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

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Lecture – 02
Medical Device Rules, 2017: Implications on Medical Devices

Welcome to Regulatory Requirement for Medical Devices Including In Vitro Diagnostic kit in India version 2. Lecture 2 Medical Device Rules 2017 Implication on Medical Devices and in vitro diagnostics.

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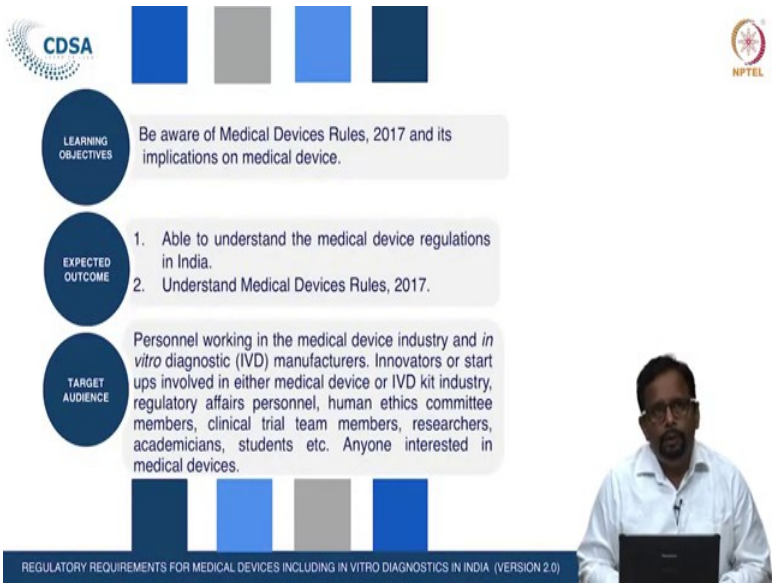

The learning objective of this presentation be aware of the Medical Device Rules 2017, its implication on the medical devices the expected outcome, we will able to understand the medical device regulation in India. We will be able to understand Medical Device Rule 2017, the target audience. The personnel working in the medical device industry and in vitro diagnostic manufacturer's, innovators or the starts up involved in either medical devices or in vitro diagnostic industry clinical trial personnel's, researchers, academicians, students and anyone interested in the medical device sector.

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Overview in this presentation, we will discuss overview of the medical device sector, medical device regulatory framework, the online portal for the medical devices, through which the application and permission will be granted. The key changes what major changes we have made in the Medical Device Rule 2017, we will discuss in detail and the guidance, document, issued for implementation of the Medical Device Rule 2017.

This guidance document Ministry of Health and Family Welfare(MoHFW) as well as the center licensing authority, that is the Drug Controller General India have issued several guidance document, which is published on the website of the CDSCO. We will discuss: what are those guidance document related to the implementation of the Medical Device Rule 2017. Now come to the Medical Device Sector.

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This medical device sector, if we compare this sector with the drug sector in India, This is very small in size the total value of this industry is approximate 6.5 billion not much as compared to the drugs. If, you compare with the drug the sector the drug sector is more than 35 billion US dollar.

The growth rate of this medical device sector is 15 percent as per the CAGR, which shows that India is one of the fastest growing market in the world, the sector mainly depends on the import, we do not have that much indigenous facility to manufacture the medical devices to cater the Indian populations, but we are importing most of the medical devices.

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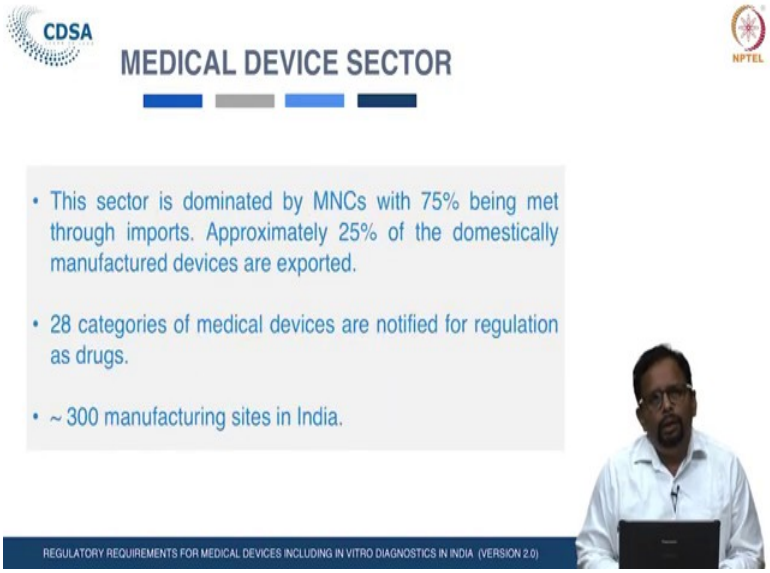

Only 25 percents of the indigenous manufacturers, they are manufacturing their medical devices. And, these medical devices are low in medical devices most of the devices belongs to disposable devices and these devices are also exported to many of the country.

In this sector the medical devices only certain medical devices are regulated, we are not regulating all the type of medical devices. Only the devices which have been notified by the Ministry of Health and Family Welfare, Government of India, from time to time these notify devices are regulating presently under the Drugs and Cosmetics Act.

And, with these notified medical devices the total approximate 350 manufacturing units are there, who are involved in the manufacturing of these notified medical devices in the country.

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Challenges; challenges with the sector as already we have discussed. This is of small size, reason for the small size, this sector has not given significant weightage as compared to the other sectors. But, this sector the growth rate of the sector which shows that this sector has very potential, and other problem, other challenges that not the all the medical devices are regulated. The devices which are regulated are considered as a drug, we don't have the separate definition for the medical devices.

The medical devices which are regulated are considered as a "Drug", the regulatory system in the Drugs and Cosmetic Act and Drugs and Cosmetic Rules 2001, 1945 The specific requirement for the medical device was not there, the harmonizer standards for the medical devices was not there, the provision for classification of the medical devices were not there, the requirement of clinical investigation for the medical devices was not there, and also the quality management system, which is applicable for the manufacturing of the medical devices those requirements was not earlier in the Drugs and Cosmetic Rules 1945.

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In order to have the harmonized regulation in the medical devices the Ministry of Health and Family Welfare government of India have taken various steps. The major steps is the Ministry of Health and Family Welfare government of India has taken is the publication of the new Medical Device Rule 2017.

This Medical Device Rule 2017 was published in the year 31st January 2017 and the implementation of this Medical Device Rule 2017 was 1st January 2018. This Medical Device Rule, 2017 have adequate provision for the requirement of import, requirement of manufacture, requirement of clinical investigation, sale and distribution, of the medical devices.

And, these new Medical Device Rule 2017 have requirement, which is at par with the globally accepted requirement. So, this rule the government of India has published to have harmonized regulation requirements throughout the world. Though in this Medical Device Rule the devices are still regulated as a drug, but separate provision and separate requirement for sale distribution, manufacture import and clinical investigation as well as, clinical performance of the medical devices and in vitro diagnostics have been given in this new regulatory framework.

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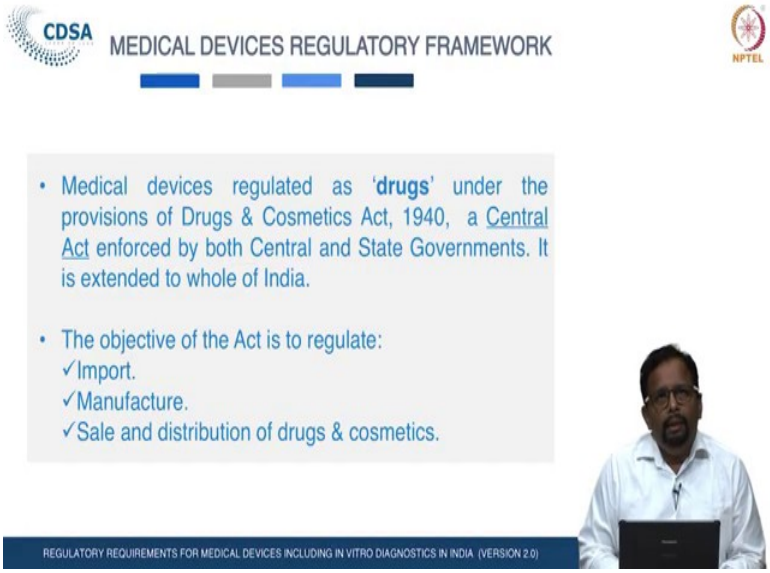

We will discuss the detail of the medical device rules, but what are the major component of this Medical Device Rule 2017? But, before go further the medical devices, we have already discussed these medical devices are regulated as a drug and these devices are defined under the definition of the drugs. And, in the Drugs and Cosmetic Act, the definition of the drugs is prescribed in section 3 b, under section 3 b there are 4 parts and in certain that provision certain devices have been notified we will discuss in subsequent presentation.

The Drugs and Cosmetic Act, 1940, this is the Central Act. This Act is enforced by both Central as well as the State Government and this act is extended whole of the India. The objective of this act is to regulate import, manufacture, sale and distribution of drugs and cosmetics . The main objective and as already I have explained.

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The devices are comes under the definition of drugs. So, automatically the devices, which are regulated ,notified and then all in vitro diagnostic kits, they are also under the regulation under this Central Act.

Also, we have discussed this Medical Device Rule 2017 have a specific requirement of the medical devices, separate tools have been given for import of the medical devices and in vitro diagnostics, separate provisions for manufacture of in vitro diagnostics and medical devices has been given, separate provision for clinical investigation and clinical performance of medical devices as well as in vitro diagnostic diagnostics has been given.

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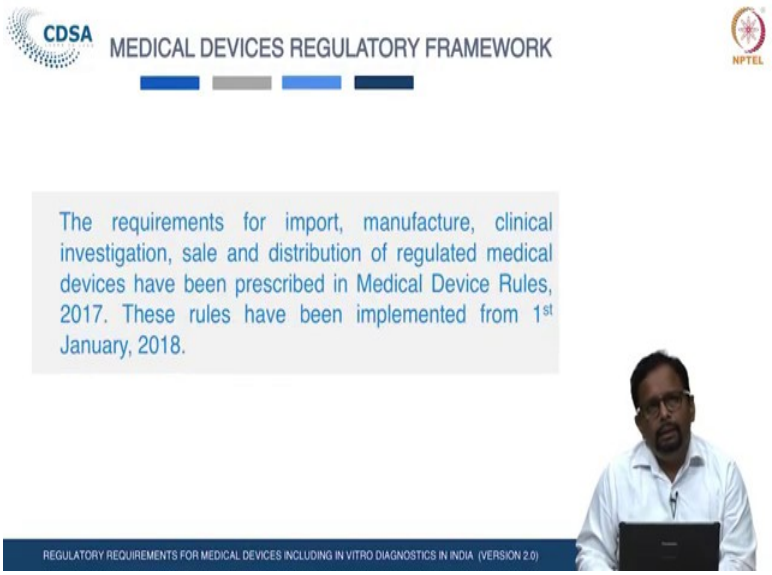

The sales and distribution also provision for sales and distribution of the medical devices and in vitro diagnostics have also been prescribed in this Medical Device Rule 2017. And, we also know that this Medical Device Rule is being implemented from January 2018.

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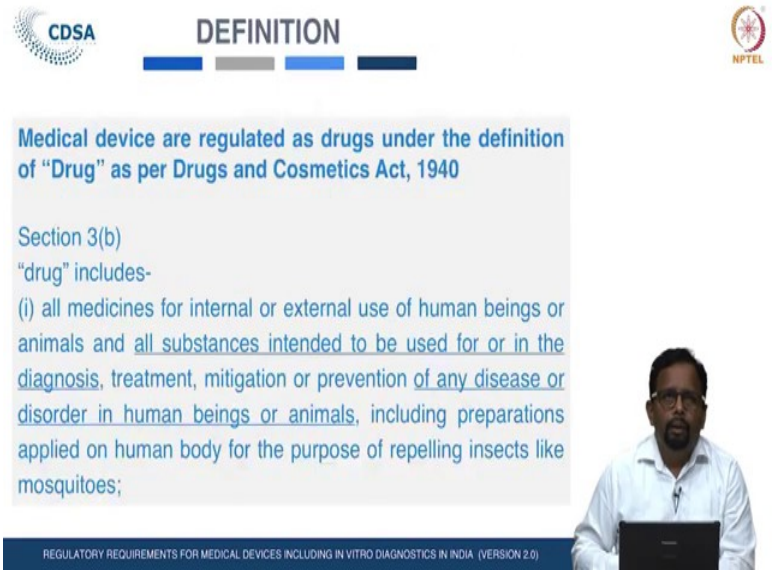

Under this Medical Device Rules, the definition of the medical device has been redefined, we also discussed that the medical devices says falls under the category of the drugs. And, drugs have 4 different parts. The section b of the drug definition which

includes all the substances intended to be used for or in the diagnosis treatment medication or prevention of any disease or disorder in the human being or animals. So, all the diagnostic kits are covered under this definition.

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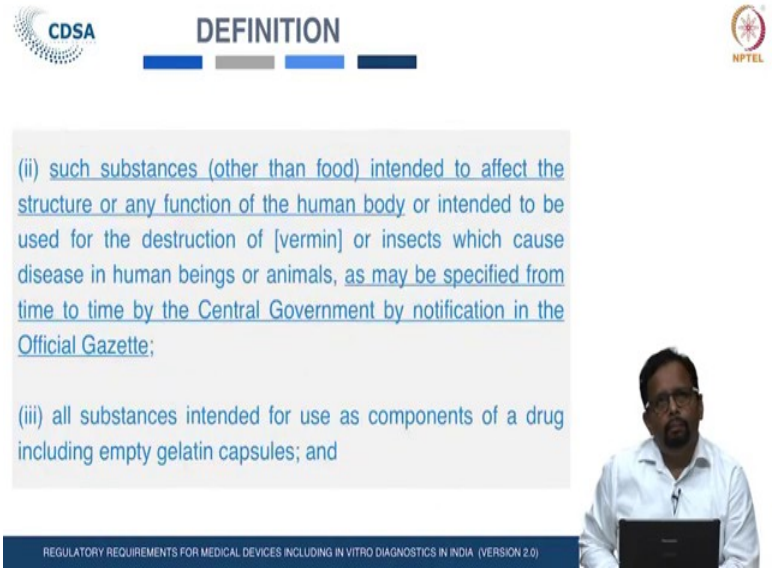

The substances intended to affect the structure or any function of the human body as may be notified from time to time by the Central Government through notification. The devices which notified under this clause are regulated and the example of this notified medical devices under this sections are the mechanical contraceptives, disinfectants.

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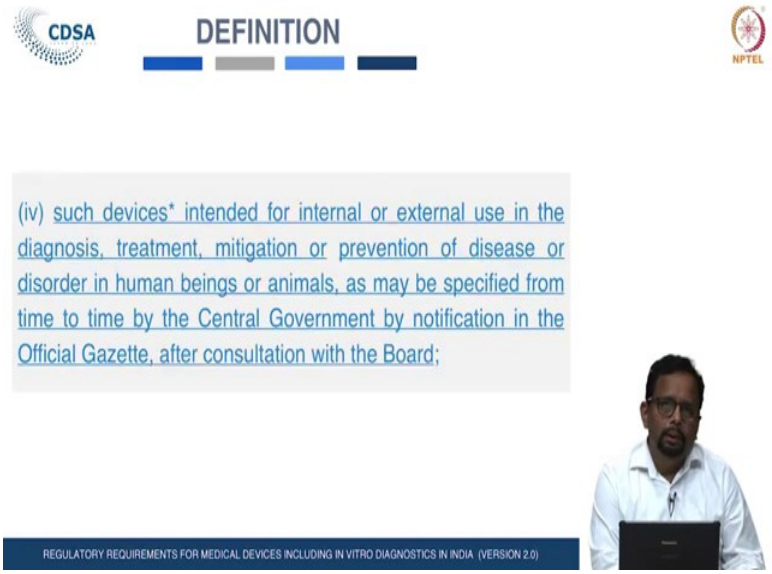

And, another one the devices intended for internal or external use in the diagnosis, treatment, mitigations or prevention of disease or disorder in human being or animals, as may be notified by the Government of India through Gazette notification, after consultation with the Board. Board means, the Drug Technical Advisory Board(DTAB), which is a Statutory Board under the Act, from time to time they will discuss the issues and based on the recommendation of the DTAB, certain changes have been made in the Drugs and Cosmetic Act and those they are under.

And, under this class whatever the devices has been notified. So, far by the Ministry of Health and Family Welfare, Government of India have regulated and from time to time many more devices have been included in this class.

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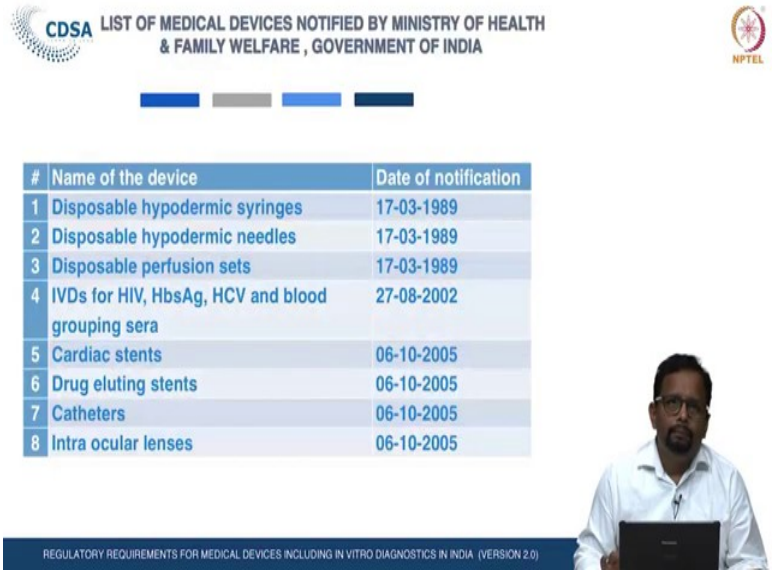

#	Name of the device	Date of notification
1	Disposable hypodermic syringes	17-03-1989
2	Disposable hypodermic needles	17-03-1989
3	Disposable perfusion sets	17-03-1989
4	IVDs for HIV, HbsAg, HCV and blood grouping sera	27-08-2002
5	Cardiac stents	06-10-2005
6	Drug eluting stents	06-10-2005
7	Catheters	06-10-2005
8	Intra ocular lenses	06-10-2005

The list of the devices, which have been notified so, far under the Drugs and Cosmetic Act, under the definition of 3b4 of the Act. These are as under you are aware that total 16 devices are presently under regulations, 12 more devices has been notified, which will be also under regulation, but the implementation date for those new 12 categories of the medical devices will be effective from the January 2020.

The devices which have been notified when they have notified since then it is regulated these are the disposable hypodermic syringes, disposable hypodermic needles, disposable perfusion sets,In vitro diagnostics for HIV, HbsAg, HCV and blood grouping sera, these 3 devices were notified in the year 1989.

Thereafter in the year 2002, the 4 category of the device in vitro diagnostics, that has been notified. Thereafter in 2005, 10 more categories of the medical devices has been notified those are cardiac stent, drug eluting stents, catheters.

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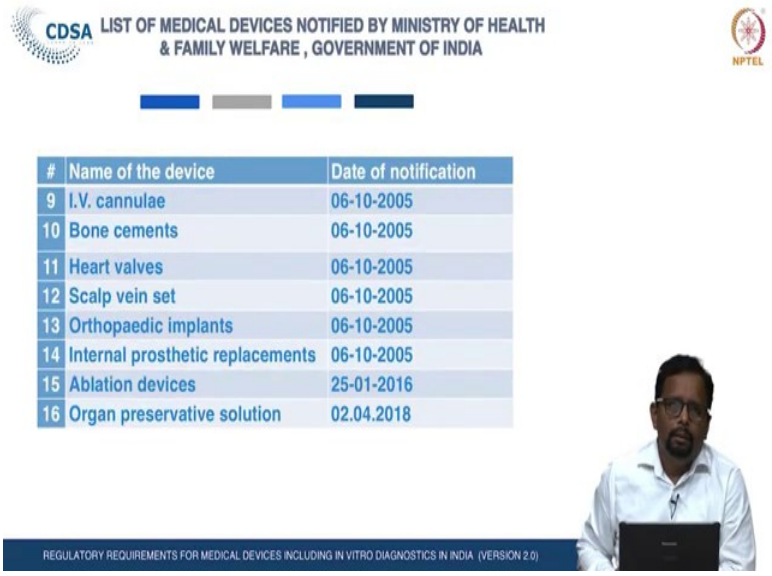

Intra ocular lenses I.V. cannulae, bone cements, heart valves, scalp vein set, orthopedic implants, internal prosthetic replacements, ablation devices and organ preservative solutions. These are the 16 notified categories of the medical devices, which are under regulation, out of the 16 the ablation devices was notified in the year 2016 and in 2018 the organ preservative solutions was notified and regulated with immediate effects since it is a notification.

So, these 16 categories of the medical devices are presently under regulation.

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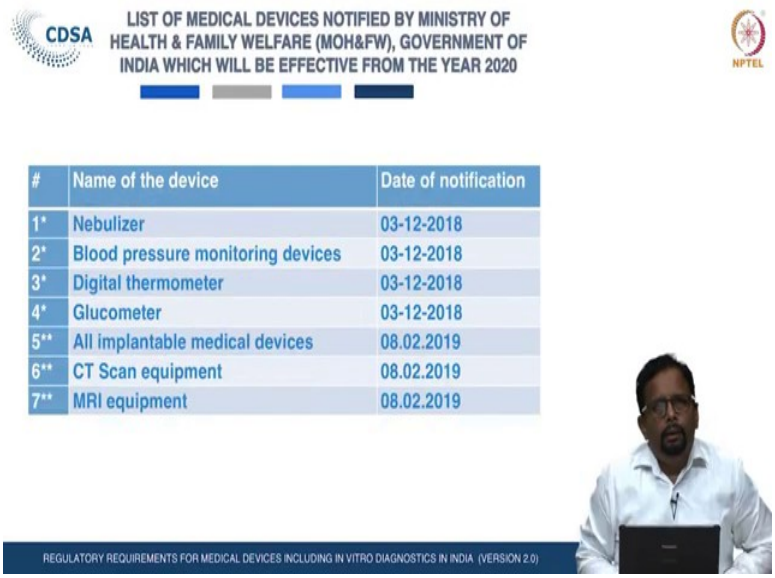

Eight most medical devices has been notified and those 8 medical devices are all implantable medical devices CT scan equipment's MRI equipment's.

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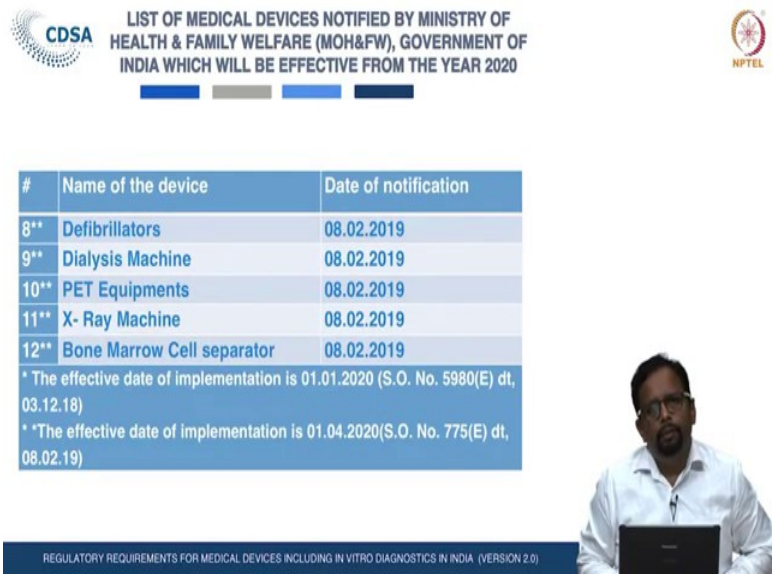

Defibrillators, dialyzer, PET Equipment's, X-Ray Machines, Bone Marrow Cells separator, these new 8 medical devices, which also includes the equipment's have been notified in the February 2019. But, the effective date of implementation for these new medical devices. First 4 medical devices which has been notified which have been notified in the year 1980, 2018, they will be implemented from January 2020 the

subsequent 8 categories of the medical devices which also includes the equipment's will be regulated from the February 2020. Now, come to the medical device rules, what are the component of this rules?

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Before, we go further the Medical Device Rule we have to again discuss that given this notification was published. As already discussed this notification was published by the Ministry of Health and Family Welfare on 31st January 2017 and implemented date of this Medical Device Rule 2017 was from the January 2018.

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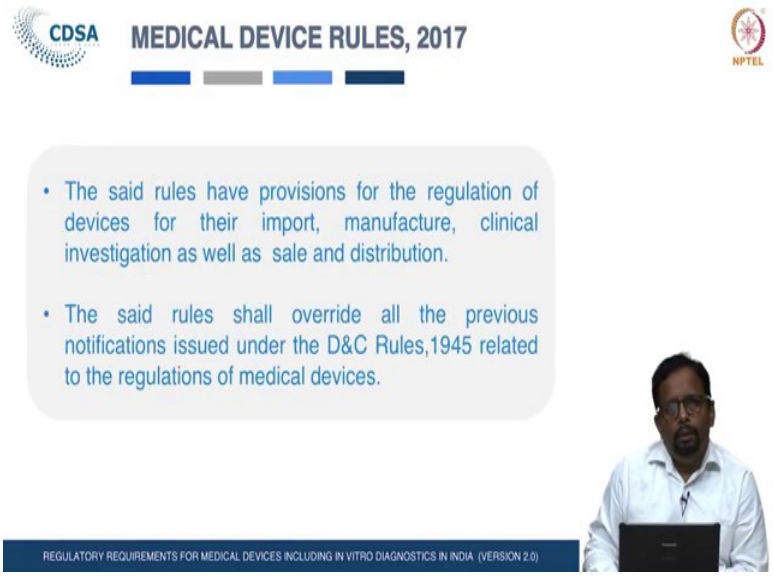

The said rules have the provision for regulation of the devices for their import, manufacture, clinical investigation as well as sale and distribution. These Medical Device Rules shall have over adding effect of all the provisions notifications issued under the Drugs and Cosmetic Rules, 1945 related to the regulation of the medical devices.

As we understand that [FL] before do Medical Device Rule 2017. These medical devices are regulated under the provisions of Drugs and Cosmetic Rules 1945. So, whatever the permissions and the provisions in the Drugs and Cosmetic Rule 1945 was there all those provisions this new rule, this new Medical Device Rule have over adding effect, and this new Medical Device Rule will be implemented and no rules related to the medical devices in the Drugs and Cosmetic Rules 1945 will be applicable.

The implementation of the Medical Device Rule 2017, the various activities under the Medical Device Rule 2017 there is a different implementation date. If, you see the implementation data of these rules as already we have discussed this Medical Device Rule 2017 was published on 31st January 2017, implementation date first January 2018. Then one new category of the medical devices has been notified on 2nd April 2018, that is organ preservative solutions.

There after the 4 new categories of the medical devices including the equipment's which has been notified on 3rd December 2018. Further the 8 new categories of the medical devices were notified on 8th February 2019. The implementation date of the 4 medical 4 category of the medical devices, which were notified on December 2018 will be the 1st January 2020. The 8 other categories of the medical devices notified on the 8th February 2019 the implementation date will be 1st April 2020.

Also in the Medical Device Rule 2017 the provision for implementation of UDI, that is the Unique Device Identification number on the label of the medical devices and in vitro diagnostics. The implementation day of this UDI system on the label of the medical devices will be 1st January 2022. So, these are the implementation stages of various activities of the Medical Device Rule 2017.

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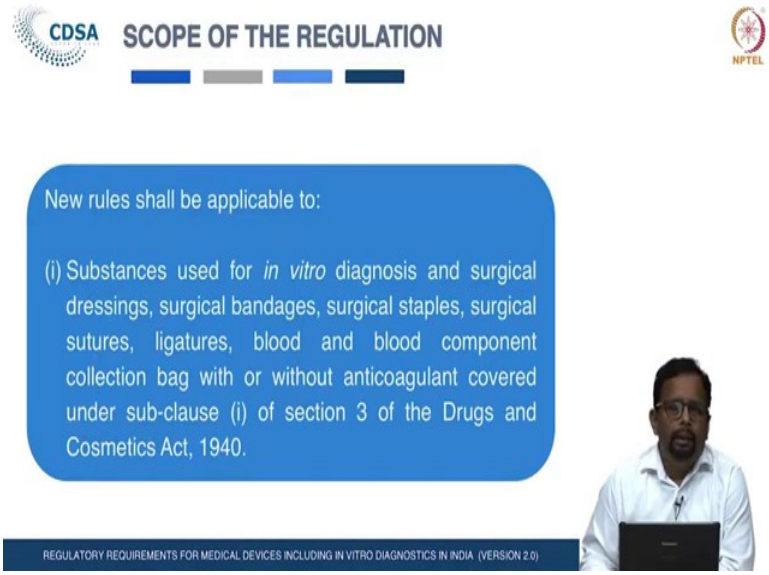

The scope of this medical device regulations we have already discussed, this rules is applicable to the in vitro diagnostics surgical dressings, surgical bandages, surgical stapler, surgical sutures, ligatures, blood and blood component collection bags with or without anticoagulants, which covers under the class one of section b of Drugs and Cosmetic Act 1940.

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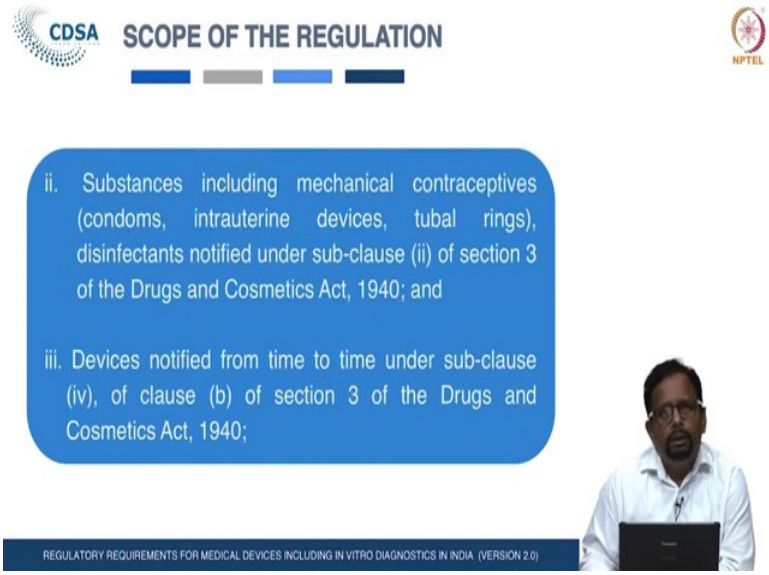

Also these new rules shall be applicable to the substances including the mechanical contraceptives like, condom, copper T, tubal rings and disinfectant solutions or fluids,

notified under the subclass 2 of section 3 of the Drugs and Cosmetic Act. This rule is also applicable for the devices, which have been notified from time to time under the subclass 4 of the subclass b of section 3 of the Drugs and Cosmetic Act 1940. The scope of this Medical Device Rule is applicable to only these devices.

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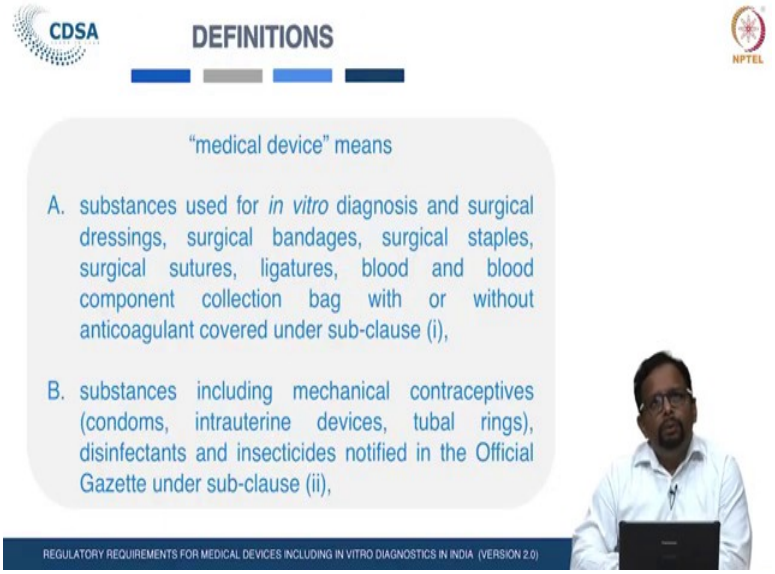

In the medical device rules certain definition related to the medical devices and in vitro diagnostics has been defined these definition were not earlier in the Drugs and Cosmetic Rules 1945.

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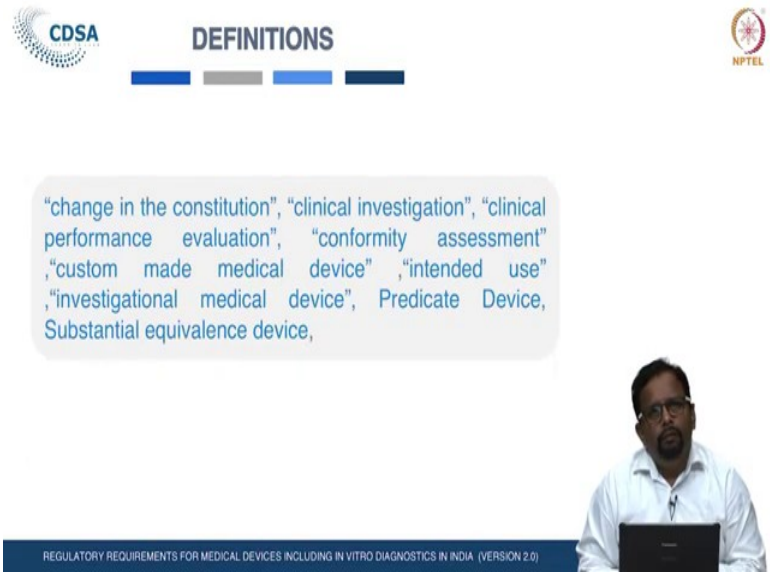

The definitions like, “change in the constitution” of the firm what is “clinical investigation”? What is “clinical performance”? “Conformity assessment” what is the “custom made medical devices”, “intended use”, “investigational medical devices”, the definition of new in vitro diagnostics devices, the definition of clinical investigation, the definition of clinical performance.

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The definition of performance evolution, definition of the post marketing surveillance, definition of quality management system and so, many other definitions related to the medical devices in this Medical Device Rule chapter 1 all these term has been defined.

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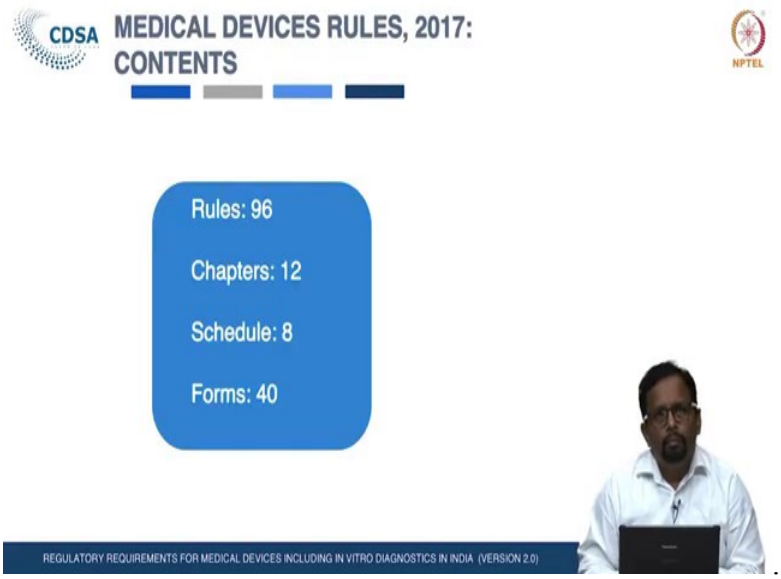

This Medical Device Rule 2017 includes 96 rules, total 96 rules related to import, manufacture, clinical investigation, sale and distribution of the medical devices and in vitro diagnostics. Total 12 chapters are there each chapter have different activities different provision for the requirement of sale distribution, import manufacture of the medical devices has been given.

This Medical Device Rule have 8 different schedule and total 40 forms has been prescribed under this Medical Device Rule 2017, which relates to import manufacture clinical investigation registration of the drug testing medical device testing laboratory, registration of the notified body, all those forms are there.

If, we see the chapters we have discussed that total 12 chapters have been incorporated into Medical Device Rule 2017.

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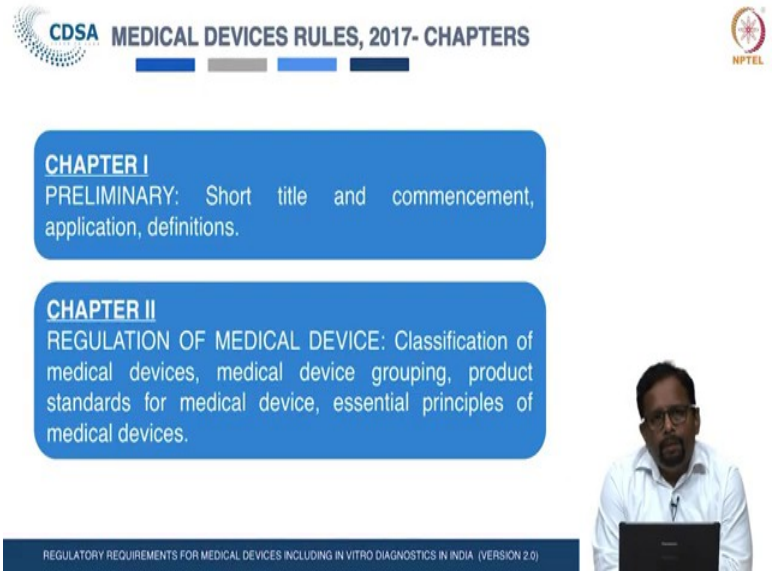

Chapter 1; that includes preliminary that short title of this rules commencement of this rules, applicability of the Medical Device Rules and the definitions. All those provision has been prescribed in the chapter 1 of the Medical Device Rule 2017.

Chapter II; that is the regulation on medical devices, under this chapter the provision for classification of the medical devices, the provision of grouping of the medical devices, the provision for standards of the medical devices, the provision for essential principle for safety and performance of medical devices and in vitro diagnostic kits.

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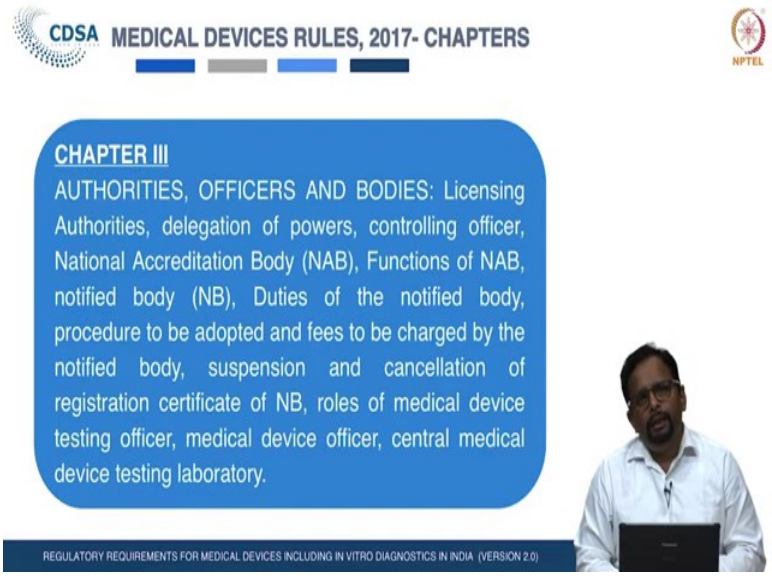

This provision has been described in the chapter II of the Medical Device Rule 2017. Chapter III includes authorities, officers and bodies. Authorities means, the authority responsible for enforcement of the medical devices, that is the Central Licensing Authority(CLA), the role of the central licensing authority has been prescribed in this chapter.

The role of the state licensing authority, the role of medical device testing officers, the role of medical device officers, the provisions for national accreditation body, the role of the notified bodies, delegation of the power to the subordinate officers, all those provision has been prescribed in the Medical Device Rule 2017 under the chapter III.

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Chapter IV; where the provision for manufacture of the medical devices and in vitro diagnostics for sale and distribution in the country has been given. Under this chapter the provision for submission of application by the manufacturers, the provision for inspection of the manufacturing premises by the medical device officers.

The provision for grant of license to the manufacturers, the provisions for validity of the manufacturing license, provision for suspension or cancellation of the license or applications, provision for manufacture of in vitro diagnostic kits and medical devices. For the purpose of test and analysis, provision for manufacture of medical devices and in vitro diagnostic kits for the purpose of clinical investigation, provision for un announced inspection at the manufacturing premises by the medical device officer.

All those provision has been given has been prescribed in this chapter IV of the Medical Device Rule.

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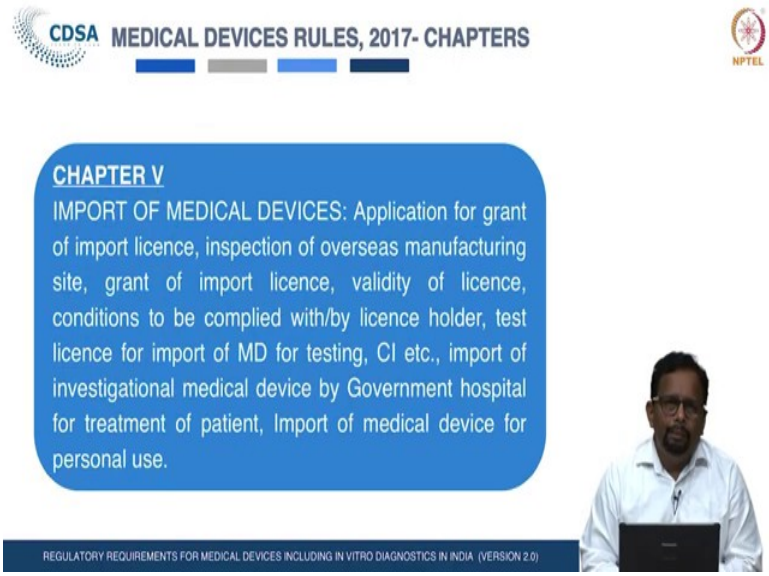

Chapter V of the Medical Device Rules, which provides the import of the medical devices and in vitro diagnostics, where in the provision for import license to import the medical devices and in vitro diagnostic kits into the country has been given, provision for the submission of application by the importer, provision for inspection of foreign manufacturing site, provision for conditions of the license, provision for import of the medical devices.

And, in vitro diagnostic kits for the purpose of test and analysis, provision for import of the medical devices or in vitro diagnostic kits for the treatment of patient by the government institution, provision for import of the medical devices for the purpose of personal use. The validity of the import license provision for grant of import license all those provisions has been included in has been prescribed in the chapter V of Medical Device Rule 2017.

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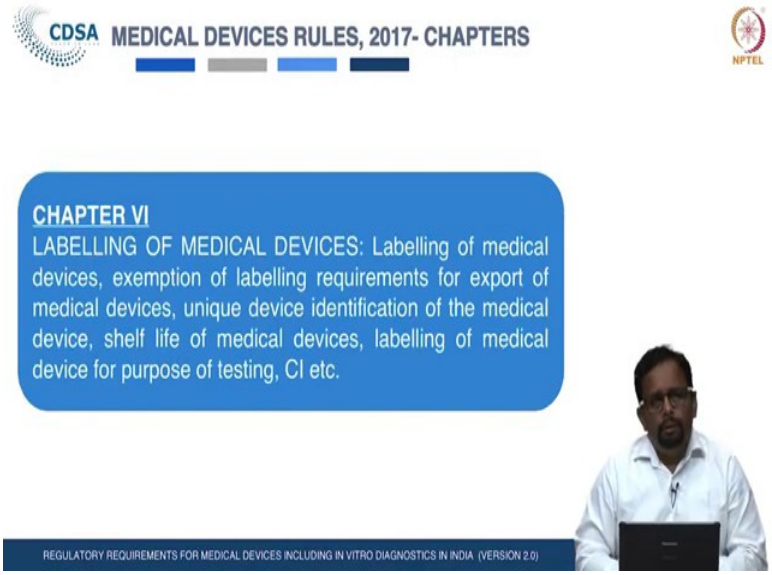

Chapter VI, wherein the provision for labeling requirement. What are the labeling requirement applicable for manufacture or import of the medical devices into the country for sale and distribution? This provision has been given in this chapter VI labeling provision for the devices, which is manufactured or imported for the purpose of test analysis or clinical investigation, provision for implementation of unique device identification number, provision for shelf-life of the medical devices and in vitro diagnostic kits.

All those provision has been prescribed in the chapter VI of the Medical Device Rule 2017.

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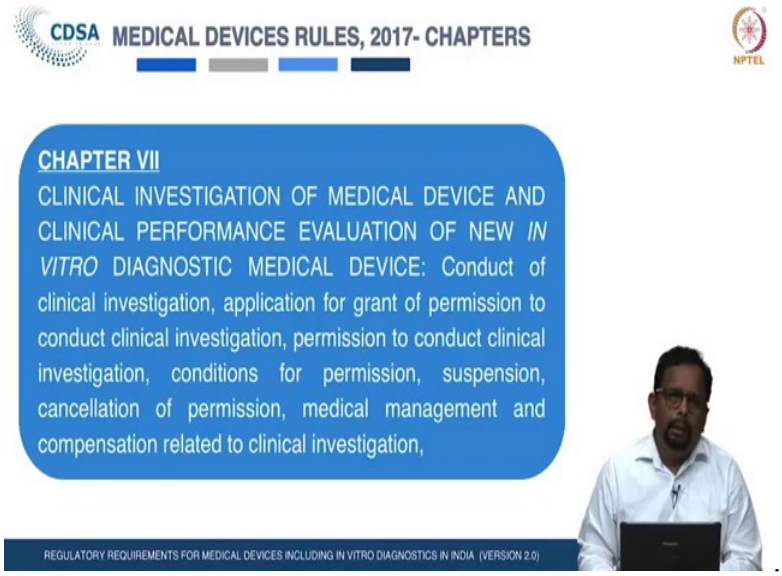

Chapter VII, wherein the provision for the clinical investigation of the medical devices and clinical performance of the in vitro diagnostic kits have been given, this provision is applicable for investigational medical devices and new in vitro diagnostics, under these chapters, the provision for conduct of clinical investigation or clinical performance of the in vitro diagnostic kits.

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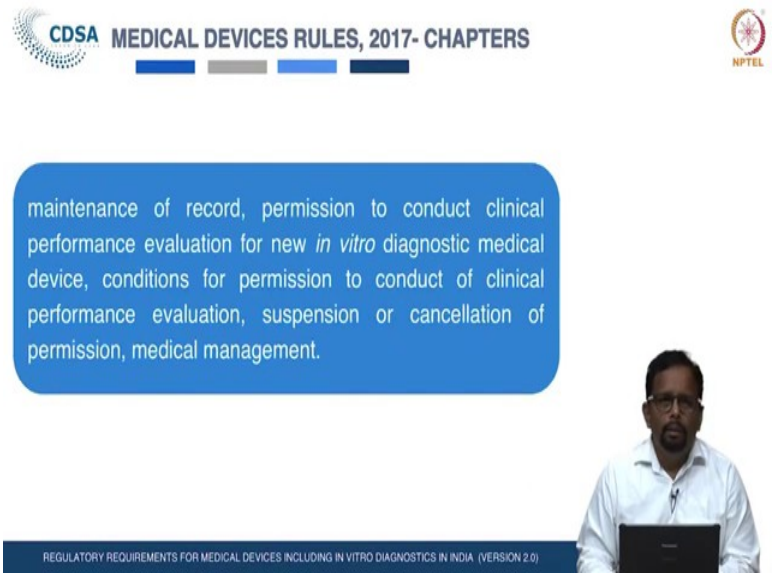

Provision for grant of permission to conduct the clinical investigation for medical devices and clinical performance for in vitro diagnostic kits has been given. Provision for

suspension, cancellation of the permissions, medical management and compensation to be provided to the patient, involved in the clinical investigation of the medical devices has been given conditions of the permissionsall those things all those things has been have been described in the chapter VII of the Medical Device Rule 2017.

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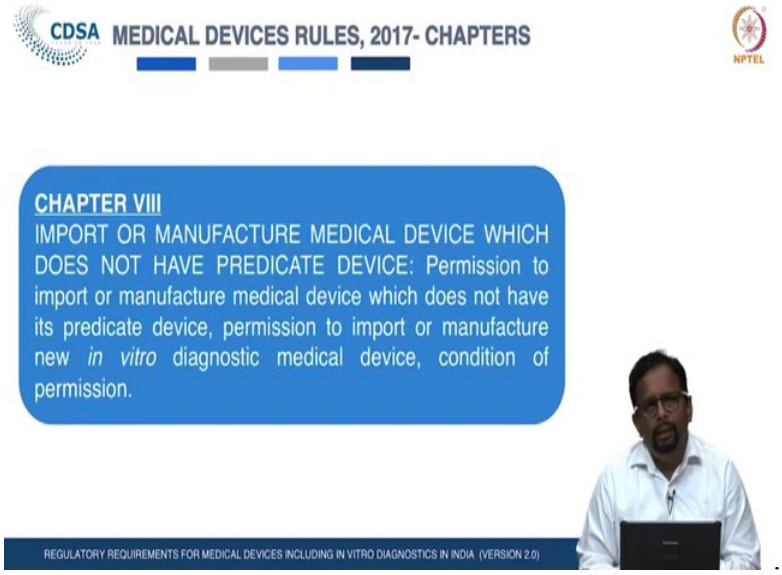

Chapter VIII, which includes the provision for import or manufacture of the medical devices, which does not have the predicate devices, under this chapter the permission to import the manufacture permission to import or manufacture the medical devices, which does not have any predicate devices. The permission to import or manufacturer of new in vitro diagnostics devices and conditions of the permissions all those provision say has been provided.

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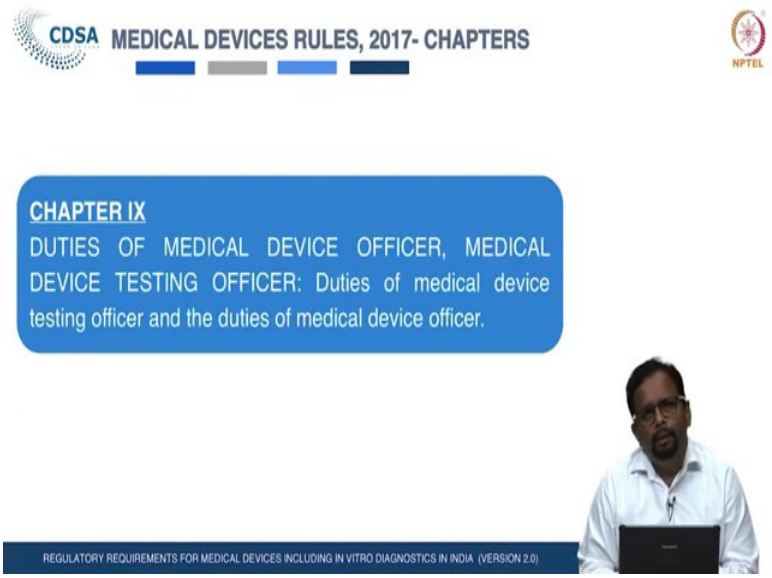

Chapter IX under this chapters the duties of the medical device officers and medical device testing officers has been prescribed.

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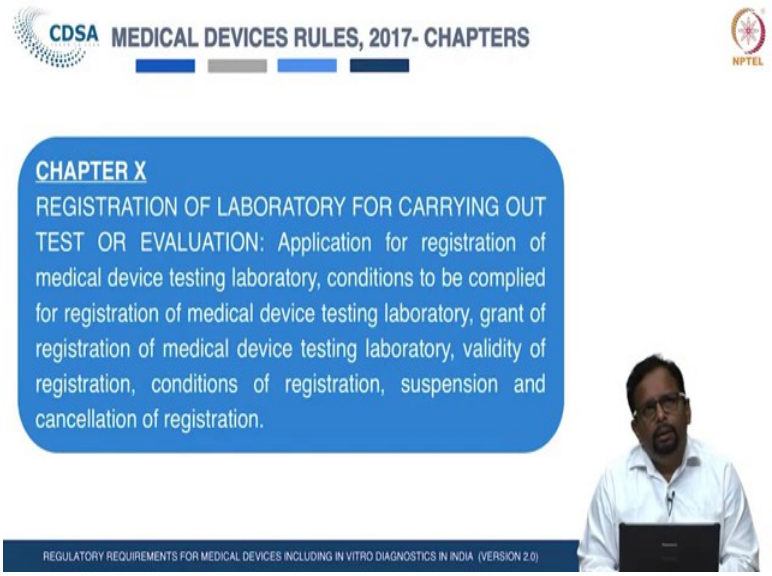

Under chapter XI the provision for registration of laboratory for carrying out test or evaluation of the medical devices that provision has been made this is the new provision. In this provisions the private testing laboratory having facility to test the in vitro diagnostic kits or medical devices they have to register with the center licensing authority.

The provision for submission of the registration application conditions to be complied for registration of the district centered grant of registration of the medical device testing laboratory, validity of the registration, conditions of the registration, suspension and cancellation of the registration, all those provision have been prescribed in the chapter X.

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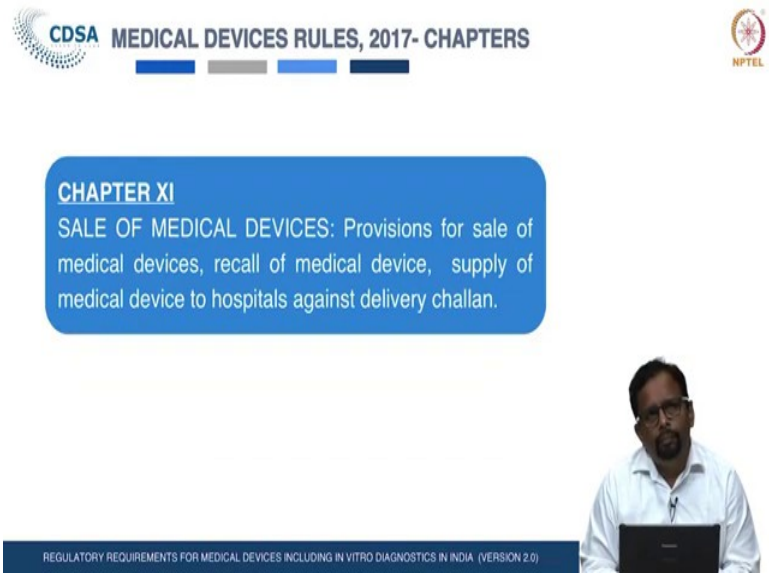

Chapter XI, wherein the provision for sale and distribution of the medical devices and in vitro diagnostic kits have been prescribed, also the provision for supply of the medical devices to hospital against the delivery channel, that provision has been made the provision for recall of the medical devices from the market in case of any serious adverse events all those provision has been given in the chapter XI of the Medical Device Rule 2017.

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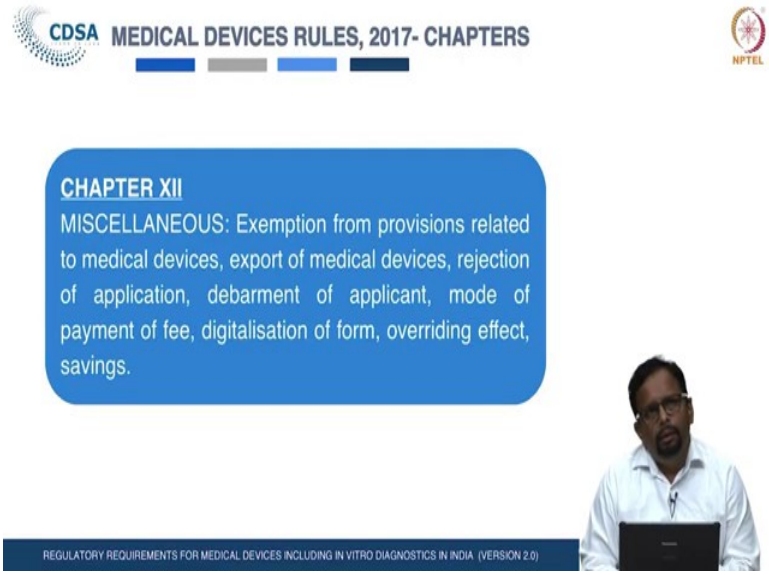

The last chapter that is chapter XII, that is miscellaneous chapter, under this chapter the exemptions from the provisions related to medical devices has been given certain conditions, where the exemption can be given that provision has been made export of the medical devices. The grant of the free sale certificate for export of the medical devices to the foreign country that provision has been made.

The provision for rejection of the application, the provision for debarment of the applications, the provision of mode of payment of the fees, the provision for digitalization of the forms, provision for over adding effect, provision for saving class, all those things have been prescribed in the chapter XII of the Medical Device Rule 2017.

So, these are all XII chapters were in the different components provisions for requirement of import license, provision for requirement of manufacturing license, provision for conduct of clinical investigation, or clinical performance, sale and distribution of the medical devices, all those provisions has been prescribed.

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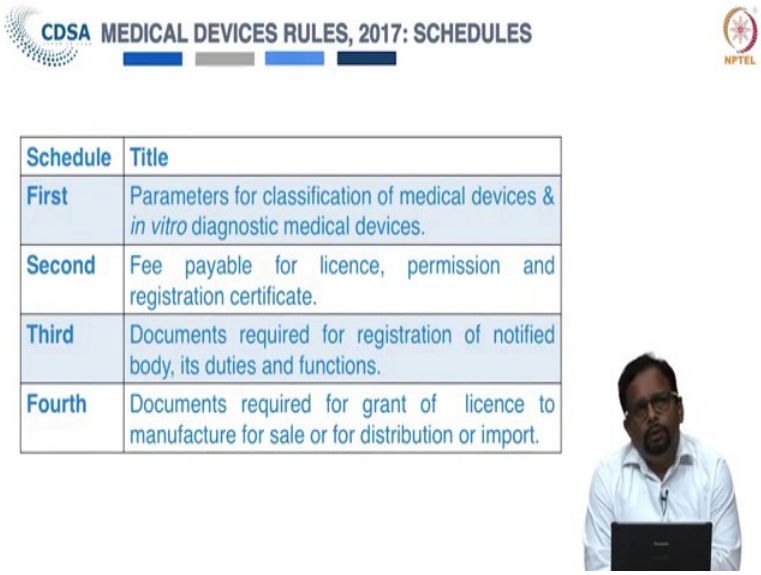

This medical device will 2017 have also include the 8 schedules. The first schedule of the Medical Device Rule, where in the parameters for classification, criteria for classification of medical devices and in vitro diagnostics has been given, based on the risk of the risk associated with medical devices and in vitro diagnostic kits.

The devices are to be classified the rules wherin the central licensing authority has been given power to classify the medical devices and in vitro diagnostic kits, which are presently under regulation. Based on their risk the central licensing authority will classify and on the basis where the center licensing authority will classify.the criteria and parameters have been given in the first schedule of the Medical Device Rule 2017. Second schedule the fees structure, for obtaining the manufacturing license, fees for obtaining import license, fees for obtaining clinical investigation permission, fees for obtaining clinical performance, fees for registration of the notified body with the center licensing authority, fees for registration of medical device testing center for testing of medical devices and in vitro diagnostic kits. All those fees structure has been given in the second schedule of the Medical Device Rule 2017.

Third schedule, the detail requirement of the documents for registration of notified body, the duties of the notified bodies, the functions of the notified bodies, all those details have been given in the third schedule of Medical Device Rule 2017. The fourth schedule where in the detail requirement of the documents. The documents which are required for

grant of license to manufacture for sale and distribution of medical devices and in vitro diagnostic kits, what documents are required to be submitted all those things all those information has been clearly mentioned in the fourth schedule of the Medical Device Rule 2017.

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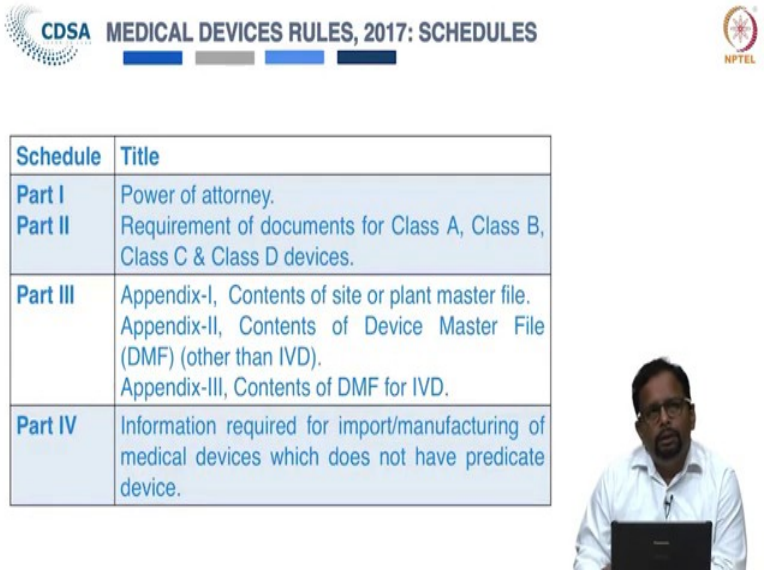

This forth schedule have 4 different part where in the part one where the pro forma for power of attorney that is applicable for the applicant, who is importing the medical devices into the country, the power of attorney has to be issued to the importer by the foreign manufacturer the prescribed form is there, they have to submit this power of attorney, while importing the while obtaining the import license for the import of the medical devices or in vitro diagnostics.

Part II that is the requirement of the document for class A and class B devices, in part II the requirement of document for class C and class D devices also there, part III have 3 different appendix. The appendix I, which prescribed the content of the site master file or plant master file, what information needs to be submitted by the applicant to the licensing authority?

Appendix I has that details, appendix II, where in the content of the device master file, other than the in vitro diagnostic kits. So, the device master file applicable for the medical devices what are the document the applicant need to submit it, all those

information has been provided in the appendix II of the part III of IV schedule. Appendix III,that is the content of the Device Master File for in vitro diagnostic kits.

And, part IV of this forth schedule were in the information and the documents required for import or manufacture of the medical devices which does not have predicate devices. The details information that need to be submitted by the applicant to the central licensing authority is given in this part IV.

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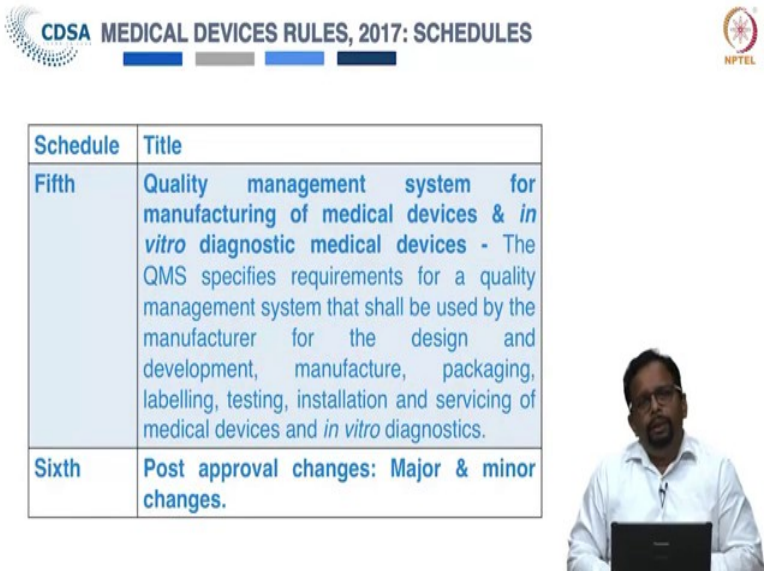

Fifth schedule, Fifth schedule is the quality management system the requirement of the quality management system for manufacturing of medical devices. And, in vitro diagnostics have been given. this quality management systems are in the line of ISO 1 3 4 8 5. And, the applicant or the manufacturer shall used these quality management system, for design of the medical devices design and development of the medical devices, for manufacturing of the medical devices, labeling, testing, installation and servicing of the medical devices and in vitro diagnostic kits.

This quality management system is applicable for the medical devices or in vitro diagnostic kits, which are having manufacturing premises in India, for manufacturing of medical devices and in vitro diagnostic kits. The sixth schedule have the provision, where in the details of the post approval changes, major and minor changes, what changes are considered as a major changes, which changes are considered as a minor changes, that are defined, for major changes the manufacturer, or the importer has to

obtain prior approval from the licensing authority. For minor changes the applicant has to notify to the licensing authority, the major changes like change in the constitution of the firm.

That will consider as a major changes. Change in the material of construction of the medical devices that is also considered as a major change, change in the indication of the medical devices, change in the shelf-life of the medical devices, change in the inner package of the medical devices. All those changes will be considered as a post major considered as a major changes and for such changes the applicant has to the manufacturer or importer has to obtain prior approval from the licensing authority.

Seventh schedule were in the requirement for permission to import or manufacture investigational medical devices, for conduct of clinical investigation, or clinical performance that requirement has been provided in the Seventh schedule of the Medical Device Rule 2017.

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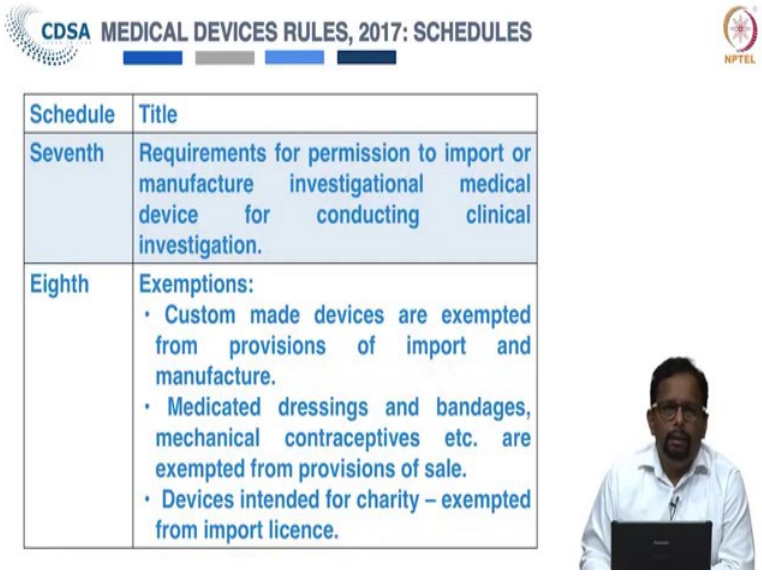

Eight schedule that is the last schedule where in certain exemptions has been given, in which cases exemption was given certain devices like custom made devices, the exemptions are given from the provisions of import and manufacture. Medicated dressing bandages, mechanical contraceptives are exempted from the provisions of the sales they do not require the sale license for marketing of these products.

If, devices is imported for the purpose of charity import license is exempted like, that certain exemptions has been given in the eighth schedule, for which certain provision of the medical device rule is not applicable. In the Medical Device Rule we have also discussed the notified medical devices and in vitro diagnostic kits, which are presently under regulations, have been classified or are to be classified based on the criteria and parameters given in the first schedule of the Medical Device Rule 2017.

And, this classification shall be made by the central licensing authority that provision has been given under rule 4 of the Medical Device Rule 2017.

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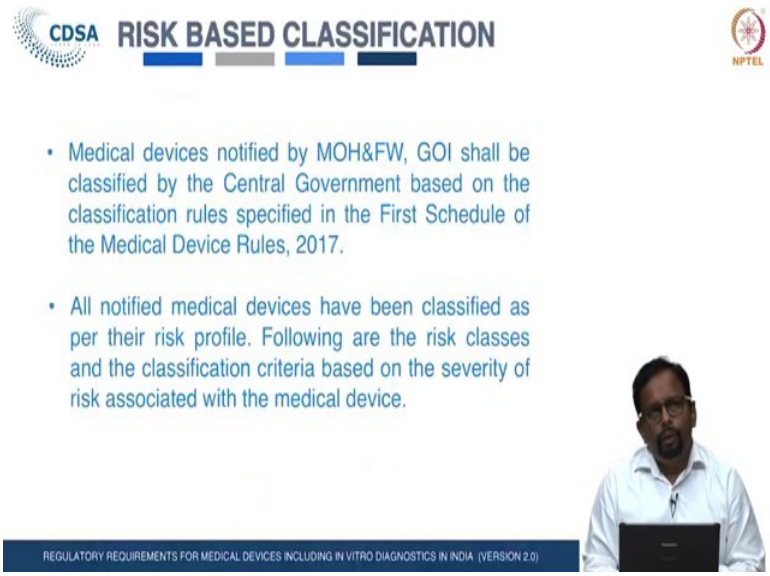

This medical device rules given power to the central licensing authority(CLA) that is Drugs Controller General India(DCGI), to classify the medical devices and in vitro diagnostic kits based on the criteria. and, the parameter given in the first schedule and this classification list shall be published for the stakeholders.

So, that based on the classification the concerned stakeholder will submit their application for grant of import, or manufacture, or clinical investigation of the particular medical devices or in vitro diagnostics. This classification are mainly based on the risk of the medical devices, risk associated with the medical devices, the severity of the risk.

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Where in the low risk devices will be classified as a class A devices and high disk will be classified as a class D devices, low to moderate will be classified as a class B devices and moderate to high will be classified as a class C devices.

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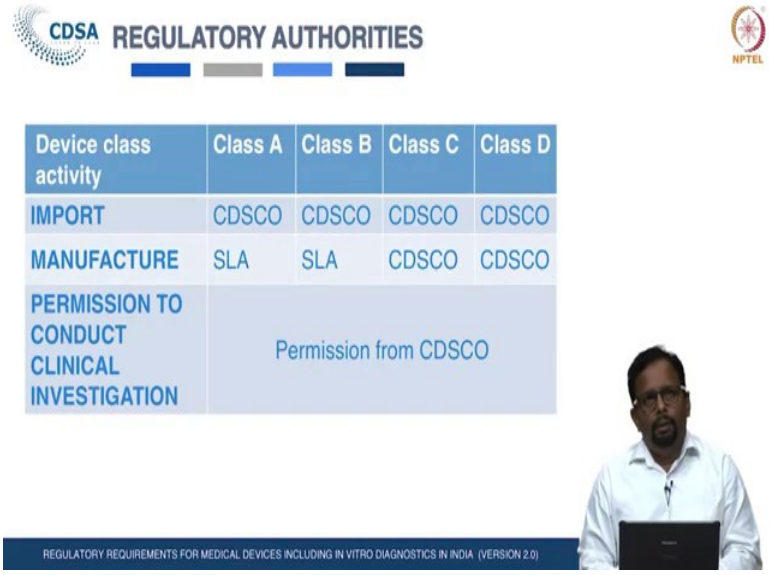

The responsibility of the regulatory authorities, the medical device rules certain responsibility has been given to the licensing authority. If you see the import the responsibility lies with the center licensing authority for import of class A, class B, class C, and class D devices. The central licensing authority is responsible for grant of import

license for manufacturing of medical devices class A and class B devices the license will be issued by the state licensing authority.

And, for class C and class D the center licensing authority will issue the license to the manufacturer's, permission to conduct clinical investigation or clinical performance of investigational medical devices, or new in vitro diagnostic kits, the responsibility lies with the center licensing authority.

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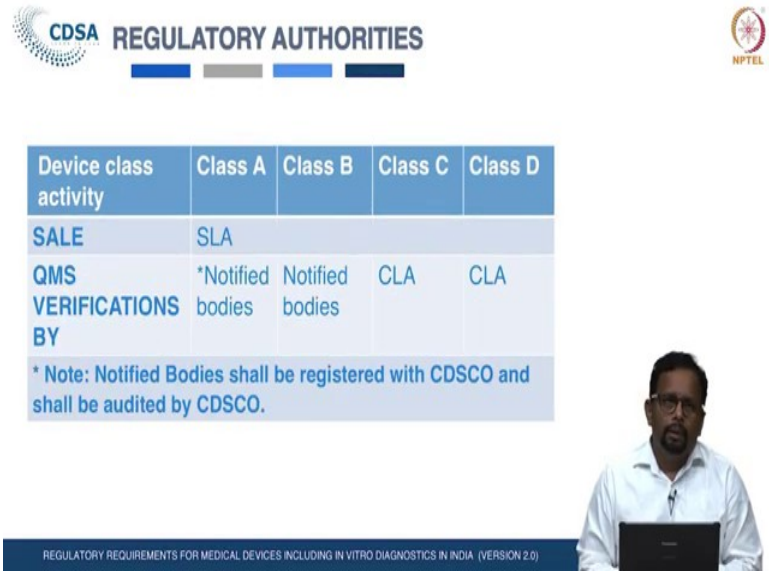

Sale of the medical devices and in vitro diagnostics, the state licensing authorities responsible for sale and distribution of the medical devices and in vitro diagnostic kits, QMS verification for class A and class B devices, the role of the notified bodies are there.

The notified bodies is responsible for audit of class A and class B manufacturing premises for grant of manufacture license, for class C and D Central Licensing Authority(CLA)responsible for grant of QMS inspection of this premises, the medical device officer is the officer who will carry out the QMS inspection of the manufacturing premises of class A and class D devices.

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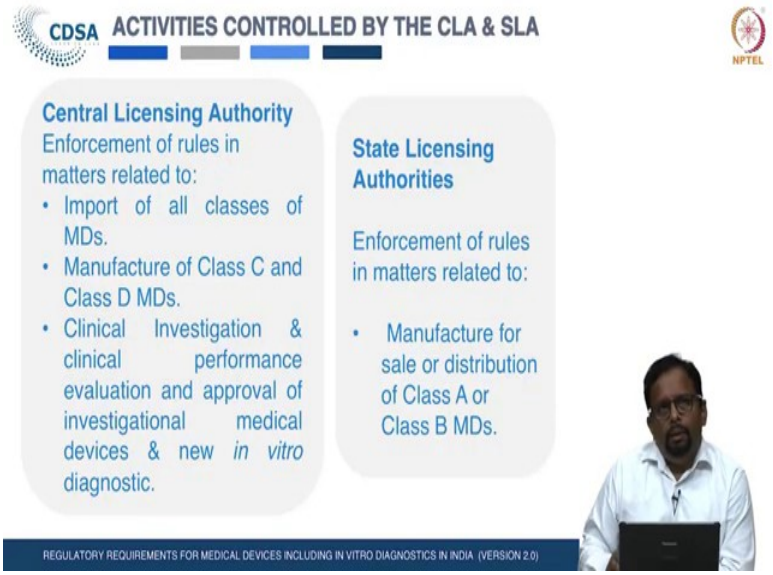

The activities controlled by the center licensing authority and state licensing authority, we have already discussed the major responsibility of the center licensing authority will be import off all the medical devices, manufacturer of class C and class D devices, clinical investigation, clinical performance of the medical of investigational medical devices and new in vitro diagnostics.

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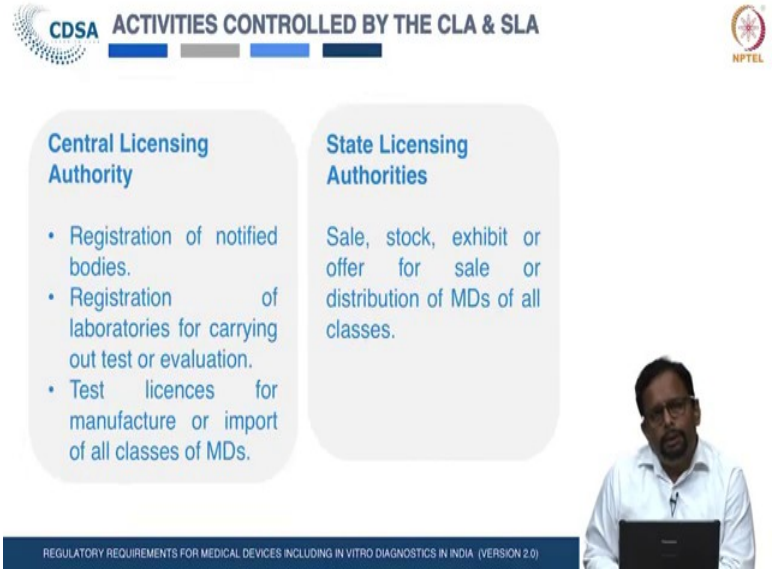

Registration of notified bodies, registration of laboratory for carrying out test and analysis, or test and evolution of the medical devices, or in vitro diagnostics, test license

to manufacture medical devices or in vitro diagnostics for the purpose of tests, or analysis or conduct of the clinical investigation, the central licensing authority is responsible for this.

And, the state licensing authority they are responsible for sale or distribution of the class A to class D devices, they are responsible for a grant of manufacturing license for sale and distribution. In case of class A and class B devices, these are the activities controlled by the state licensing authority as well as the center licensing authority.

The notified body as we have already discussed they are responsible for quality management inspection of the premises of class A and class B devices, and based on the inspect QMS inspection of the notified body, the license will be granted by the state licensing authority.

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So, only the notified body which is registered with the central licensing authority or the response bill for carry out carrying out the QMS inspection of class A and class B manufacturing unit. They have to register if it is not registered with the central licensing authority that is CDSCO.

They will not eligible for carrying out the QMS inspection for grant of manufacturing license for manufacture class A and class B devices. This registered notified body, they had to accredited by the national accreditation body, for this purpose Quality Council of

India(QCI) is the notified body is the body, who has given the power to act as a national accreditation body.

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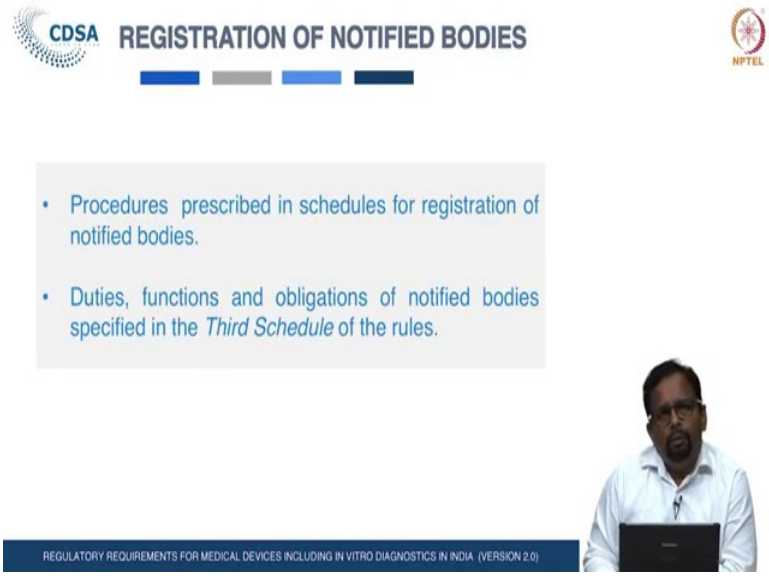

And, they will, audit they will let down the procedures and the standards for conformity assessment of the notified body. The duties and functions of the notified body as we have already discussed, it is clearly defined in the third schedule of the Medical Device Rule 2017.

The procedures for registration of the notified body with the central licensing authority, that procedure is also given in the third schedule of the Medical Device Rule 2017. So, only the notified body which has been registered with the central licensing authority, they are responsible for audit of the QMS inspection of class A and class B medical devices.

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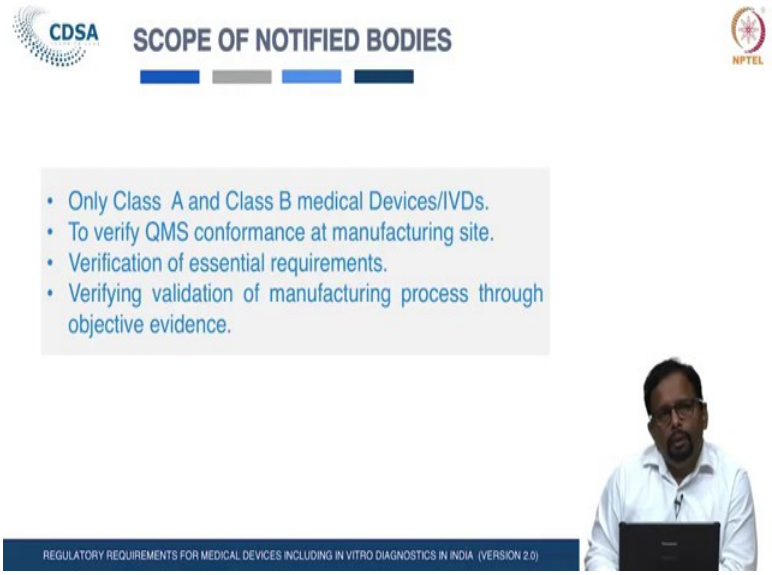

The scope of the notified body the certain scope have been given to the notified body under the Medical Device Rule 2017. They have to verify the QMS conformance at the manufacturing site of the class A and class B devices; they have to verify the essential requirement at the premises with respect to the safety and performance of the medical devices or in vitro diagnostics. They have to verify the validation procedure of the manufacturing process, quality control process.

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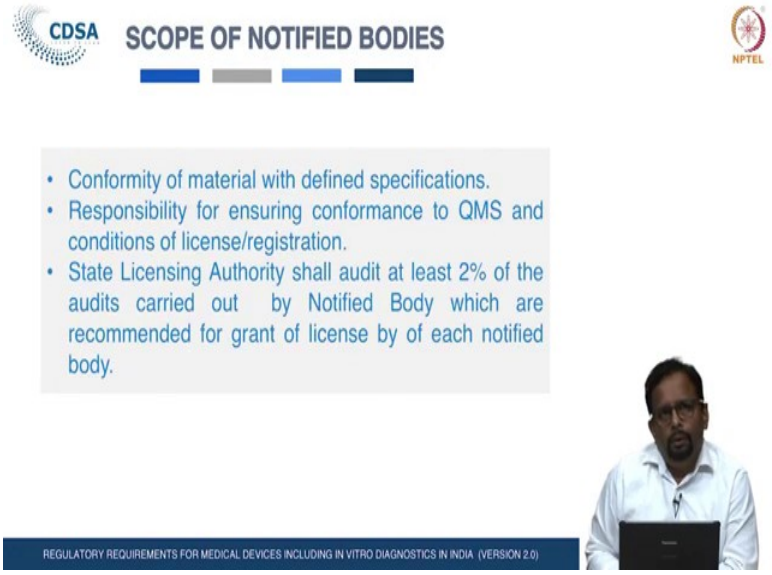

They have to verify the conformity assessment of the premises; they are responsible for ensuring the conformance to the QMS and conditions of the license or the registration, and the state licensing authority. They shall audit at least 2 percent of the audits carried out by the notified body, which are recommended for grant of license by or each notified body, this is the scope of the notified body.

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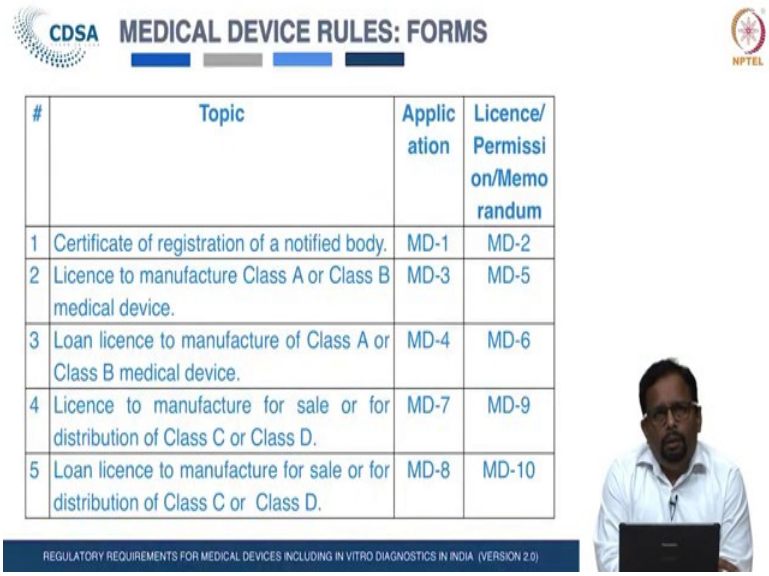

#	Topic	Application	Licence/ Permission/Memorandum
1	Certificate of registration of a notified body.	MD-1	MD-2
2	Licence to manufacture Class A or Class B medical device.	MD-3	MD-5
3	Loan licence to manufacture of Class A or Class B medical device.	MD-4	MD-6
4	Licence to manufacture for sale or for distribution of Class C or Class D.	MD-7	MD-9
5	Loan licence to manufacture for sale or for distribution of Class C or Class D.	MD-8	MD-10

In the Medical Device Rules 2017, we have discussed that total 40 forms have been prescribed for different activities. If you see what are those forms? So, for each activity like application for registration of the notified body, if the notified body has to register with the central licensing authority, they have to submit application in MD-1 to the licensing central licensing authority. And, after satisfying the requirement, the center licensing authority will register the notified body and they will issue the permission in MD-2.

Other forms that is the application for grant of manufacturing license. If, you see application MD-3 is the application for grant of manufacturing license for class A and class B devices MD-4 is the application for grant of loan license for class A and class B devices. And, the license for manufacture of class A and class B devices will be issued in MD-5 and loan license will be issued in MD-6, MD-7 is the application for grant of license to manufacture class C and class D devices.

After satisfying the requirements MD-9 that is the license to manufacture medical devices of class C and class D devices, central licensing authority will issue the license in MD-9. Loan license application has to be submitted in MD-8 license will be issued by the central licensing authority in MD-10.

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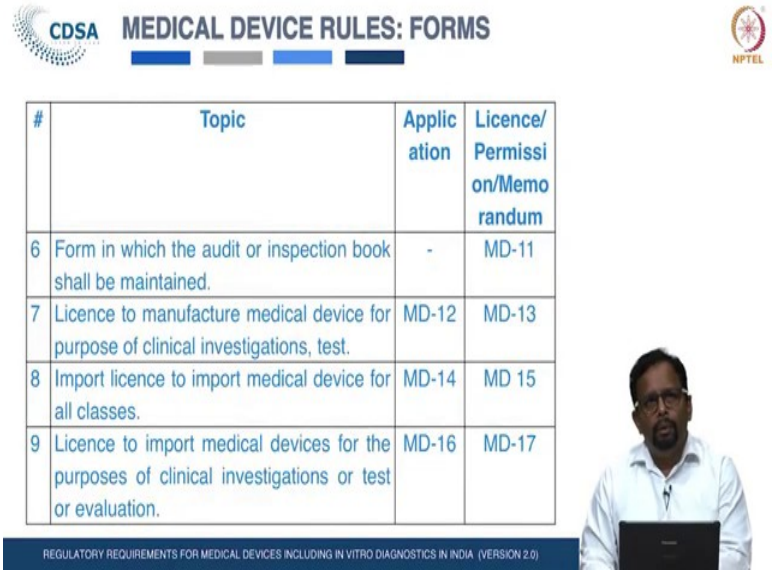

#	Topic	Application	Licence/ Permission/Memorandum
6	Form in which the audit or inspection book shall be maintained.	-	MD-11
7	Licence to manufacture medical device for purpose of clinical investigations, test.	MD-12	MD-13
8	Import licence to import medical device for all classes.	MD-14	MD 15
9	Licence to import medical devices for the purposes of clinical investigations or test or evaluation.	MD-16	MD-17

The forms in which the audit or inspection shall be maintained by the manufacturer, that MD-11 is the forms. The license to manufacture medical devices for the purpose of clinical investigation test or analysis, license will be issued in MD-30 and the application in MD-12 has to be submitted by the manufacturer to the center licensing authority. Import license MD-14 that is the application form MD-15 is the import license.

MD-16 that is the application for license to import the medical devices for the purpose of clinical investigation of clinical evolution, and the license will be issued in MD-17 by the center licensing authority.

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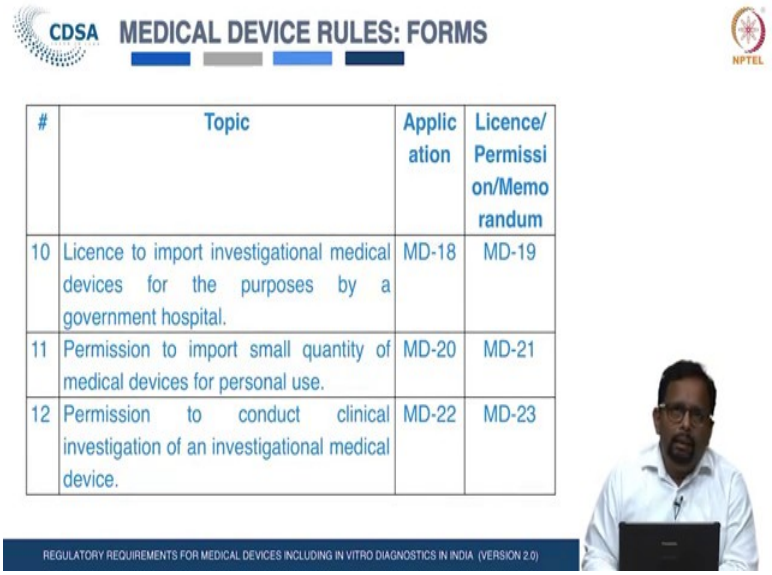

#	Topic	Application	Licence/ Permission/Memorandum
10	Licence to import investigational medical devices for the purposes by a government hospital.	MD-18	MD-19
11	Permission to import small quantity of medical devices for personal use.	MD-20	MD-21
12	Permission to conduct clinical investigation of an investigational medical device.	MD-22	MD-23

MD-19 that is the license to import investigational medical devices for the purpose of government hospitals and the application is in MD-18. MD-20 is the application for obtain permission to import the small quantity of the medical devices for personal use. And, the permission will be issued in MD-21. MD-22 is the application for obtaining permission to conduct the clinical investigation of the investigational medical devices. And, the permission in MD-23 will be issued after satisfying the requirements by the central licensing authority.

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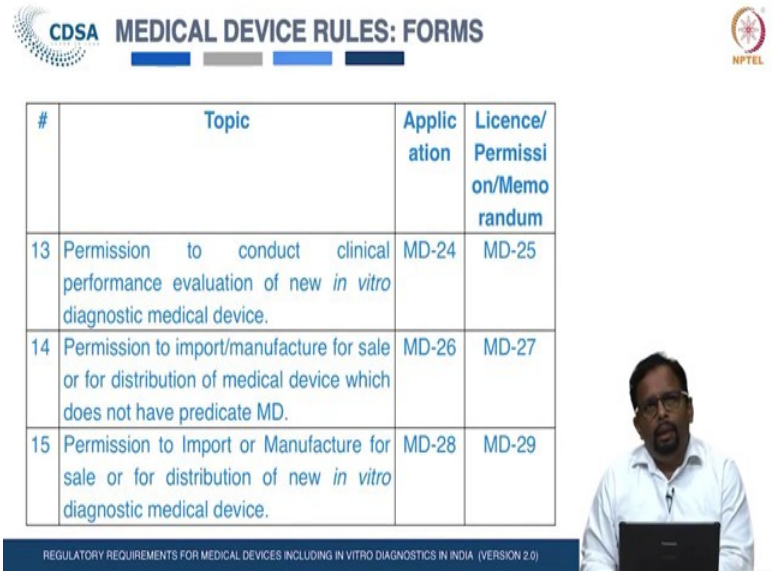

#	Topic	Application	Licence/ Permission/Memorandum
13	Permission to conduct clinical performance evaluation of new *in vitro* diagnostic medical device.	MD-24	MD-25
14	Permission to import/manufacture for sale or for distribution of medical device which does not have predicate MD.	MD-26	MD-27
15	Permission to Import or Manufacture for sale or for distribution of new *in vitro* diagnostic medical device.	MD-28	MD-29

MD-24 is the application for permission to conduct clinical performance of new in vitro diagnostics. MD-25 is the permission issued by the central licensing authority for conduct of clinical performance of the new in vitro diagnostics. Permission to import or manufacture for sale and distribution of the medical devices, which does not have the predicate devices. The permission will be issued in MD-27 and the MD-26 is the application, MD-28 the permission to import medical devices for manufacture or sale of new in vitro diagnostic medical devices.

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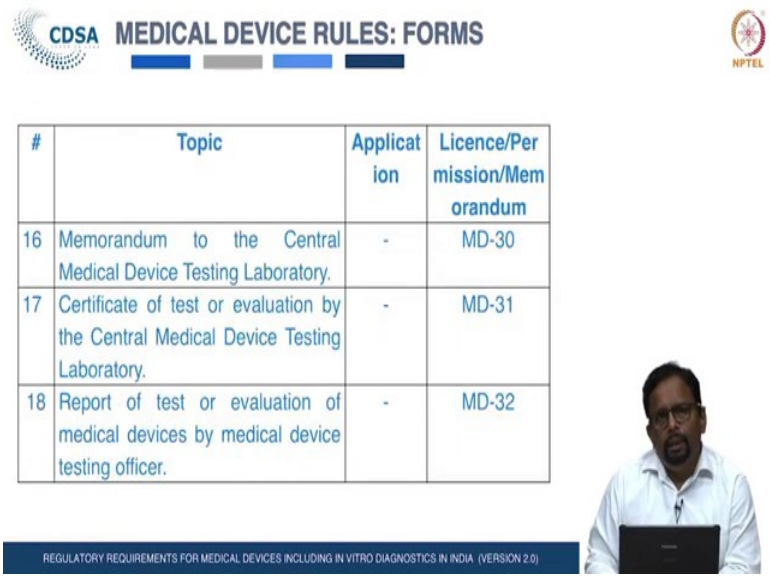

The license the permission for import of import or manufacture of new in vitro diagnostic devices will be issued in MD-29 by the central licensing authority. Other forms are MD-30 that is the memorandum to the central medical device testing laboratory MD-30; MD-31 the certificate of the test or evolution issued by the central medical device testing laboratory. Report of test or evolution of the medical device by the medical device testing officer, that is MD-32.

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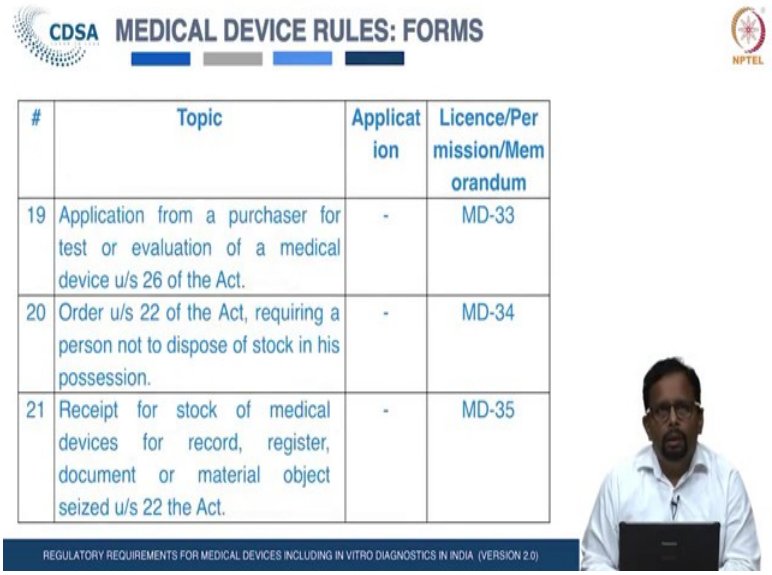

MD-33 is the application from a purchaser or the for test or evolution of the medical devices under secion 26 of the Act like, that other forms that is MD-34, MD-35, MD-36, MD-37, MD-38 that is the memorandum to medical devices testing officers.

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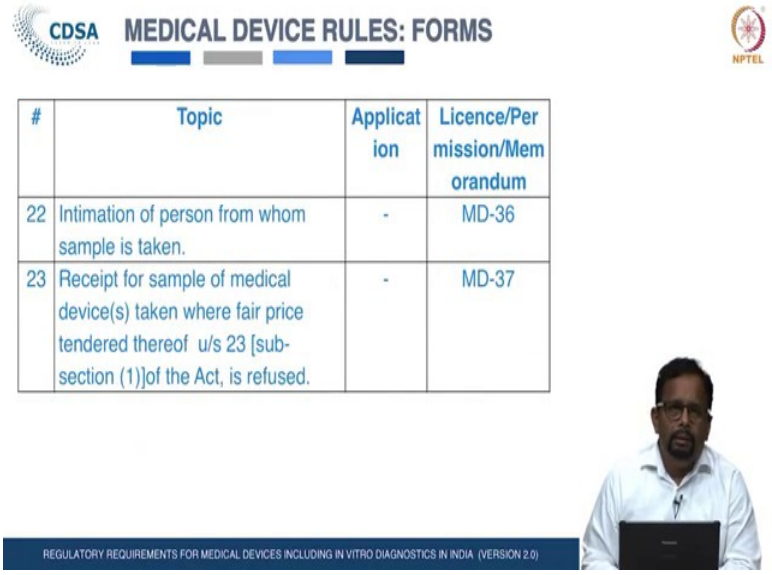

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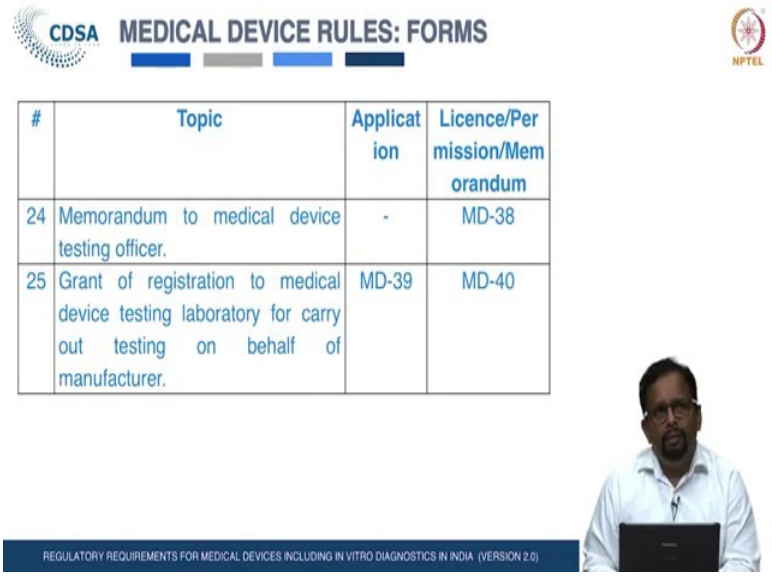

And, MD-40 that is the grant of registration to medical device testing center for carrying out the test on behalf of the manufacturer. And, application to obtain MD-40 is MD-39. These are the various forms prescribed in the Medical Device Rule for obtaining various license to manufacture or import medical devices or in vitro diagnostics, permission to conduct the clinical investigation, registration of the medical device testing laboratory registration of the notified bodies.

So, these all covered in the Medical Device Rules 2017. The application submitted to the central licensing authority or the state licensing authority for grant of license or permission. Online portal is there CDSCO MD online portal is established by the central licensing authority that is the central portal.

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This central portal have provision for submission of all types of application related to the medical devices and in vitro diagnostics. The web links for this online portal that is cdscomdonline..gov..in. Through this online system all the application related to grant of manufacturing license, grant of loan license, grant of permission to import investigational medical devices or new in vitro diagnostic kits, grant of license to manufacture test batches.

For test analysis or clinical investigation or clinical performance. All those application has to be submitted through online to the central licensing authority or the state licensing authority.

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And, the application will be reviewed through online only and after reviewing and satisfying the requirement the permissions or license will be issued to the applicant through online only.

The applicant has power to know the status of their application through this portal. Under the Medical Device Rule 2017 various guidance documents have been published by the central license authority or Ministry of Health and Family Welfare Government of India.

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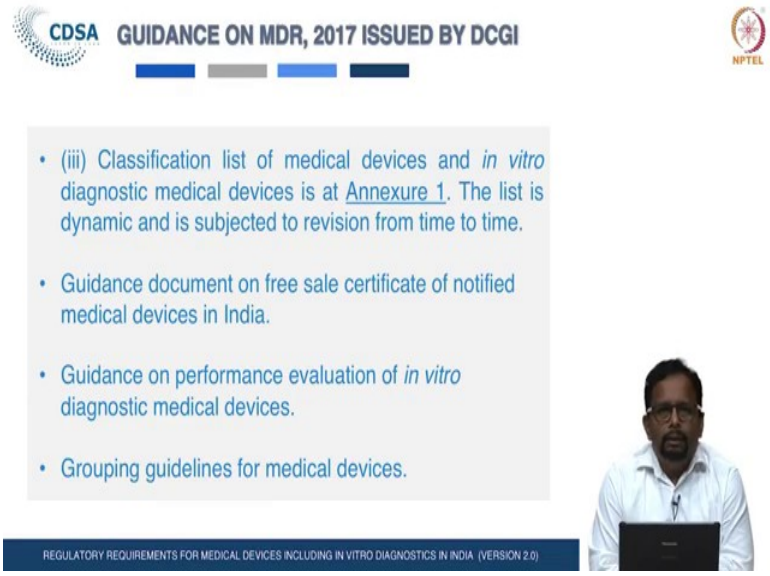

This guidance documents have been uploaded in the website of the CDSCO. The guidance document related to the medical devices and in vitro diagnostics like, classification of the medical devices and in vitro diagnostics. This list has been published whatever the notified medical devices and in vitro diagnostics kits are there all those devices and in vitro diagnostics has been classified by the central licensing authority, based on the risk of the classes.

This classification list is dynamic list from time to time based on the certain evidence the classification of particular medical devices or in vitro diagnostic, can be changed from low risk to high risk or high risk to low risk. However, a certain clinical evidence has to be provided to the central licensing authority to review that and based on the evidence, they can reclassify the particular medical devices. Under this classification list the components and accessories which is to be used with the medical devices or in vitro diagnostic kits have also been included.

The guidance document for certificate of the notified medical devices is also published. The guidance for the performance evolution of the in vitro diagnostic kits, the guidelines on grouping of the medical devices has also been published and it is uploaded on the website. Based on this guidance the manufacturers has grouped their medical devices or in vitro diagnostic kits. And, then they will apply to the concern state licensing authority or the central licensing authority for a grant of necessity approval.

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Guidelines for essential principles, for safety and performance of the medical devices, the medical device adverse event reporting forms these forms that is the adverse event associated with the medical devices. This is the requisite forms provided under the material visions program of India. And, through this form whatever the adverse event associated with the medical devices or in vitro diagnostic kits that has to be submitted to the licensing authority, as per the stipulated time line given in the Medical Device Rule 2017.

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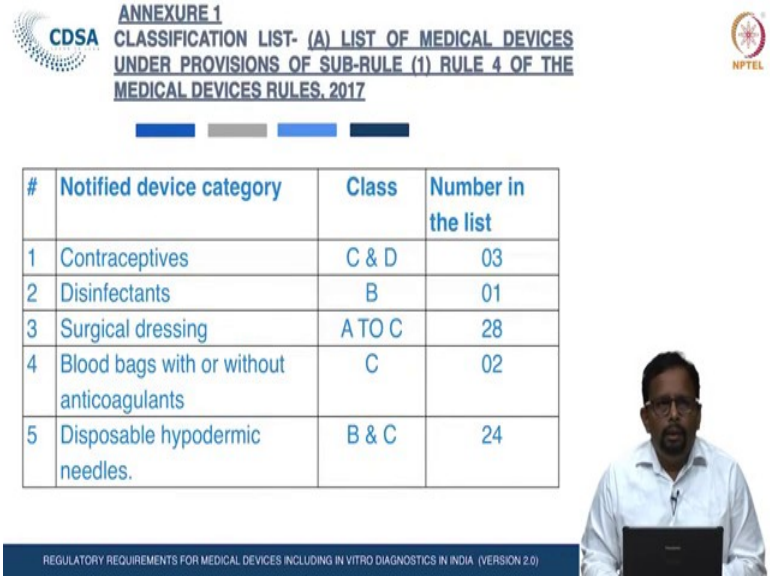

#	Notified device category	Class	Number in the list
1	Contraceptives	C & D	03
2	Disinfectants	B	01
3	Surgical dressing	A TO C	28
4	Blood bags with or without anticoagulants	C	02
5	Disposable hypodermic needles.	B & C	24

The list of the notified laboratory for testing of the in vitro diagnostic kits or medical devices, that list is published.FAQ on the Medical Device Rule 2017 certain Frequently asked questions(FAQ) has been formulated and uploaded on the website for certain clarifications. These are the various documents which is published for smooth implementation of the Medical Device Rule 2017.

In the classification list published by the central licensing authority, the notified medical devices total so, far 28 medical devices has been notified. And, based on the risk of these different types of the medical devices under this notified category, the central licensing authority is published this classification list. This classification list include all the medical devices. part one includes the medical devices classification.

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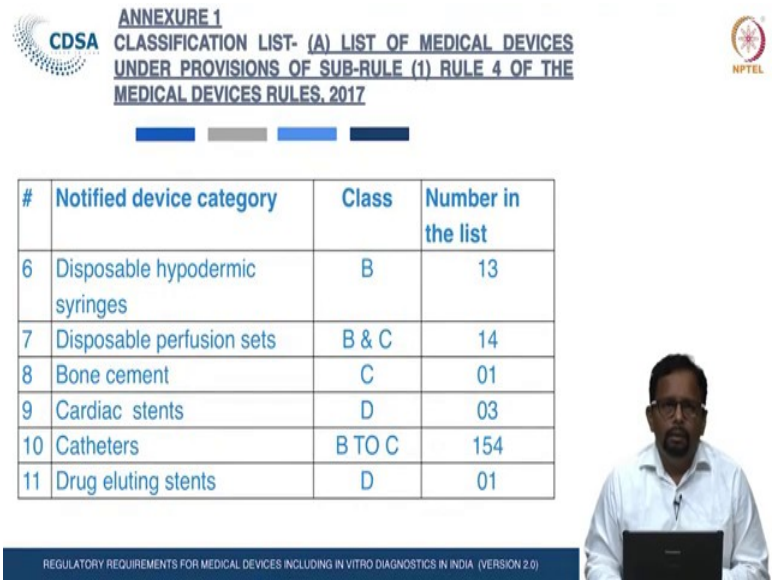

#	Notified device category	Class	Number in the list
6	Disposable hypodermic syringes	B	13
7	Disposable perfusion sets	B & C	14
8	Bone cement	C	01
9	Cardiac stents	D	03
10	Catheters	B TO C	154
11	Drug eluting stents	D	01

And, part 2 of this classification list includes the classification of in vitro diagnostics. And, all the different categories of the medical devices based on the risk based classification or the criteria described in the first schedule.

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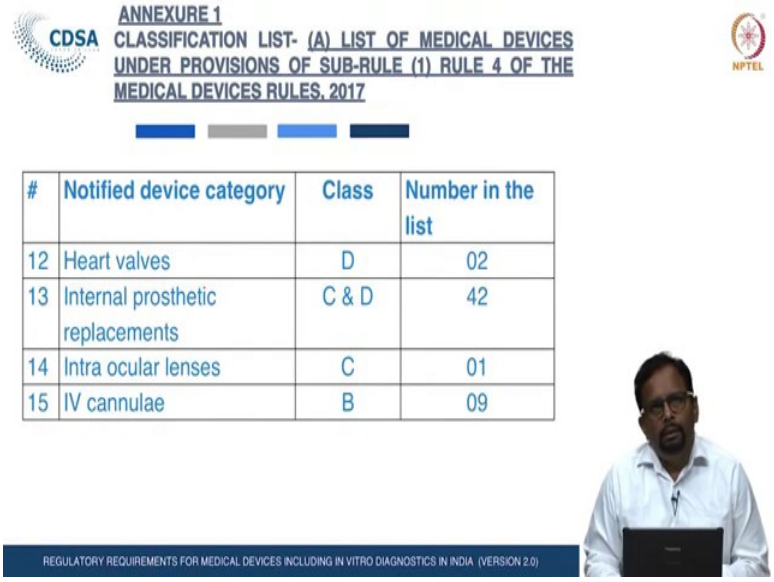

#	Notified device category	Class	Number in the list
12	Heart valves	D	02
13	Internal prosthetic replacements	C & D	42
14	Intra ocular lenses	C	01
15	IV cannulae	B	09

It has the medical devices has been classified and under the 18 different categories of the medical devices total 379 different types of the medical devices has been classified from class A to class D devices.

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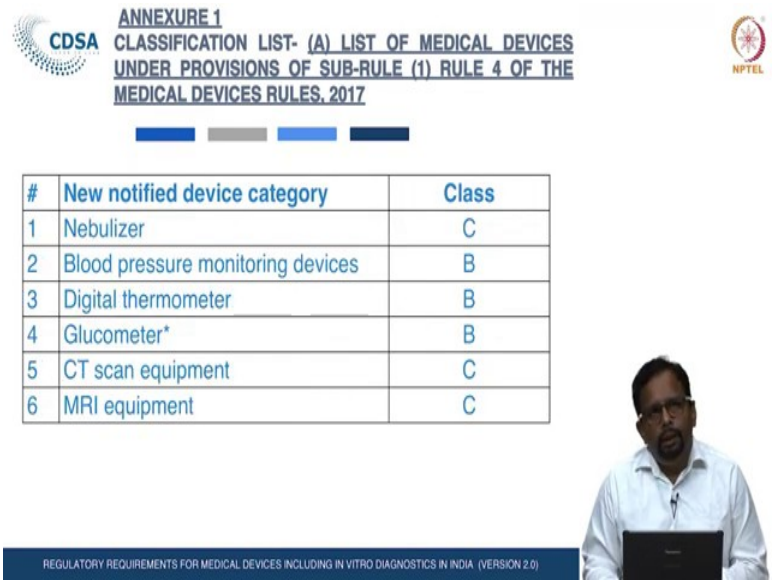

#	New notified device category	Class
1	Nebulizer	C
2	Blood pressure monitoring devices	B
3	Digital thermometer	B
4	Glucometer*	B
5	CT scan equipment	C
6	MRI equipment	C

The new medical devices which has been notified recently they have also classified based on the disk from class B to class C devices.

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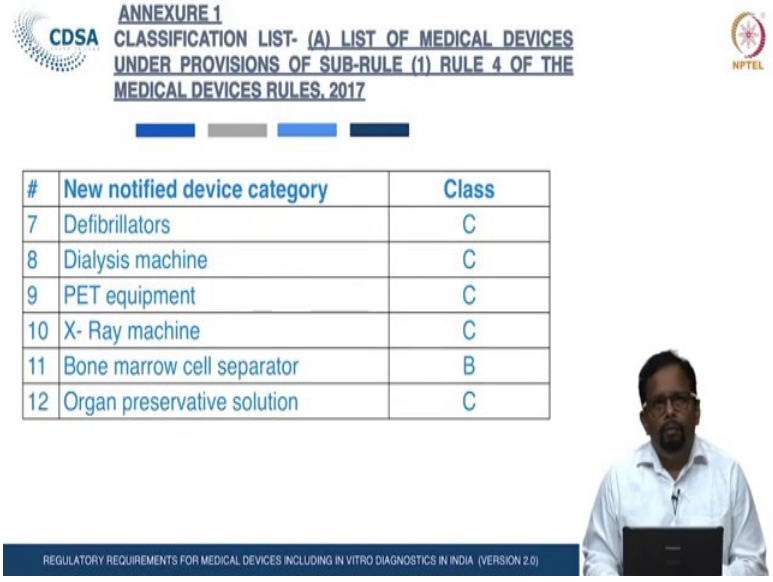

#	New notified device category	Class
7	Defibrillators	C
8	Dialysis machine	C
9	PET equipment	C
10	X- Ray machine	C
11	Bone marrow cell separator	B
12	Organ preservative solution	C

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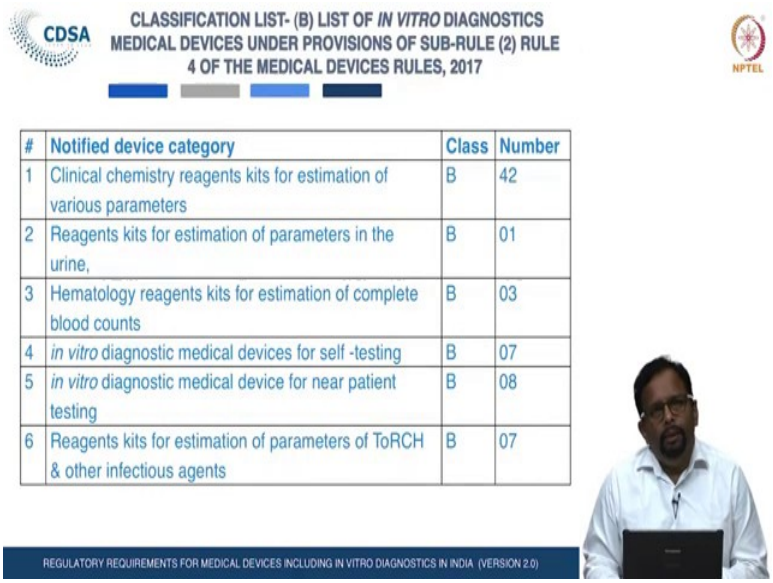

#	Notified device category	Class	Number
1	Clinical chemistry reagents kits for estimation of various parameters	B	42
2	Reagents kits for estimation of parameters in the urine,	B	01
3	Hematology reagents kits for estimation of complete blood counts	B	03
4	*in vitro* diagnostic medical devices for self -testing	B	07
5	*in vitro* diagnostic medical device for near patient testing	B	08
6	Reagents kits for estimation of parameters of ToRCH & other infectious agents	B	07

In vitro diagnostic kits the different types of the in vitro diagnostic kits.

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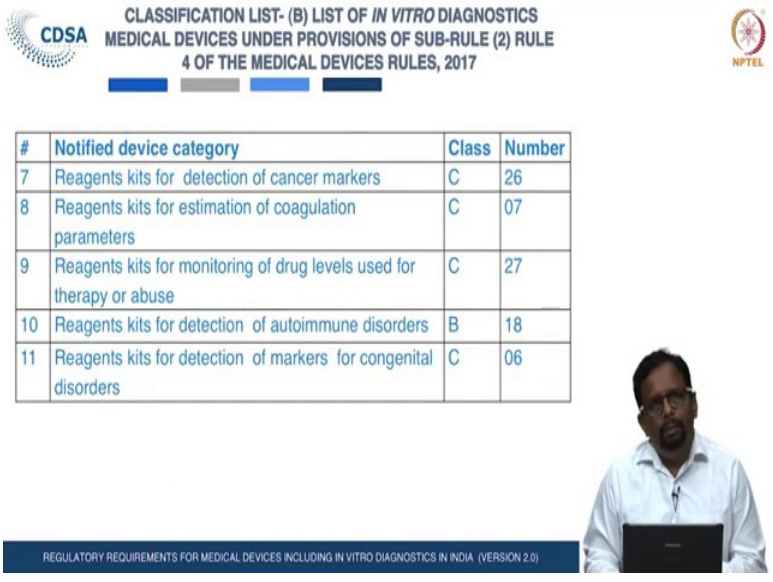

#	Notified device category	Class	Number
7	Reagents kits for detection of cancer markers	C	26
8	Reagents kits for estimation of coagulation parameters	C	07
9	Reagents kits for monitoring of drug levels used for therapy or abuse	C	27
10	Reagents kits for detection of autoimmune disorders	B	18
11	Reagents kits for detection of markers for congenital disorders	C	06

They have been classified and total 247 of in vitro diagnostic kits.

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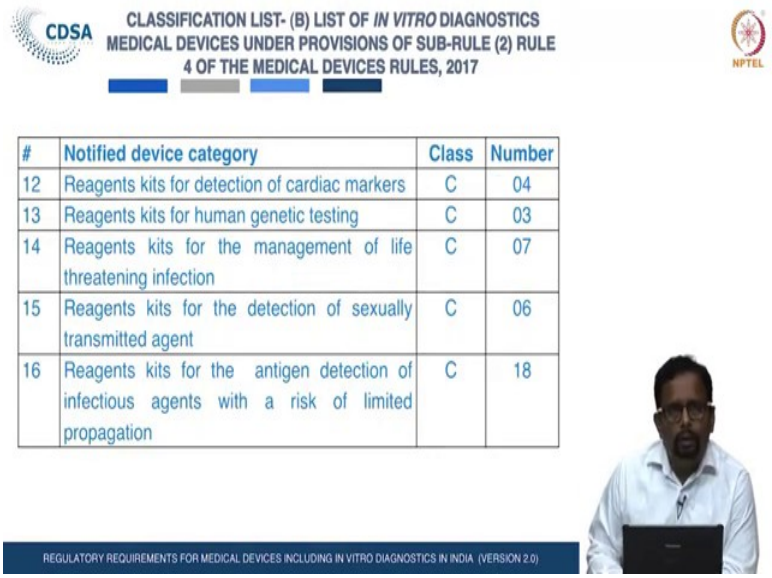

#	Notified device category	Class	Number
12	Reagents kits for detection of cardiac markers	C	04
13	Reagents kits for human genetic testing	C	03
14	Reagents kits for the management of life threatening infection	C	07
15	Reagents kits for the detection of sexually transmitted agent	C	06
16	Reagents kits for the antigen detection of infectious agents with a risk of limited propagation	C	18

Based on the, based on their risk classification.

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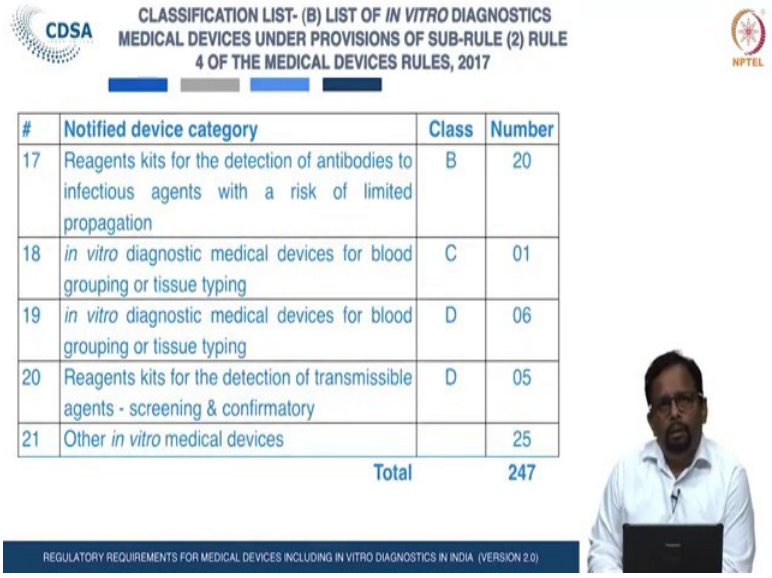

#	Notified device category	Class	Number
17	Reagents kits for the detection of antibodies to infectious agents with a risk of limited propagation	B	20
18	*in vitro* diagnostic medical devices for blood grouping or tissue typing	C	01
19	*in vitro* diagnostic medical devices for blood grouping or tissue 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

They have classified and published in the classification list that is published by the central licensing authority, Drugs Controller General India has published this classification list this is dynamic list as already explained.

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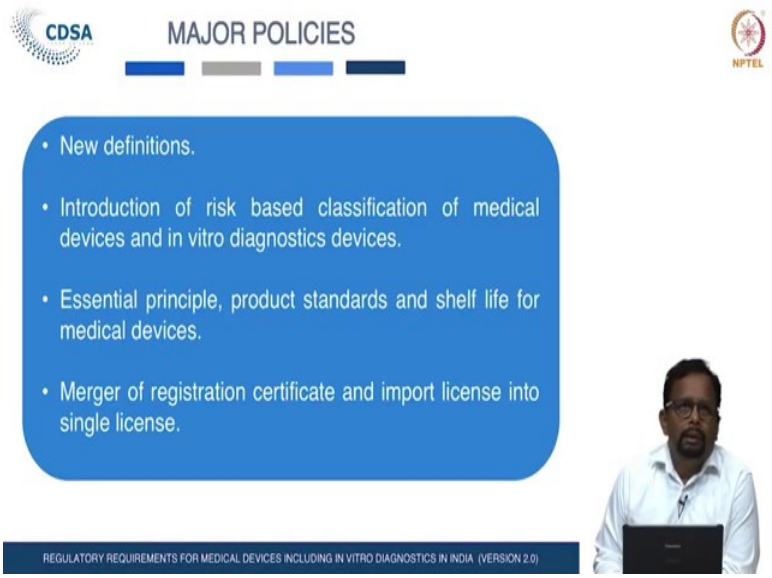

And, from time to time this medically classified medical devices will be reclassified.

the key changes in the Medical Device Rule 2017. What are the changes have been incorporated, which was not earlier in the drugs and cosmetic rules 1945.

The definitions that, new definitions of the medical devices and in vitro diagnostic kits has been incorporated in this Medical Device Rule 2017, which was not earlier in the Drugs and Cosmetic Rule 1945. Introduction of the risk based classification of the medical devices and in vitro diagnostic kits, the earlier drugs and cosmetic rules does not have this criteria of the classification of the medical devices in vitro diagnostic kits.

Essential principles productive standards shelf-type of the medical devices, which is not clearly mentioned in the Drugs and Cosmetic Rules 1945 for the medical devices or in vitro diagnostic kits. This standards and shelf-life of the medical devices has been clearly specified in the medical device rule 2017.

Merger of the registration certificate and import license into the single license in the Medical Device Rule 2017 only import license is required to be obtained by the importer. However, in the Drugs and Cosmetic Rules 1945, first they have to registered with the center licensing authority, after registration they again need to obtain the import license, then they will import the medical devices or in vitro diagnostic kits for marketing into the country. So, in the medical investment 2017 only the import license is there.

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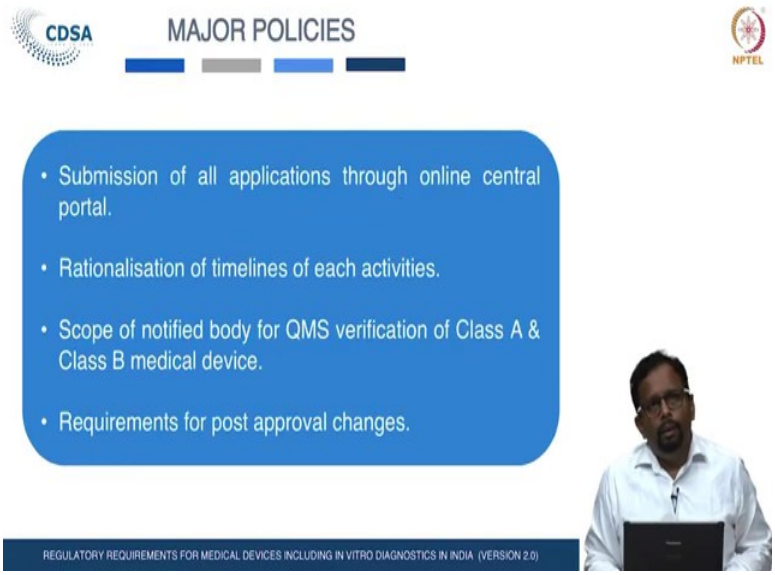

Submission of all the application through online in the Drugs and Cosmetic Rule1945 for import it is there, but for manufacture of clinical investigation the provision was not there. The timeline for each activity of import license activities of grant of the manufacturing license, activities for inspection of the manufacturing site. The timelines for each activity has been clearly prescribed in the Medical Device Rule 2017.

However, in Drugs and Cosmetic Rules 1945 this was not there. The scope of the notified body for the QMS verification of class A and class B devices the concept of the notify body is the new is new provision that is not in the earlier rules. The requirement of the post approval changes that is clearly defined in the Medical Device Rule 2017, in the earlier rule, it is not there.

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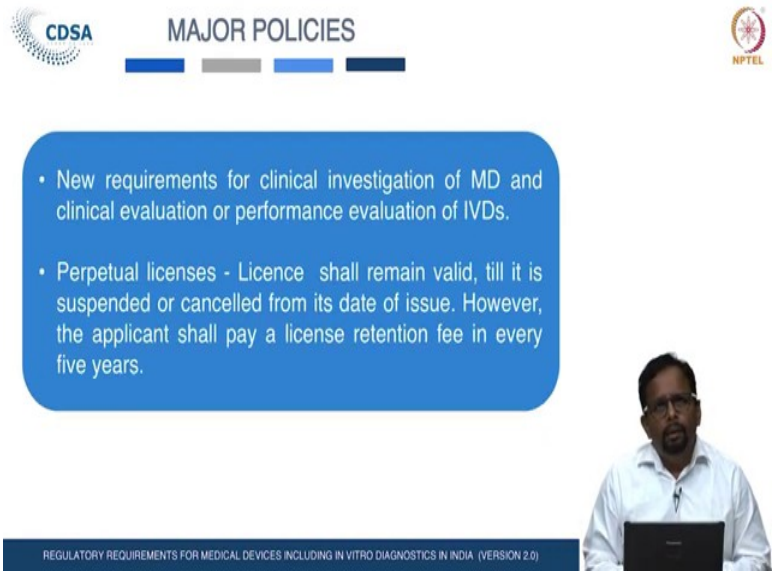

The need requirement for clinical investigation of the investigation of medical devices and clinical performance of the new in vitro diagnostic medical devices has been prescribed in these rules. However, it is not earlier in the earlier rule only the clinical trial is there provision for the clinical trial is there which is not actually applicable for the medical devices and in vitro diagnostics. Perpetual license in the provision for grant of license in perpetuity has been given in the Medical Device Rule 2017.

However, in the earlier rule the license is granted till the specific time period like for manufacturing the validity of the license was 5 years and for the import the validity of the import licence was 3 years from the date of issue. However, in the Medical Device Rule whatever the license is to be issued that license is issued in perpetuityprovided the manufacturer or the importer has to submit the requisite fees at a interval of every 5 years from the expiry of their license, their license will be valid till it is suspended cancelled or withdrawn by the licensee.

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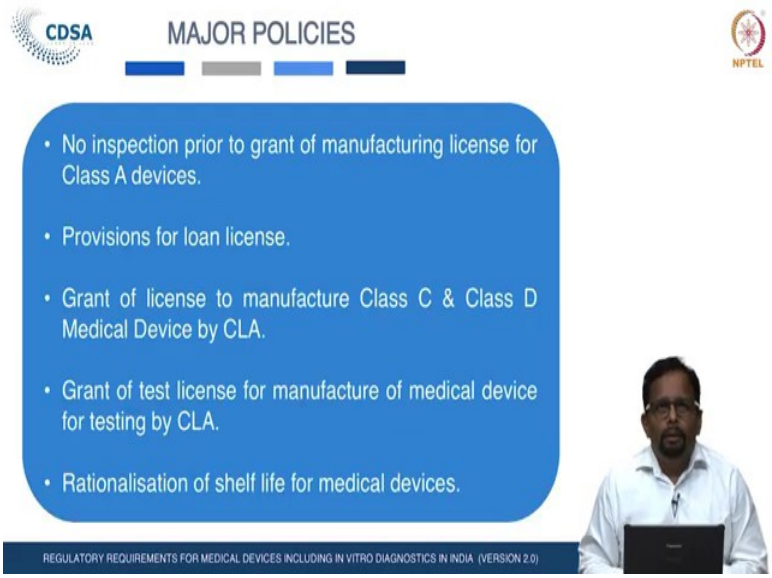

For class a medical devices prior inspection is not required as per the Medical Device Rule 2017. The provision of the loan license, which is not earlier in the drugs and cosmetic rule 1945 or medical devices only the grant of manufacture license is there, but in the Medical Device Rule 2017 these provision of the loan license is there. The grant of license to manufacture class C and class D devices by the central licensing authority, that is the new provisions.

However, in the earlier rule the license is granted both from the state authority as well as the central licensing authority, in dual licensing system provision was there. Now, in the Medical Device Rule the responsibility lies only with the central licensing authority, the grant of the test license for manufacture of medical devices for the purpose of testing or analysis, that is granted by the central licensing authority. However, in the earlier law it is granted by the state licensing authority.

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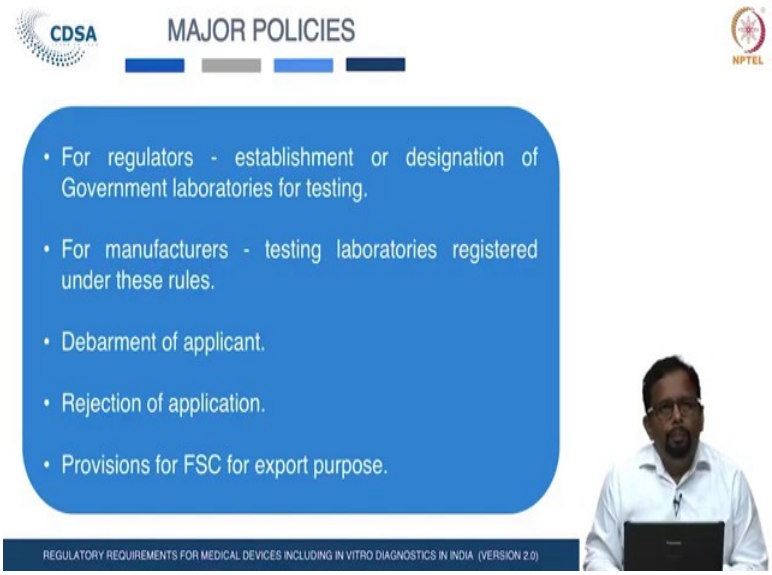

The provision for debarment of the applicant, the provision for rejection of the applications, that provision has been made which were not in the earlier law. In case of any fake or fabricated document submitted by the applicant the provision for debarment of the applicant, and also the rejection of their application has been given in the medical device rule.

However, in the earlier law it is not there. The provision for grant of resale certificate for export of the medical devices is included in the Medical Device Rule 2017. However, in the earlier rule it is not there, the provision for testing laboratory registered under this rule for the manufacturers has been given.The private medical device testing centers, who have registered with this inter licensing authority, shall be carried out test and analysis of the medical devices or in vitro diagnostic kits.

On behalf of the manufacturer .this new provision has been incorporated into Medical Device Rule 2017. The establishment or designation of the government laboratory for testing of medical devices and in vitro diagnostic kits, that provisions have been made. However, this provision was not in the earlier law. So, this is all about the Medical Device Rule 2017 and in summary.

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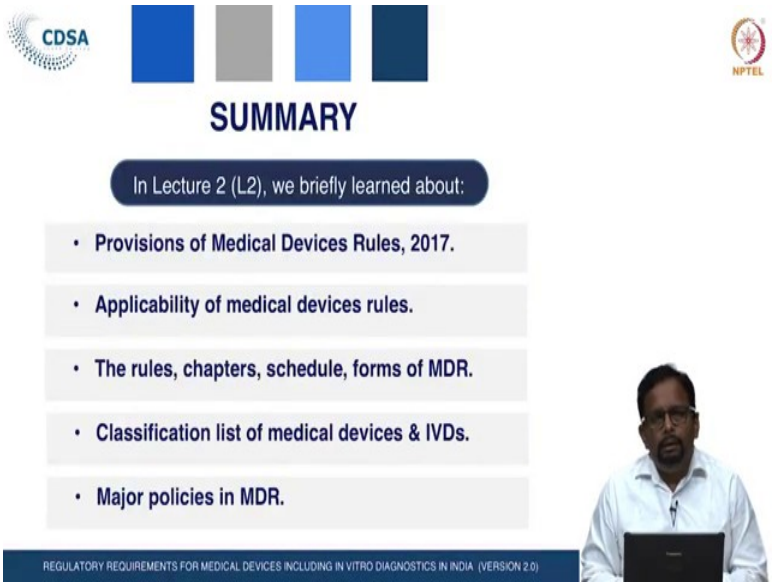

We have covered in this presentation what are the different provisions of the Medical Device Rule 2017. Applicability of the Medical Device Rule, the various rules chapters schedules, forms of the medical devices, classification list of the medical devices in vitro diagnostics, we have covered in this lecture, what are the new policies the key changes in the Medical Device Rule we have discussed.

And, now we have brief idea about the classifications, manufacture, import, clinical investigation of the medical devices. All those details requirement for all this activity, we will discuss in the subsequent lectures , but in this lecture we have aware what are the provisions made into Medical Device Rule 2017, for regulation of medical devices and in vitro diagnostic kits. For details you can go in the CDSCO website and you will have detailed information about the Medical Device Rule 2017, you can consult the website of the CDSCO.

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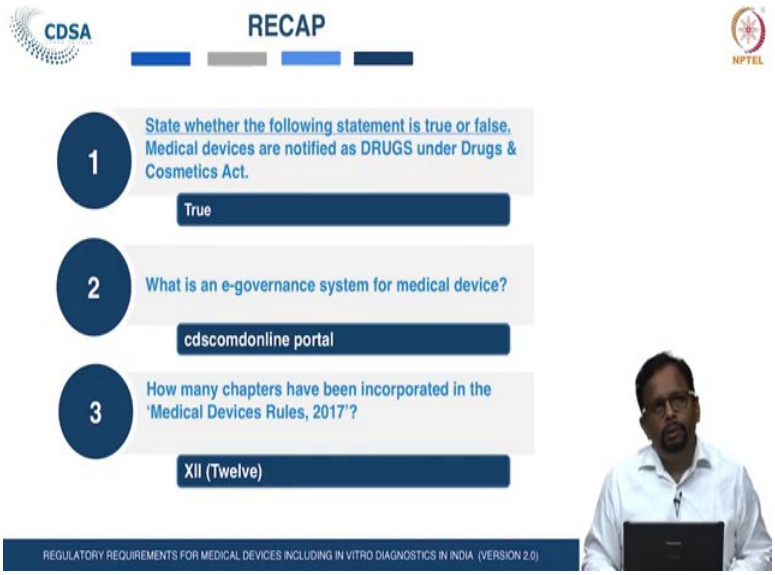

Now, let us have some question answer session, whatever we have discussed just will have 1 or2 questions and you have to give the answer for that. Now, first question you state whether the following statement is true or false, that is the medical devices are notified as a drug under the definition under the provisions of Drugs and Cosmetic Act, this statement is true or false can you answer that question.

Yes, it is a true. Now, another question what is an e-governance system for the medical devices? Can anybody give answer for that yees it is a CDSCOMD online portal, which is the e governance system for the medical devices. Now, tell me how many chapters have been incorporated in the Medical Device Rule, 2017? Guess anybody yes total 12 chapters are there, we have discussed in this lectures. So, this is all about the Medical Device Rule 2017.

Thank you very much.