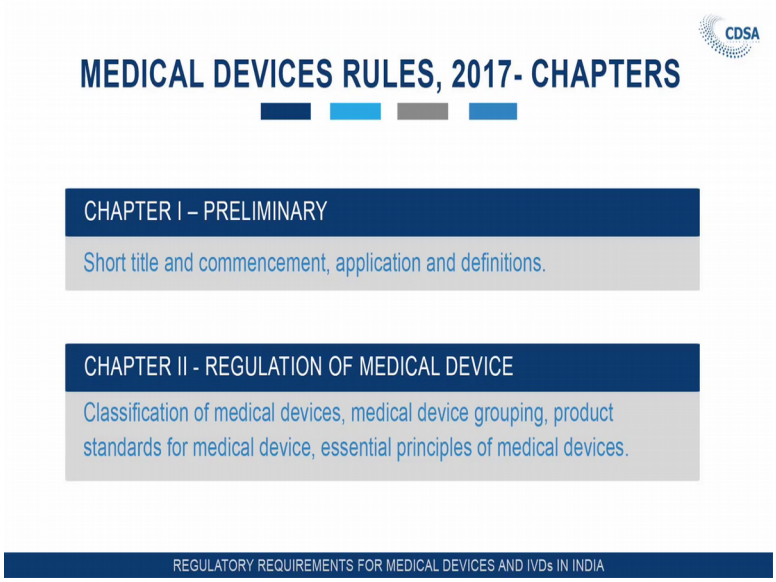

Now, come to the chapters; we will discuss the summary of the chapters, what are the chapters that is 12 chapters and each chapter have different their provisions. Chapter I if

you see the chapter I; chapter I in the Medical Device Rule that is the preliminary chapter; under this chapter short title commencement of the rules, application and definitions. Definitions we have discussed, title that is the Medical Device Rule 2017 we have also understand that. Commencement of these Medical Device Rule we have also discussed that [FL] this rule will be this rule which was published in the year January 2017 effective date of the rule was 1st January 2018.

Application where the applicability; applicability of this rule to; all the medical devices which covered under Section 3b i, Section 3b iii, Section 3b iv of the drug definition and that definition also redefined the Medical Device Rule we have also discussed that. So, under chapter I all those information and those provision has been made.

Chapter II; chapter II deals with the regulation of the medical devices; now what provision have been made in the chapter II under regulation of the medical devices. Provision for classification of the medical devices under this provision; the Central Licensing Authority that is CDSCO Central Licensing Authority is responsible for classification of the medical devices which are presently under regulation. So that provision have been made in the chapter II.

Medical device grouping; provision for medical device grouping, each medical devices has to be grouped into particular system or kits or single, how the grouping will be done that provision has been made in the; that provision has been made to have the medical device grouping and these grouping for this grouping the guidance document is to be issued by the Central Licensing Authority. Also provision for essential principle of the medical devices the guidance document on the essential principle of the medical devices for safety and performance; the Ministry of Health and Family Welfare that is the Central Licensing Authority; central government will publish this guidance document for the stakeholders.

Provision for product standard for the medical devices have been made in the chapter II. The product standard if you talk about the product standard of the medical devices whatever the standards applicable for the product; that provision have been made. A particular product have the standard of the bureau of Indian standards or the standards approved by the Central Licensing Authority that is CDSCO that standard is applicable for the particular medical devices.

If the BIS that is the Bureau of Indian Standard the standard setting organization in India; if they do not have if the BIS have do not have the standards for particular medical devices; so other international standards is applicable for that product. What are those International Standard Organization; that is ISO IEC; if that standard is there that will be applicable for those medical devices. If there is a no international standard is available product standard for medical devices is not available.

In such cases whatever the standards manufacturers standards which is approved by the Central Licensing Authority that will be applicable. So, these provision have been incorporated in the chapter II of the Medical Device Rule 2017.

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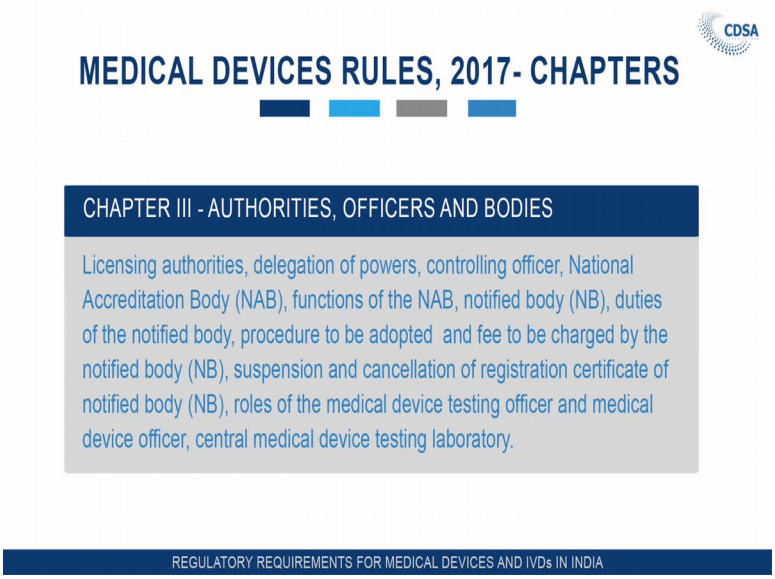

Chapter III the authorities, officers and body. Authority is responsible for implementation of these Medical Device Rules, authority is responsible for grant of license to manufacture the medical devices or in vitro diagnostics. Authorities for inspection, quality management system, verification of the quality management system of the manufacturing premises.

Authorities is for test and evolution of medical devices, controlling officers, National Accreditation Body, functions of national accreditation body, notified body; these are the authority notified that third party have given responsibility for audit of the class a class b medical devices, audit of the QMS inspection of the class a and class b devices.

So, all those provision has been made in the chapter III. There is duties of the notified body, what procedure to be adopted, what fees that they will charge from the manufacturers, issuance of the registration certificate by the Central Licensing Authority, suspension and cancellation of the registration certification of the notified body.

Testing labs for the medical devices that is central medical device testing laboratory, medical device officer all those provision have been incorporated in the chapter III of the Medical Device Rule 2017.

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Chapter IV deals with the manufacture of the medical devices; here the provisions procedures for the submission of the application for grant of manufacturing license to manufacture in vitro diagnostics or medical devices has been given. The conditions of the license what condition is required or the condition has been given, provision for inspection of the site, provision for grant of the license, conditions of the license, provision for change in the constitution if there is a change in the constitution of the manufacturers test license is required to be obtained, unannounced inspection by the State Licensing Authority.

The State Licensing Authority will inspect the premises of the class a and class b devices which have already been approved, which have already been recommended by the notified body for the grant of manufacturing license; that 2 percent of that manufacturing unit will be audited by the State Licensing Authority through the unannounced

inspection, validity of the manufacturing license, provision for suspension and cancellation of the manufacturing license. Also the test license to manufacture test batches for test evolution or clinical investigation of medical devices and in vitro diagnostic kits; that provision have been included in the chapter IV.

So, the procedure for grant of manufacturing license, conditions of the license, suspensions, validity of the license all those provision have been included have been made in the chapter IV of the Medical Device Rule 2017.

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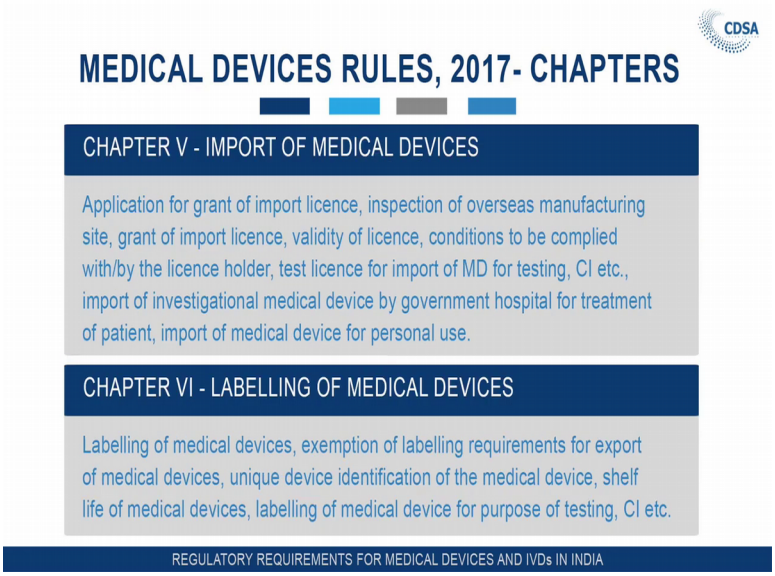

If you see the chapter Vof the Medical Device Rule which deals with the import of the medical devices. Here also the provisions for procedure or provision for grant of the import license for manufacturing and marketing into the country, import license for test or evolution purpose or clinical investigation purpose or the demonstration purpose, provision for import of investigational medical devices for the treatment of the patient, import of the medical devices for personal use by the patient all these provision have been made under chapter V of the Medical Device Rule 2017.

Chapter VI what are the labelling requirement for the medical devices; this requirement has been clearly prescribed in the chapter VI of the Medical Device Rules. The labelling of the medical devices, certain exemptions have been given for export of the medical devices; what are that provision; the provision for exemption also made in the chapter VI

of the Medical Device Rules 2017. UDI number for the medical devices, 5 years time has been given to implement this UDI system presently that provision has been made.

The shelf-life of the medical devices, what will be the shelf-life of the medical devices based on the stability study data submitted by the firm, the licensing authority will give the approval for the shelf-life of the medical devices. Maximum shelf-life for 5 years have been given in the that provision have been given in the Medical Device Rule 2017 under this provision.

However, if the there is a significant data sufficient data to prove the stability study to prove the shelf-life of the product more than 5 years; the based on the documents and the document generated the licensing authority bill consider that shelf-life which is beyond 5 years of the provision has made in the Medical Device Rule 2017.

Labelling of the medical devices for the purpose of testing of clinical investigation; it is not [FL] whatever the product which is meant for the marketing in the country the same labelling provision will be applicable for the product which is meant for testing or the clinical investigation purpose. So, specific provision have been made for these medical labelling requirement for these medical devices for the purpose of the testing and clinical investigation.

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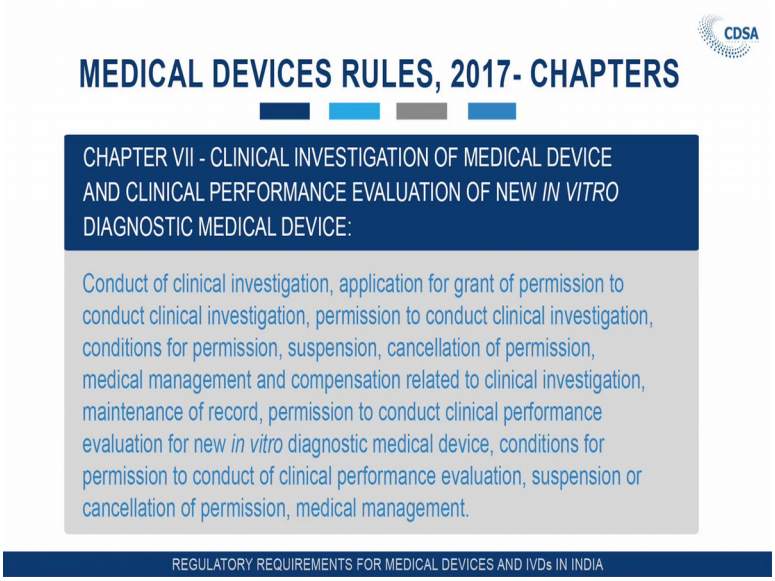

Chapter VII where in the provision for clinical investigation of the medical devices or clinical performance and evaluation of the in vitro diagnostic medical devices. New in vitro diagnostic medical devices has been made; under this provision the provision for conduct of clinical investigation, application for grant of permission to conduct the clinical investigation, clinical performance evaluation, conditions of the permission, suspension, cancellation, provision for medical management and compensation related to the clinical investigation, provision for maintenance of records, permission to conduct the clinical performance evaluation for new in vitro diagnostic medical devices all those (Refer Time: 46:20) all those particulars have been provided in the chapter VII of the Medical Device Rule.

Chapter VIII that is import for manufacture of the medical devices which does not have predicate devices that is applicable for the new in vitro diagnostic medical devices or new investigational medical devices; what are the requirement, what provision, the permission to import the medical devices or to manufacture the medical devices.

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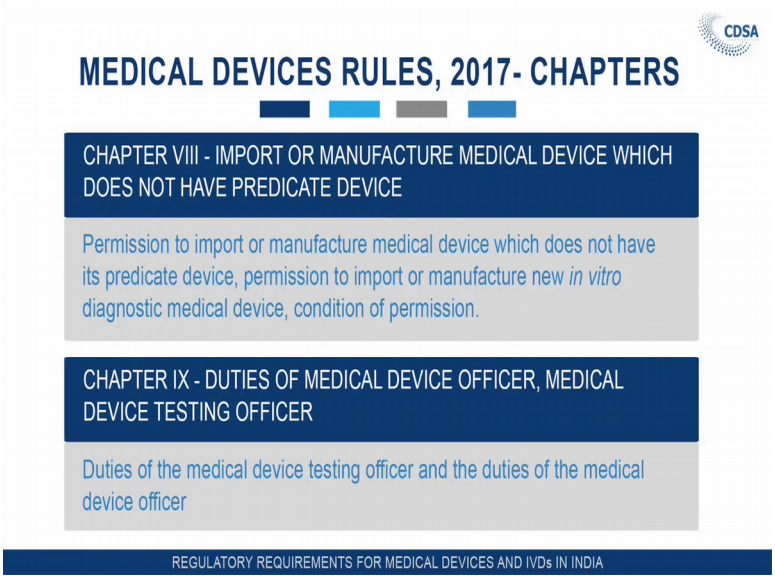

Conditions of the permission all those provision has been made in the chapter VIII of the Medical Device Rule 2017. Chapter IX where the duties of the medical device officers and medical device testing officers has been prescribed, what procedure the medical device officer follow for effective implement enforcement of this Medical Device Rule

2017, what are the procedures their duties all those things have been defined in the chapter IX of the Medical Device Rule 2017.

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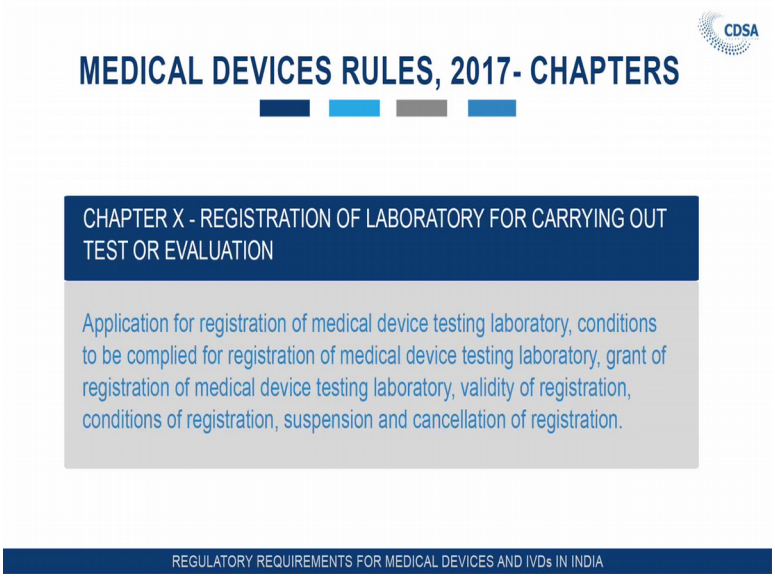

Chapter X that is the provision for registration of the laboratory for carrying out the test or revolution of the medical devices on behalf of the manufacturer. To facilitate the manufacturer if the private testing laboratory carrying out the test and analysis of the in vitro diagnostics; if they want to evaluate the medical devices (Refer Time: 47:57) manufactured by the manufacturers.

If it is registered the they can test the medical devices or in vitro diagnostics on behalf of the manufacture that data will be considered by the authorities for grant of registration, for granted manufacturing license or for grant of import license. Under this chapter the registration of the laboratory, conditions of the registration issued to that laboratory, grant of the registration of the medical device laboratory, validity of the registration, conditions, suspension, cancellation all those provision have been made.

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Here this provision for sale and distribution of the medical devices have been made. Recall of the medical devices from the market; provision for supply of the medical devices to the hospitals on delivery challan that provision has been made.

Chapter XII; last chapter; that is miscellaneous chapters; under this chapter provision for exemptions related to the medical devices where what exemption shall be given to the what type of medical devices that provision has been made. Export of the provision for export of the medical devices, rejection of the application if that application received by the Central Licensing Authority and State Licensing Authority; if any documents submitted found fake or fabricated the application can be rejected by the concerned licensing authority, that provision has been made in the chapter XII.

Debarment of the applicant the applicant who whose data found fake or fabricated; the licensing authority shall debar the applicant after giving the so cause. Mode of the payment of the fees; fees which is required to be submitted for grant; grant on import of the manufacturing license or clinical performance or clinical evaluation of the medical devices in vitro diagnostic kits.

The mode of payment of the fees for that particular purpose that provision has been made in the chapter XII. Digitalization of the forms all the physical forms can be digitalized by the Central Licensing Authority that provision has been made under this chapter. Overriding effect; this rule have overriding effect that provision has been made in the

chapter II. Savings; saving class whatever the license or the permissions issued under earlier rule that is Drug and Cosmetic Rules the saving class has been given, the license will be valid till the expiry of the license granted earlier by the licensing authority.

So, these 12 chapters cover all the provisions of import, manufacture, clinical investigation, sale and distribution of the medical devices and in vitro diagnostic. I hope you have basic idea now on the chapters included in the drug and Medical Device Rule 2017.

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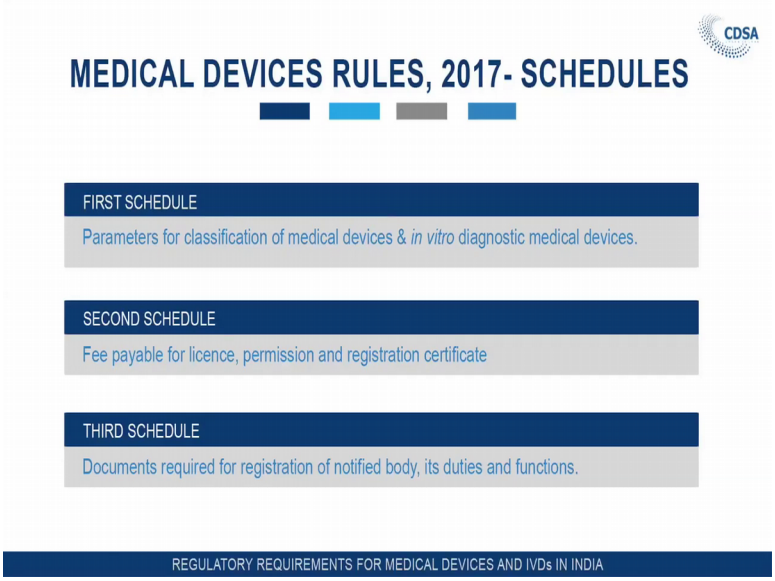

Now, come to the schedules; initial slides we have discussed that in the content of the Medical Device Rule 2017; the rules have 12 chapters, 8 schedules. What are those 8 schedules; first schedules, the first schedules prescribes the requirement, parameters, basic principles for classification of the medical devices and in vitro diagnostics. The first part of the schedule part I of the first schedule that is the parameter requirement parameter for the classification of the medical devices and in vitro diagnostic kits have two part; one prescribes the requirement and basic principles for classification of the medical devices and part II of the first schedule describes parameters, principles or criteria for classification of in vitro diagnostics.

Second schedule that is fees payable for the license permission and registration certificate; what are the fees required for each type of activity that second schedule

prescribes the fees for each type of activities, third schedule that is document required for registration of the notified body, its duty, its functions.

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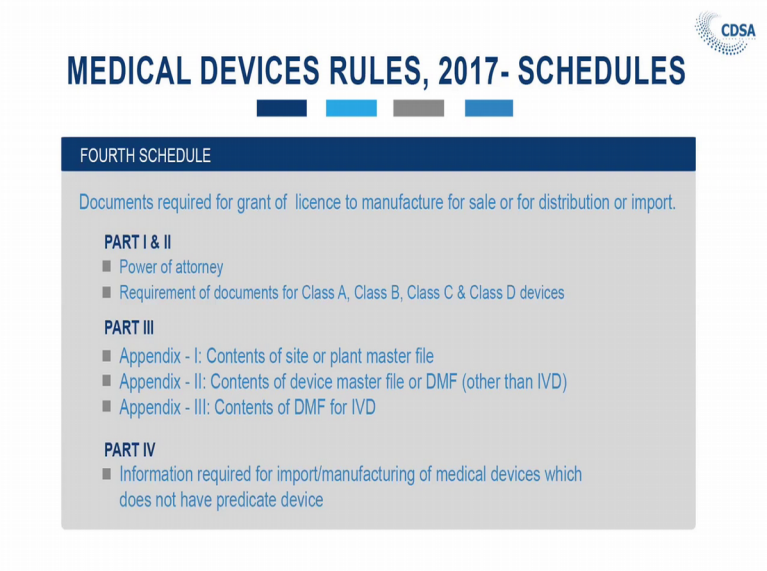

Fourth schedule; fourth schedule is technical requirement. The documents required to be submitted by the applicant for grant of license to manufacture or license to import, the medical devices in vitro diagnostics part I of the fourth schedule power of attorney that is the legal document, that is required by the authorized agent who is responsible, who is going to submit the import applications for the import and marketing of the medical devices manufactured by the foreign manufacturers.

Part II the requirement of the documents for class A, class B, class C and class D devices. Here it is not [FL] for the class D devices whatever the technical document is required that is applicable for the class A; it is not so; based on the risk of the devices different type of that document technical document required to be submitted.

Part III of the fourth schedule have 3 appendix. Appendix-I is the plant master file what content in the plant master file that is given in the fourth schedule part I; part III of the appendix-I. Content of the device master file for medical devices other than IVD; what content, what information, what technical document required to be submitted for as a part of the device master file for the medical devices; it is given in the appendix-II of part III of fourth schedule.

The content of the device master for file for IVD separate appendix is there because the requirement technical requirement for in vitro diagnostic kits also different from the devices so that information that detailed requirement has been given in the appendix-III. Part IV the information required for import for manufacturing of medical devices which does not have predicate, that requirement has been given in the part VI of the; part IV of the fourth schedule.

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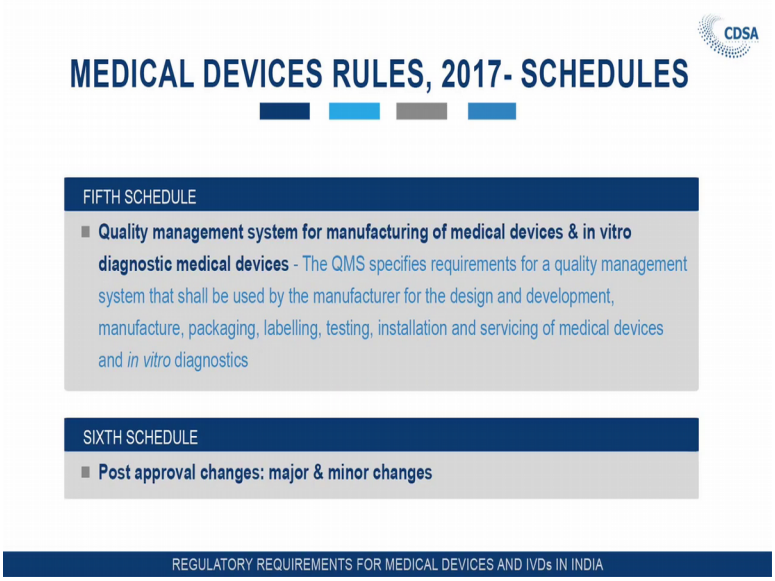

Fifth schedule that is the quality management system for manufacturing of the medical devices and in vitro diagnostic medical devices. Here in this schedule the quality management system is specifies the requirement for quality management system; that shall be used by the manufacturers for the design and development, manufacture packaging, labeling, testing, installation and serving of the medical devices and in vitro diagnostics that is in the line of the globally accepted quality management system 13 4 8 5.

Sixth schedule post approval changes; what changes consider as a major changes and what will be consider as a major changes all that details have been given. If the device material of construction is changed that is considered as a major changes; other major changes are the intended use of the device is changed, the sterilization procedure of the devices is changed, that will consider as a major changes. Change in the manufacturing activity, quality control activity, quality control parameter, change in the specification of

the medical devices, change in the shelf-life of the medical devices these changes will consider as a major changes.

Change in the constitution of the firm manufacturers or authorized agent will also consider as major changes, change in the label of the medical devices or in vitro diagnostics excluding the font size, colour, design of the label that will consider as a change in major changes, change in the design of the device is also considered as a major changes. If the intended use of the devices is changed due to change in the design that will consider as a major changes.

All such major changes the applicant has to obtain the approval from Central Licensing Authority or State Licensing Authority other than these changes that changes will consider as a minor changes; for that they need to notify the same to the licensing authority.

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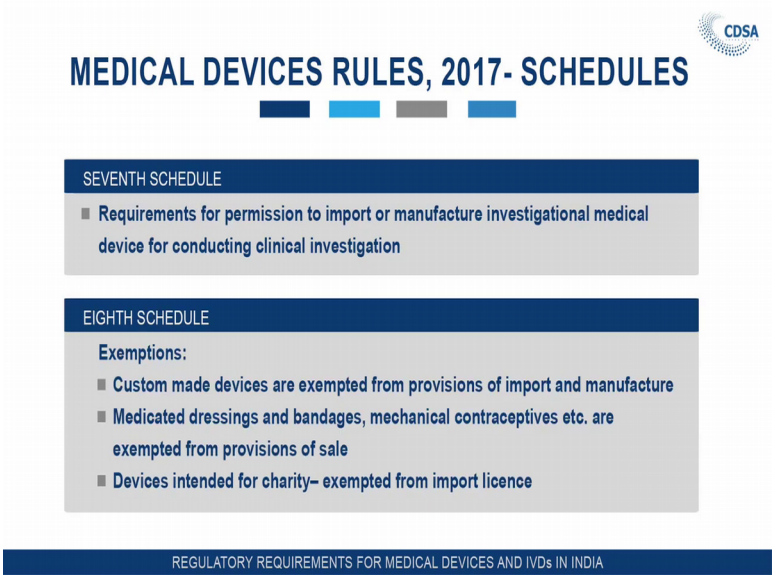

Seventh schedule the requirement for permission to import or manufacture investigational devices for conducting clinical investigation; that provision has been made that requirement has been made. The eighth schedule; last schedule in that exemption certain exemption has been given; what are those exemptions.

The exemptions for custom made devices; the custom made devices are exempted for the provisions of import and manufacture, no import or manufacturing license is required if

the custom made devices is imported or manufactured into the country for the patient on the basis of the prescription issued by the registered medical practitioners.

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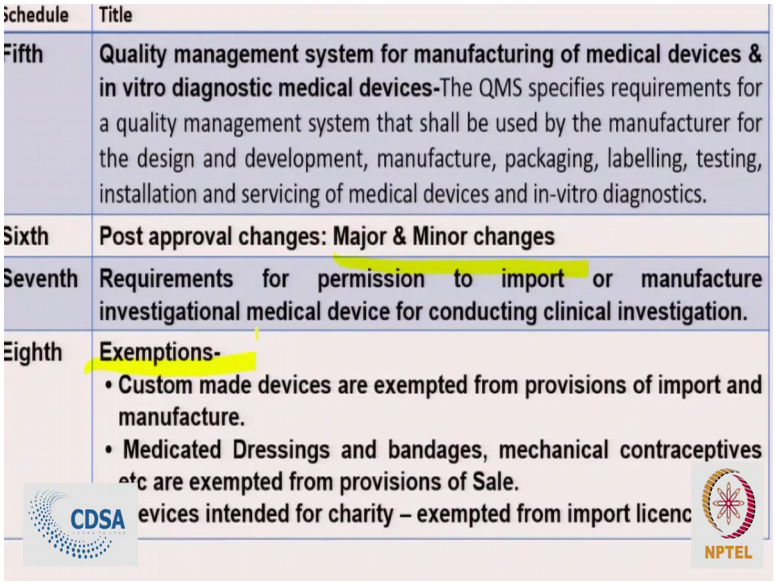

Medicated dressings and bandages, mechanical contraceptives they are exempted from the provision of sale.

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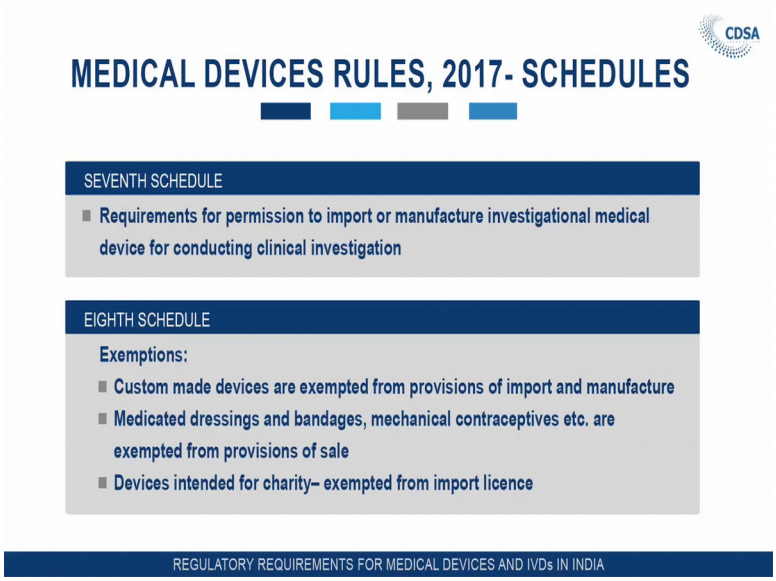

No sale license is required for sale of these products. Devices intended for the charitable purpose, import license is exempted; however permission from the Central License Authority is required.

So, those for 8 schedule cover all this requirement. Now the risk based classification we have discussed. The first schedule of the Medical Device Rules gives the parameters criteria and principles for the classification of the medical devices. The classification is mainly based on the risk of the classes, their intended use.

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The risk based classification has been adopted; the criteria made in the first schedule is in the line of the globally accepted classification requirement. So, here the low risk to high risk devices that has been classified based on the criteria where the low risk devices is considered as a class A devices and high risk class D, low to moderate class B and moderate to high will classified as a class C devices.

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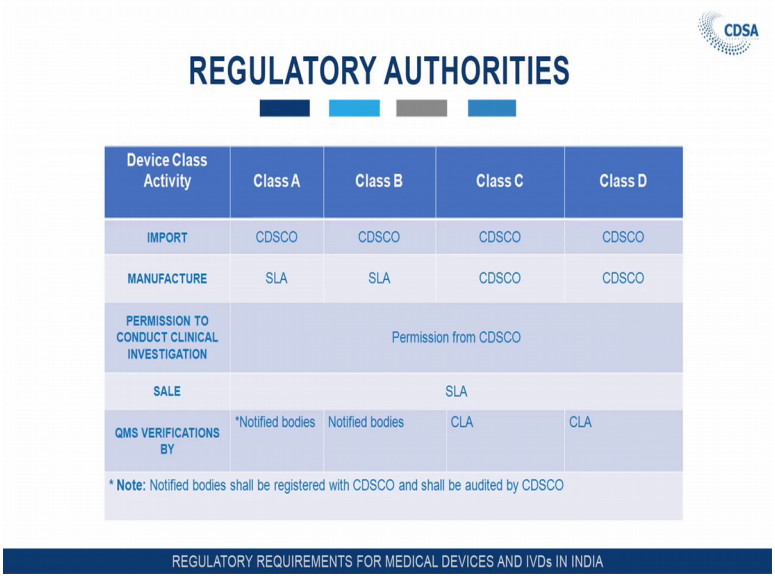

So, these classification has been made. Authorities under the Medical Device Rule 2017 authorities for different responsibility, authorities for grant of different activity has been given.

If you see the import that is the responsibility of the Central Licensing Authority as per the Medical Device Rule 2017. For manufacture class A and class B devices the license; grant of license is responsibility of the State Licensing Authority. However, for class C and class D; the Central Licensing Authority is responsible for grant of manufacturing license, permission to conduct the clinical investigation that is the responsibility of the Central Licensing Authority that is CDSCO, sale State Licensing Authority, QMS verification here the QMS verification we have discussed that there is a role of the notified body.

Notified body will be responsible for QMS inspection of class A and class B devices and based on the audit report of the notified body the State Licensing Authority will grant the license to class A and class B manufacturers if the document and report found satisfactory.

For class C and class D devices the state; the Central Licensing Authority is responsible. They will audit the manufacturing premises with respect to the quality management system and after receiving the satisfactory inspection report of the QMS as well as technical document as required in the Medical Device Rule 2017 they will grant the

manufacturing license to class C and class D manufacturers. Activities; already we have discussed in the previous slides.

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Here also that Central Licensing Authority and State Licensing Authority what activity, what enforcement rules related to the central licensing authority.

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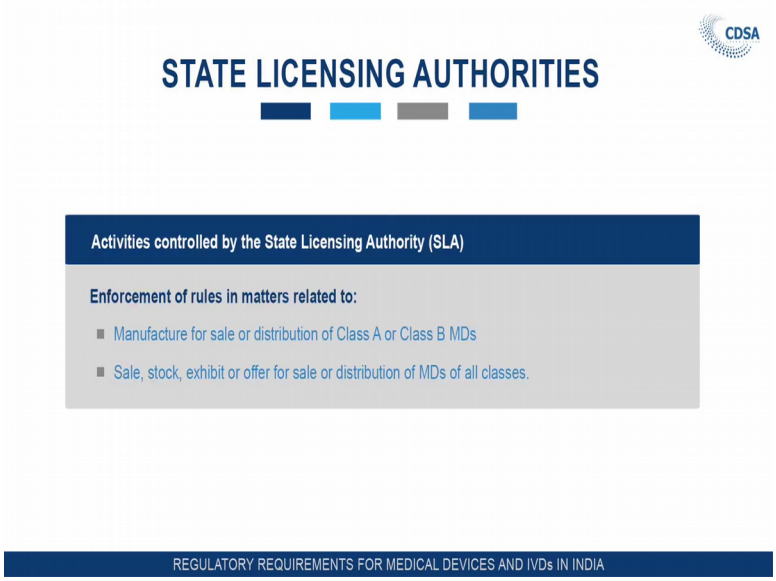

Enforcement of the rules related to the State Licensing Authority we have discussed.

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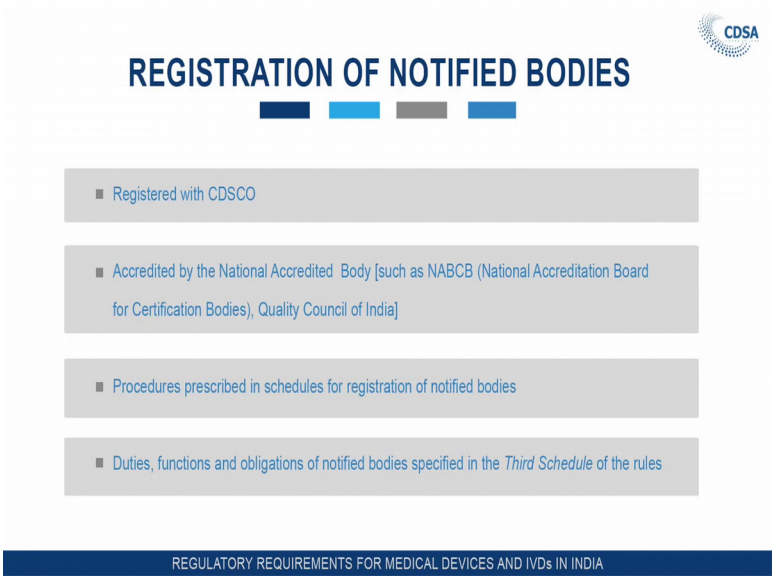

Registration of the notified body it is not [FL] the notified body which is responsible for the QMS; the notified body has to register with the CDSCO. The provision have already been given, we have discussed the third schedule of the Medical Device Rules. Procedure have been given in the third schedule of the Medical Device Rules, registration with CDSCO.

Accreditation of the notified body by the national accreditation body that presently in the Medical Device Rule quality council of India has given as designated as a National Accreditation Body. They will responsible for audit of the notified body before registering with the CDSCO. Procedure, duties, functions and obligations of the notified body have been given in the third schedule of the Medical Device Rule 2017.

So, once it is registered with the Central Licensing Authority that is CDSCO then they will be responsible for audit of audit with respect to the QMS quality management system for class C and class B manufacturing units.

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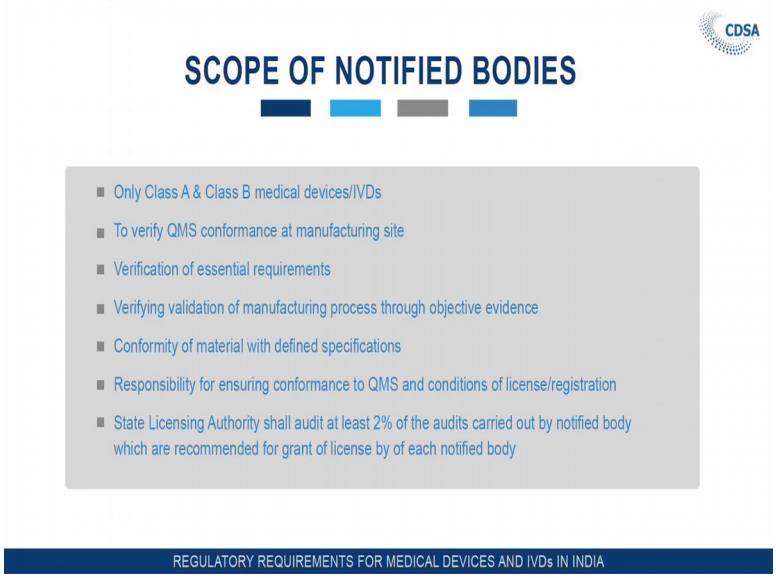

Scope of notified body; what is their scope; only to audit the class A and class B medical device manufacturing unit. They will verify the QMS conformance at the manufacturing site, they will verify the essential principle for requirement for safety and performance of the medical devices. Verifying the validation of the manufacturing process through the objective evidence, conformity of the material with defined specification. Responsibility for ensuring conformance to QMS and conditions of the license or registration; this is the scope of the notified body.

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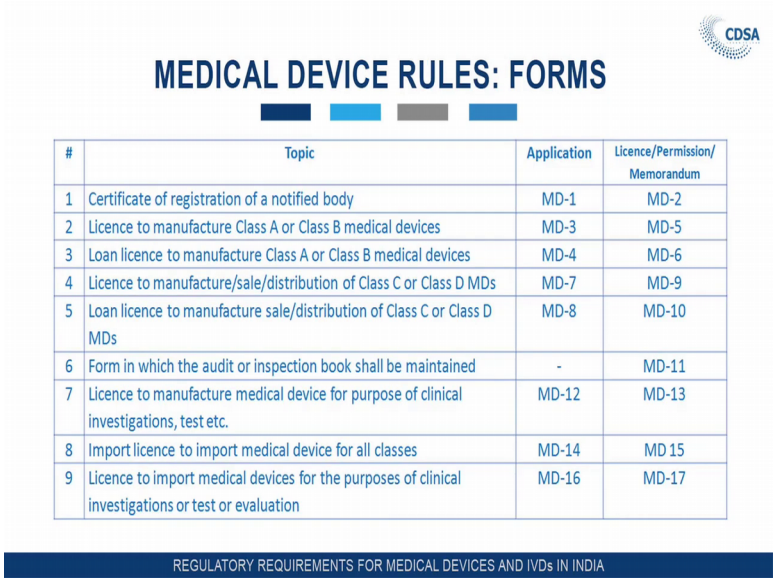

#	Topic	Application	Licence/Permission/ Memorandum
1	Certificate of registration of a notified body	MD-1	MD-2
2	Licence to manufacture Class A or Class B medical devices	MD-3	MD-5
3	Loan licence to manufacture Class A or Class B medical devices	MD-4	MD-6
4	Licence to manufacture/sale/distribution of Class C or Class D MDs	MD-7	MD-9
5	Loan licence to manufacture sale/distribution of Class C or Class D MDs	MD-8	MD-10
6	Form in which the audit or inspection book shall be maintained	-	MD-11
7	Licence to manufacture medical device for purpose of clinical investigations, test etc.	MD-12	MD-13
8	Import licence to import medical device for all classes	MD-14	MD 15
9	Licence to import medical devices for the purposes of clinical investigations or test or evaluation	MD-16	MD-17

Now, come to the forms; in the Medical Device Rules we have discussed total 40 forms have been included. The forms with respect to submission of the application of for grant of import or manufacturing license, application for grant of permission for clinical investigation clinical performance, application for registration of the notified body and issuance of that test and evaluation report of the medical devices.

All those activity different forms have been prescribed that in the tabular form; what are the application required; for what activity in under which license the permission or license is issued? For certificate of the registration of the notified body application has to be submitted in MD-1, license prescribed in MD-2 license to manufacture class A and class B medical devices application is MD-3, license is MD-5.

Loan license to manufacture class A class B devices application MD-4, license MD-6 for class C and class D manufacture license, license to manufacture class C and D application is given is to be given in MD-7, MD-9 is the license, MD-8 for class C class D loan license, MD-10 for loan license, MD-11 that inspection book to be maintained by the manufacturers.

License to manufacture medical device for the purpose of clinical investigation application in 12, license will be issued in MD-13, like import license to import medical devices application is shall be made in MD-14, license will be issued in MD-15, license to import medical devices for the purpose of clinical investigation applicant has to submit application MD-16, MD-17 will be issued after satisfying the requirement.

For investigational application is in 18 license will be issued in MD-13, permission to import small quantity of the medical devices application shall be made in MD-20, license will be issued in MD-21 after satisfying the requirements, permission to conduct clinical investigation MD-22 is the application, MD-23 is the permission for that.

Permission to conduct clinical investigation application in MD-24, 25 will be the permission for that, permission to import or manufacture for sale of distribution of the medical devices does not have predicate devices MD-26 application, MD-27 permission. Permission to import manufacture for sale or distribution of in vitro diagnostics; for new in vitro diagnostic application is MD-28, license or permission will be issued in MD-29.

Memorandum to the Central Medical Testing Laboratory that is MD-30, certificate of test evaluation by the central medical testing laboratory certificate will be issued in MD-31.

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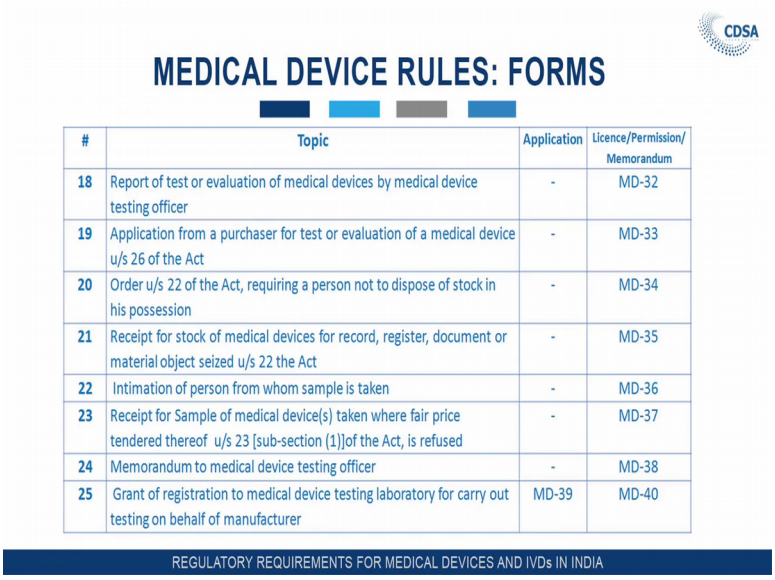

#	Topic	Application	Licence/Permission/ Memorandum
18	Report of test or evaluation of medical devices by medical device testing officer	-	MD-32
19	Application from a purchaser for test or evaluation of a medical device u/s 26 of the Act	-	MD-33
20	Order u/s 22 of the Act, requiring a person not to dispose of stock in his possession	-	MD-34
21	Receipt for stock of medical devices for record, register, document or material object seized u/s 22 the Act	-	MD-35
22	Intimation of person from whom sample is taken	-	MD-36
23	Receipt for Sample of medical device(s) taken where fair price tendered thereof u/s 23 [sub-section (1)]of the Act, is refused	-	MD-37
24	Memorandum to medical device testing officer	-	MD-38
25	Grant of registration to medical device testing laboratory for carry out testing on behalf of manufacturer	MD-39	MD-40

Report of test or evaluation of the medical devices by the medical device testing of (Refer Time: 66:25) that is the test report in MD-32, application from a purchaser for test evaluation of the medical devices under section of the Act 26 under section 26 of the Act; that is MD-33. Order for not to dispose of the stock of the medical devices and vitro diagnostics under section 22 of the Act that is MD-34.

Receipt of for stock of the medical devices for record register document or material objects seized under the section 22 of the Act by the medical officer MD-35. Intimation to the person whom the sample is to be taken MD-36. Receipt of the samples under section 23 of the Act if it is refused MD-37 is there.

More memorandum to the medical device testing of officer MD-38, grant of registration of the medical device testing laboratory to carry out the test on behalf of the manufacturer MD-39 and MD-40 is the permission registration permission.

So, these are the various forms incorporated in the Medical Device Rule 2017. Now what is the online portal for the medical devices. In the provisions in the Medical Device Rules; the provisions for online submission of all the application has been made.

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And the for submission of the applications all the application respect to the import, in respect of the manufacture shall be submitted through central online portal established by the Ministry Of Health And Family Welfare. In this record that CDSCO has established e-Governance portal for the medical devices that is called CDSCO MD online portal.

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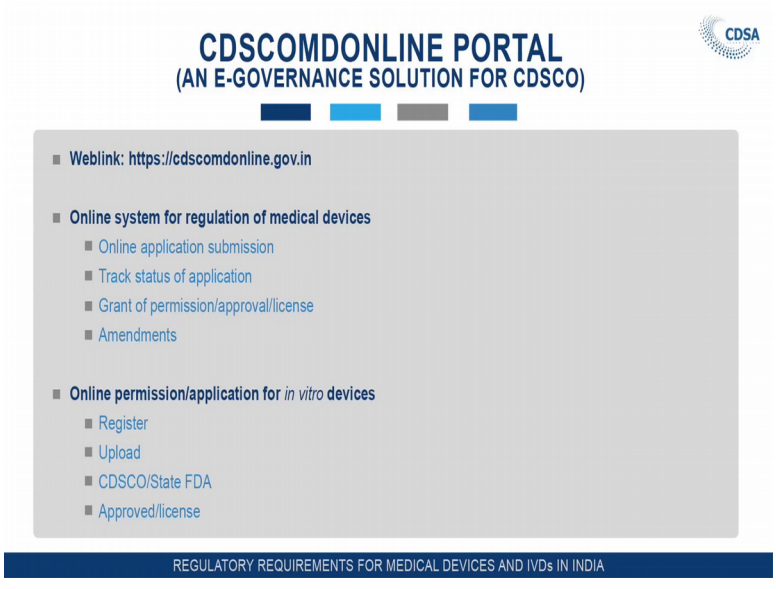

In this portal all the provisions for submission of the application, uploading of the data registration of the firm, grant of the license all those provision has been made. This online system is for the regulation of medical devices and in vitro diagnostics. Through

the e-Governance platform all the application is to be submitted reviewed by the central by the licensing authority and after satisfying license or permission will also be granted through this online portal.

For each of the activity with respect to the import, with respect to the manufacture, with respect to the test license, with respect to the registration of the laboratory, with respect to the registration of the notified body; different different checklist as per the requirement of the Medical Device Rule has been mentioned and that checklist by way of submitting the by way of uploading that requisite technical data has been made in the online portal.

Once the data requisite data is submitted and found satisfactory; the relevant permission license will be issued to the applicant. Now the guidance issued by the DCGI office for implementation of the Medical Device Rule 2017; certain guidance that has been issued.

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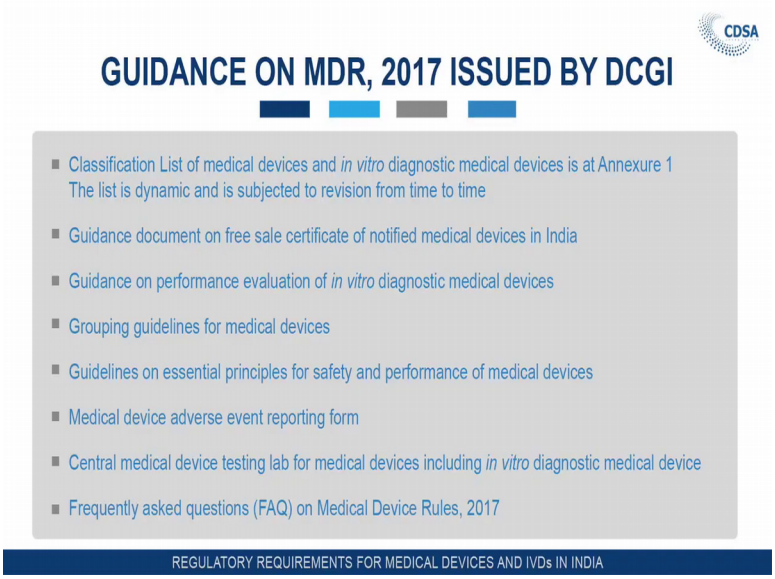

Classification list that is one of the documents where the all the devices which are presently regulated, all the different categories of the devices which are presently regulated. Classification exercise has been done by the Central Licensing Authority based on the criteria mentioned in the first schedule and that list has been published.

We will discuss summary of the list, we will discuss in the next slide. This classification list is dynamic list subject to the revision from time to time based on the technical

evidence or documents. The guidance document on the free sale certificate for the notified medical devices for the purpose of export of the medical devices that has been published by the DCGI of a Central Licensing Authority that is.

Guidance on the performance evaluation of the in vitro diagnostics; grouping guidelines for the medical devices and guidelines for essential principle for safety and performance of the medical devices that has been published by the Ministry of Health and Family Welfare. Medical device adverse event reporting form it is published to report the adverse event associated with the medical devices and in vitro diagnostics.

Central medical device testing lab notified by the central licensing; central government Ministry of Health and Family Welfare under the provisions of Medical Device Rule 2000 has also been published. They will responsible for testing of the medical devices notified under the that notification. Also to have certain clarification on the implementation or regulation of the medical devices in vitro diagnostic as per Medical Device Rule 2017. Frequent asked question has been published that is available on the website of the Central Licensing Authority and the website of the Central Licensing Authority is CDSCO dot g o v dot in.

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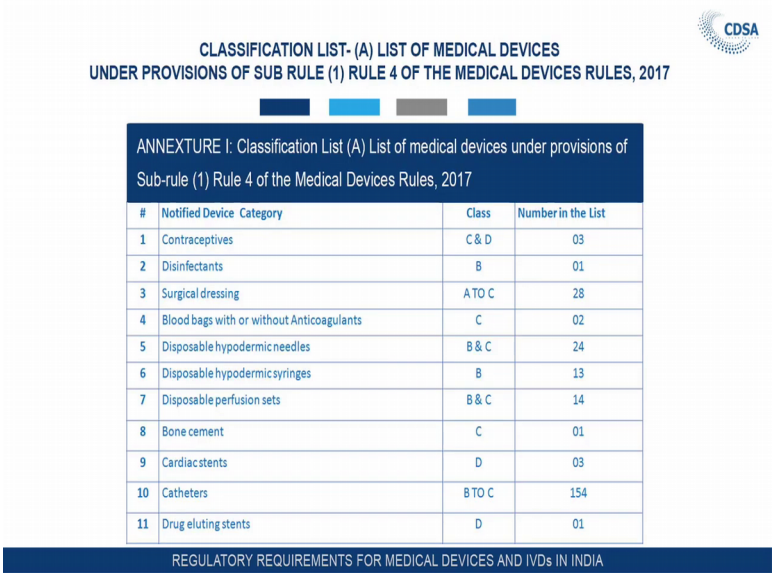

You will see all the documents even the Medical Device Rule is also published also uploaded on the website that can be downloaded from the website and you will have the more detailed information about the Medical Device Rules 2017. Classification list that

is published by the Central Licensing Authority; under this classification list different categories of the devices have been further classified based on the risk.

Contraceptive category devices total 3 devices are have been included; that C to D based on the risk, disinfectant only one that is class B, surgical dressing total 28 devices are there A to C based on the risk of these devices, blood bag with or without anticoagulant class C devices only 2 devices has been included classify, disposable needles B and C based on the risk total 24 numbers, disposable syringes B 13 devices have been classified so far.

Disposable perfusion set B and C category total 14, bone cement C category total 1 devices has been classified, cardiac stent class D only 3 devices has been notified has been classified, catheter based on the risk B to C class and total 154 catheters have been classified, drug eluting stent class D devices.

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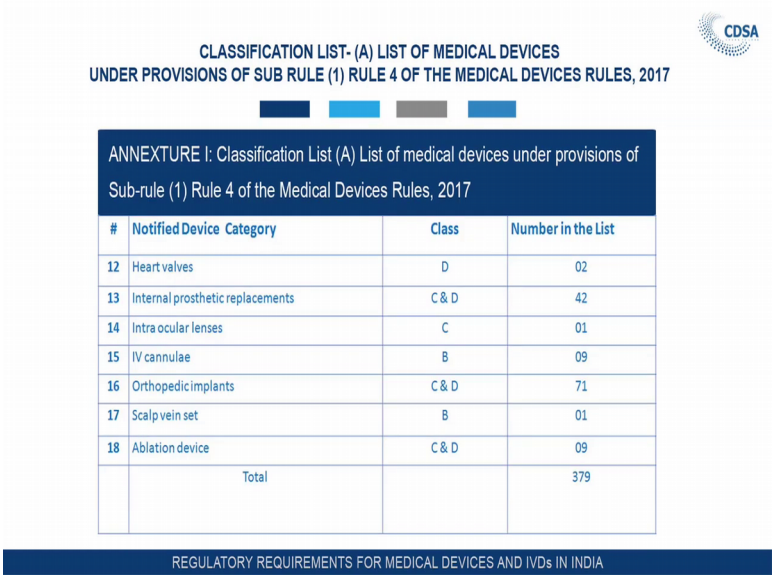

Only 1 device is there, heart valves class D devices 2 devices are classified, internal prosthetic replacement class C and D based on the risk. Total 42 devices are have been classified, intra ocular lenses class C only 1 device is there, orthopedic implants C and D total 71 devices has been classified under this category, scalp vein set class B only 1, ablation devices class C and class D devices based on the risk and total 9 devices so far have been classified and total 379 medical devices have been classified under these different 18 categories of the medical devices.

And based on the classification the applicant has to submit the application along with the requisite information to the licensing authority for grant of license for import or manufacture.

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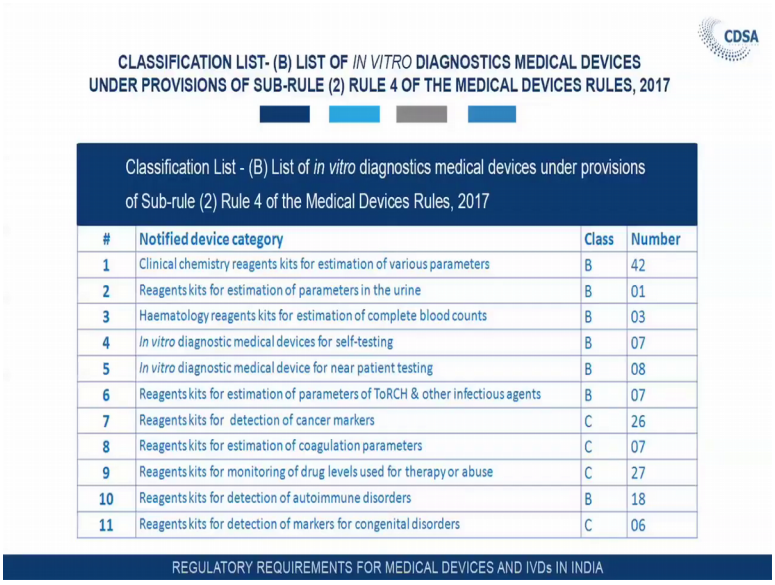

Likewise, classification list- b that is for the in vitro diagnostic different types of reagent kits have been classified, these are the categories under this category total number of the devices if you see clinical chemistry reagent kit for the estimation of the various parameter; class B devices total 42. Likewise different categories of the in vitro diagnostic kits have been classified.

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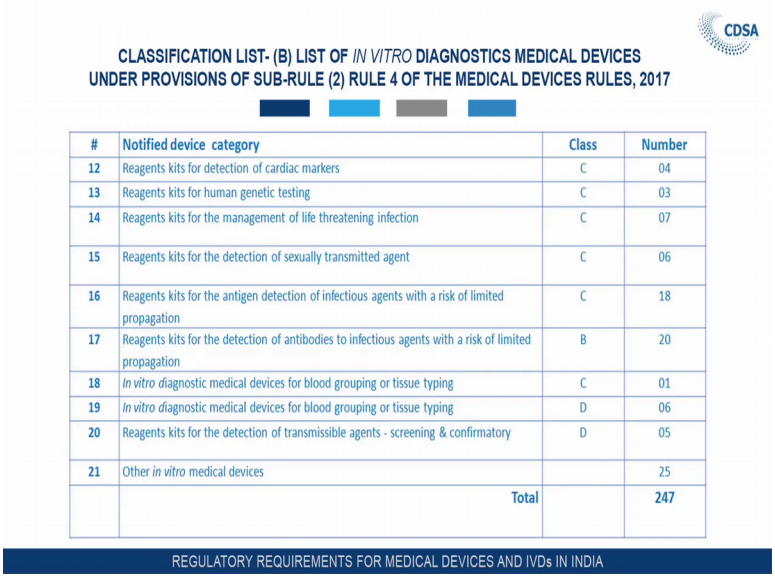

#	Notified device category	Class	Number
12	Reagents kits for detection of cardiac markers	C	04
13	Reagents kits for human genetic testing	C	03
14	Reagents kits for the management of life threatening infection	C	07
15	Reagents kits for the detection of sexually transmitted agent	C	06
16	Reagents kits for the antigen detection of infectious agents with a risk of limited propagation	C	18
17	Reagents kits for the detection of antibodies to infectious agents with a risk of limited propagation	B	20
18	*In vitro* diagnostic medical devices for blood grouping or tissue typing	C	01
19	*In vitro* diagnostic medical devices for blood grouping or tissue typing	D	06
20	Reagents kits for the detection of transmissible agents - screening & confirmatory	D	05
21	Other *in vitro* medical devices		25
	Total		247

And total 247 in vitro diagnostics have been classified under different class from A to class D based on the risk and that is available on the website of the CDSCO. Now, the major policies; what major policies has been taken in this Medical Device Rules?

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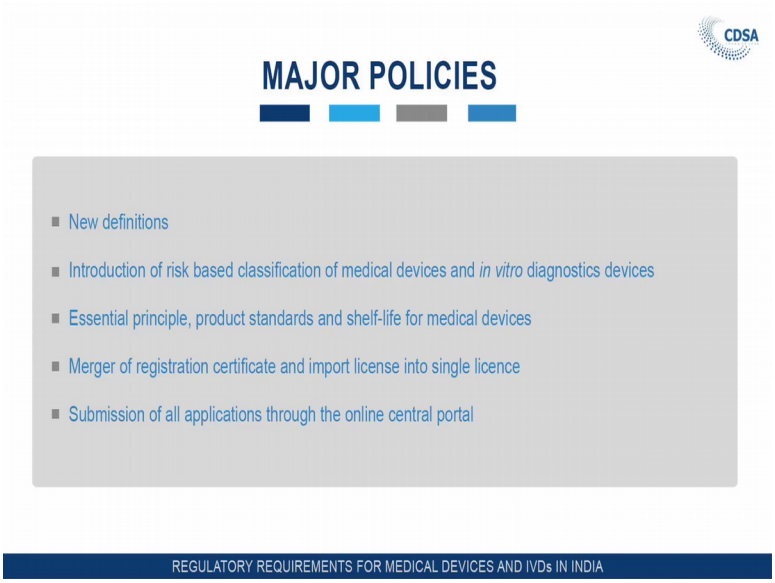

In this rules the new provision for the definition new definition has been included, introduction of the risk based classification which was not earlier in the Drugs and Cosmetic Rules, essential principles, product standard, shelf- life of the medical devices

that is also the new policy merger of the registration certificate and import license into single license.

Earlier the license import license will be issued only after registration of the manufacturing site and the product; here only one single license for import is required, submission of the all the application through online that online information has been incorporated.

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Rationalization of the timeline of the each activity; like for grant of import license 9 month time is given for grant of the manufacturing license certain timeline has been prescribed in the Medical Device Rule 2017.

Scope of the notified body has been given in that is the new policy for QMS inspection of class A and class B devices. Requirement of the post approval changes to have the (Refer Time: 76:14) what are the major changes considered as a post of approval; what post approval change is considered as the major changes that has been given in the separate schedule.

Requirements for the clinical investigation of the medical devices and clinical performance evaluation of the in vitro diagnostic kits that is also given in the Medical Device Rule; that is the new policies for medical devices which was not earlier.

Perpetuity of the licenses whatever the license granted under the Medical Device Rule 2017 that is in perpetual provided the licensee or the applicant has to submit the retention fees at the interval of every 5 years from the date of issue of the license. Their license will be considered in perpetual till it is cancelled, suspended by the Central Licensing Authority or State Licensing Authority or withdrawn by the licensee.

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Other major policies; no inspections for grant of manufacturing license for class A devices, prior inspection is not required. However, the inspection will be done after issuance within 60 days after issuance of the manufacturing license by the State Licensing Authority. Provision for loan license; the license premises if the manufacture if the person want to manufacture their manufacture; their medical devices by using the facility of the licensee manufacturers under the supervision they may obtain the loan license to manufacture their medical devices on the facility.

Grant of license for class C and class D devices and grant of test license to manufacture all classes of the devices these responsibility has been given to the Central Licensing Authority; earlier it is lies with the State Licensing Authority. Rationalization of the shelf- life of the medical devices for imported medical devices earlier the provision was there if there is a less than 60 percent of the regital shelf-life of the devices, that cannot be allowed.

Here if the devices have the if the devices have shelf-life of upto 1 year 6 50 percent 50 percent shelf-life regital shelf life will be allowed if it is more than 1 year than 60 percent will be allowed. For less than that specific that provision has been made for rationalization of the shelf-life of the medical devices for its imported to the country.

Regulators for regulators the establishment of the government testing laboratory for testing of medical devices or in vitro diagnostic, for manufacturers private testing laboratory registered with the Central Licensing Authority, for testing of the medical devices on in vitro diagnostic on behalf of the manufacturer that provision has been incorporated; that is a new policy.

Debarment of applicant, rejection of the applications we have discussed in case if the documents submitted by the applicant is found fake or fabricated the applicant can be depart and also their application will be rejected that provision has been incorporated.

Provision for free sale certificate for export of the medical devices earlier this was not there, but for regulated medical devices is Central Licensing authority will issue the free sale certificate for the purpose of export of the particular medical devices. These are the major policies which have been incorporated in the Medical Device Rule 2017.

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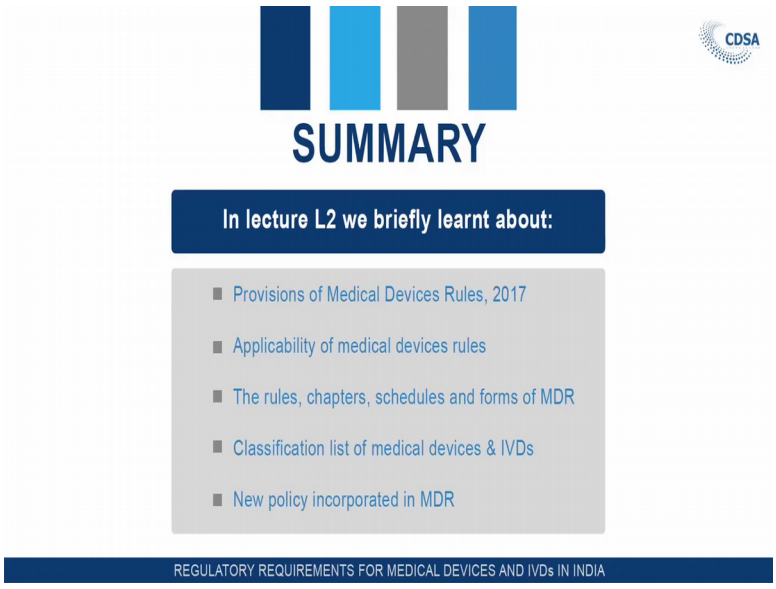

I hope you have that basic idea about the Medical Device Rules, what are the provisions of the rules, what are the forms, what rules related to import, what tools related to the

manufacture, what is the applicability of the Medical Device Rules, classification which criteria, what is the risk based classification, what are the new policies incorporated in the Medical Device Rules. So, with these I will finish the; this Medical Device Rule 2017.

If you have more detailed information, if you want to have more detailed information each criteria, each provision of the chapters of the medical device you must go to the website of the CDSCO that is Central Licensing Authority, download the Medical Device Rule 2017, go through it and if you have any doubt or any further clarification you can approach to the Central Licensing Authority and also to the CDSCO for further clarification. The other provisions of the Medical Device Rule that will be covered in the subsequent lecture.

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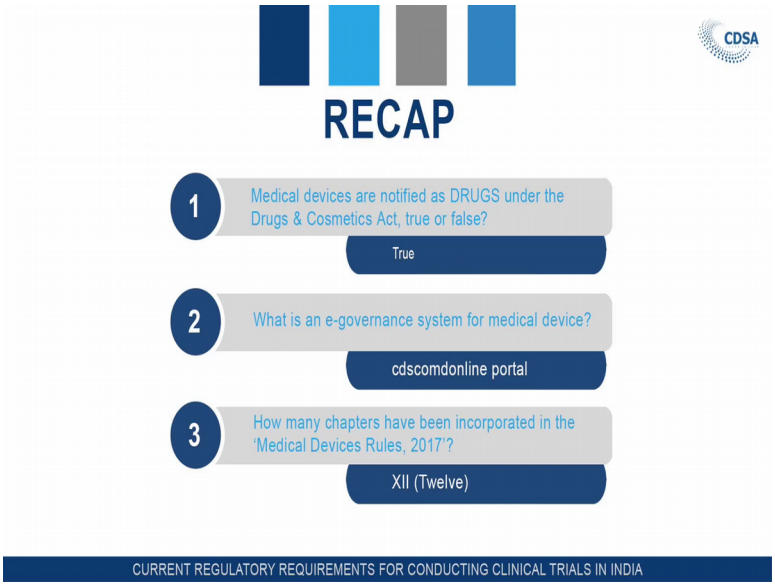

Before that, before conclude the lecture just have some questions on the what we have discussed in this slides that is whether the medical devices are regulated as a drug, it is true or false; it is true it is regulated as a drug. Question 2; what is an e-governance system for the medical devices; that is the CDSCO MD online portal. Through this portal all the application of with related to the import, related to the manufactures, permissions, registrations all those thing will be submitted through this online portal and license will be issued, permission will be issued through this online portal only.

How many chapters have been incorporated in the Medical Device Rule 2017; that is 12 chapters. So, with this I conclude.

And thank you very much for listening.