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

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Lecture – L3B
Labelling Requirement Of Medical Devices & In Vitro Diagnostics

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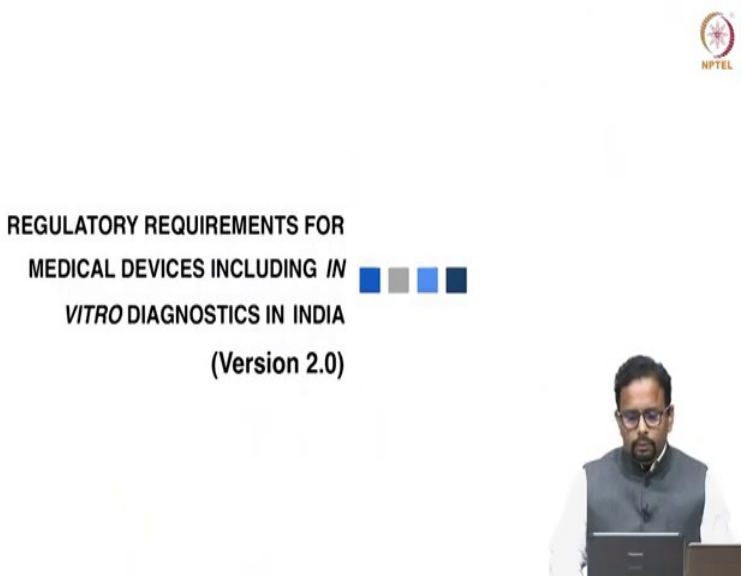

Dear friends, welcome to this new lectures that is Labeling requirement of the Medical Devices and In Vitro Diagnostics. In the earlier lectures we have covered what is the medical devices, what is the regulatory requirement for the medical devices, what is the classification, what provision for the classification of the medical devices?

How the classification of the medical devices is carried out, which devices are regulated under the Medical Device Rule 2017. Now, in this lecture we will discuss the details of the labeling provisions of the medical devices and in vitro diagnostics, what are the labelling requirement prescribed in the Medical Device Rule 2017.

We will cover in this lecture, the objective of this lecture is to learn or to know what is the label, what is the label of the medical devices, what is the labeling of the medical devices, what provisions have been given in the Medical Device Rule for labeling of

medical devices and in vitro diagnostics and, we will review some key labeling provisions for different types of the medical devices and in vitro diagnostic kits.

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In this lecture we will discuss overview of the labeling requirement, definitions, definitions of the labels, labeling, regulations and labeling requirement for the medical devices and in vitro diagnostics. Also the concept of Unique Device Identification Number (UDIN) and the shelf life of the medical devices, we will discuss in this lectures.

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Now, it has been seen that the many hazards associated with the medical devices do not arise from the design or manufacturing issue of the medical devices, but rather from the manner of which the device are used that is the main cause of hazard in the human being most of the time it has been observed.

What I mean to say the devices, if it is not properly labeled as to specific operation instruction and if it is a high risk devices, it may cause hazard to the patient. So, labeling is very important for medical devices in in-vitro diagnostics.

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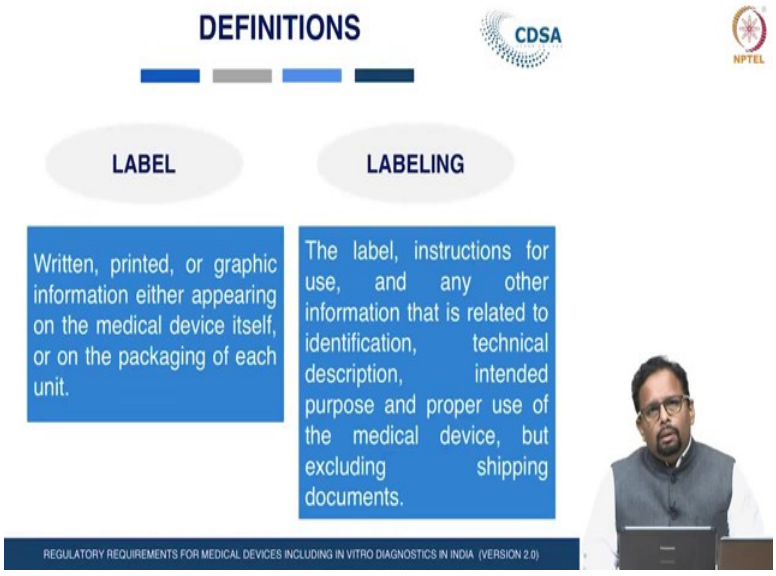

Now, what is label? Though in the Medical Device Rule 2017 the label has not been defined, but internationally the labels are the information, written information, printed informations or graphic information either appearing on the medical devices itself or on the packaging of each unit of the medical devices or in vitro diagnostics. This is the definition of the label as per the international regulations.

and the labeling if you see the labeling the labeling includes the label, label of the devices, instruction for use, any other information that is related to identification of the medical devices, the technical description of the medical devices, intended purpose and proper use of the medical devices. All those information related to the labeling of the medical devices and in-vitro diagnostics.

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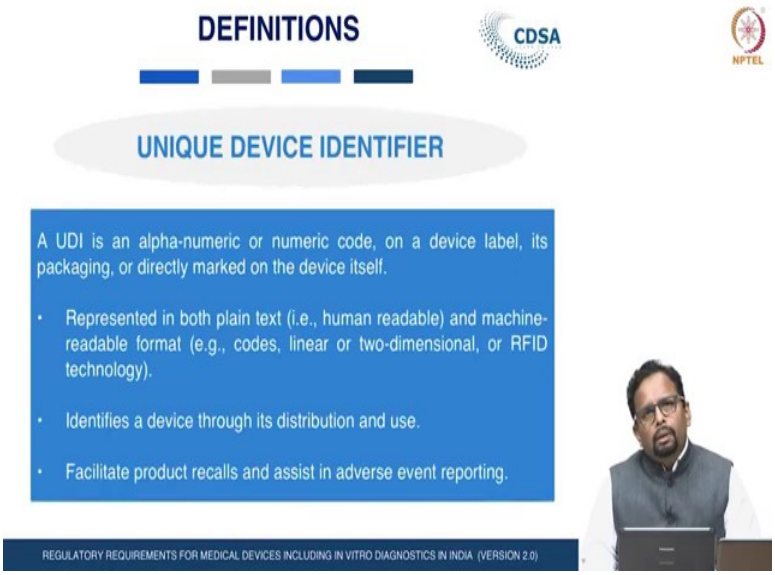

Now, in the labeling provisions the concept of unique identification, unique device identification number (UDIN) is there that provision have already been made in the Medical Device Rule 2017 though it is not yet implemented. Because, 5 years time has been given to the stakeholders for implementation of this UDI system, but it has the provision have already been made in the Medical Device Rule 2017. What is the unique device identifier?.

It is a alpha numeric or numeric code on a device label, its packaging or directly marked on the device itself which represent both in a plain text that is human readable form and machine readable format like codes, linears, two dimensional or RFID technology. These UDI identifies a device through the distribution and uses.

This UDI system facilitate the product recalls and assist in the adverse event reporting. This is important tool of identify the device from the market from its distribution and use. So, the system has already been incorporated in the Medical Device Rule 2017.

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Now, come to the requirement of the labelling, regulation of the labelling. Under the Medical Device Rule 2017 the Central Licensing Authority(CLA) or the State Licensing Authority(SLA) has the statutory authority to regulate labeling of all the medical devices and in-vitro diagnostics under the provisions of Drugs and Cosmetic Act and Medical Device Rule 2017.

Now, we had the provision for labeling has been prescribed. In the previous lecture we have discussed that chapter 6 of the Medical Device Rule 2017, prescribed the labeling requirement of the medical devices and in vitro diagnostics.

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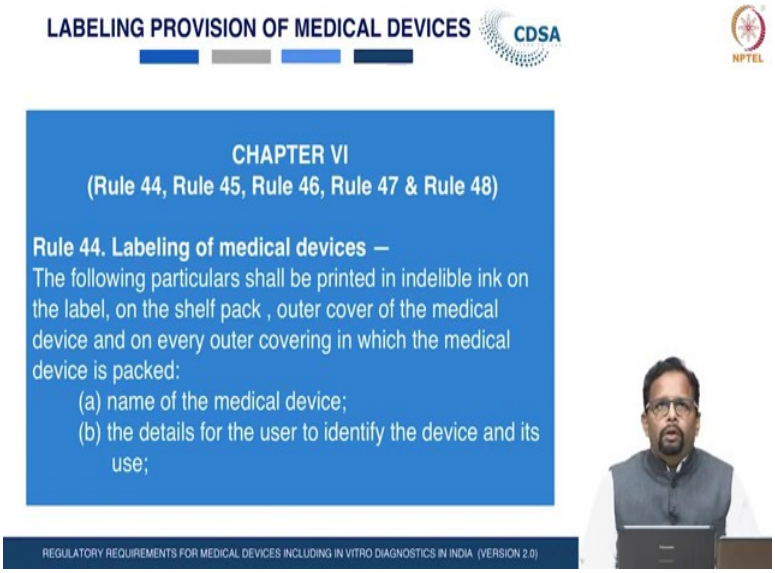

And rule 44 to rule 48 relates to the labeling provisions as well as the shelf-life of the medical devices. We will discuss what are the detail information, detail particulars to be printed on the label of the medical devices which is imported or manufactured for sale into the country or which is for the purpose of test our analysis or which is for the purpose of free distribution by the registered medical practitioners.

So, what provisions and what information that need to be mentioned on the label that provision has been clearly described in the chapter 6 of the Medical Device Rule 2017. Rule 44 of this chapter, this Medical Device Rules give the labeling requirement; the labeling of the medical devices what particular has to be printed on the label. The information or the particular that has to be printed in indelible ink on the label on the shelf pack or on the outer cover of the medical devices.

And, on every outer covering in which the medical device is packed, the information that is the name of the medical devices has to be clearly mentioned on the label of their particular devices. The detailed information for users to identify the device and its use, if it is applicable.

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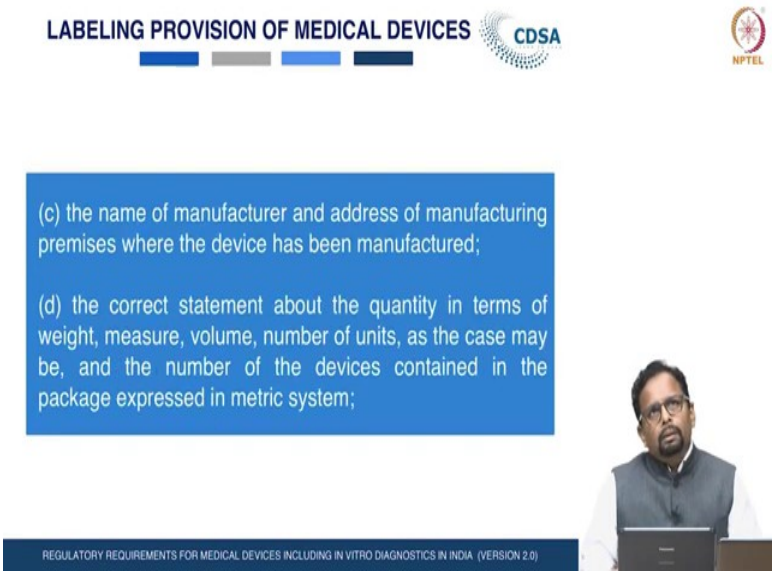

This information has to be mentioned on the label of the medical devices, the name of the manufacturers, the address of the manufacturer premises where the device has to be manufactured. The information related to the correct statement about the net quantity in terms of weight, measures, volume, number of units wherever applicable and the number of devices contained in the packages expressed in the matrix system.

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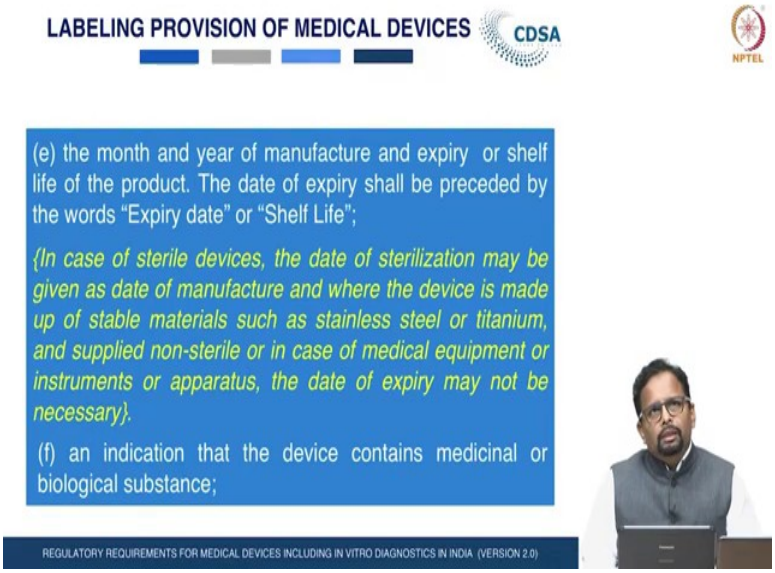

Information with respect to the shelf life the month and the year of the manufacture, the expiry should be mentioned on the label of the medical devices or the shelf life of the

product should be mentioned on the label of the devices. The date of expiry shall be preceded by the words expiry date or the shelf life should be mentioned on the level of the devices. If required the indication that the device content medicinal or the biological substance that information has to be provided in the label of the product.

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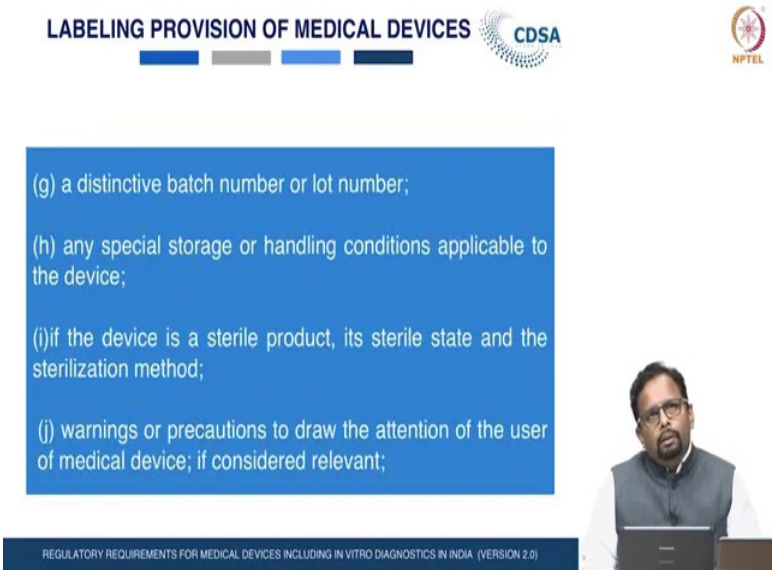

The batch number or lot number of the medical devices or in vitro diagnostic should be there on the label of the devices. The storage condition is especially storage conditions or handling condition, if applicable it has to be mentioned on the label of the devices. If the device is supplied as this style product, its trial state and the sterilization method has to be clearly mentioned on the level of the medical devices.

If the medical devices is imported as a non-style medical devices in such cases shelf life or the expiry date is not required. Also for the equipments, instruments which is non-style the expiry date or shelf life is not mandatory for such type of medical devices or equipments. The warnings or precautions to draw the attention of the users on the medical devices, if the devices is such that information has to be clearly provided on the level of the medical devices.

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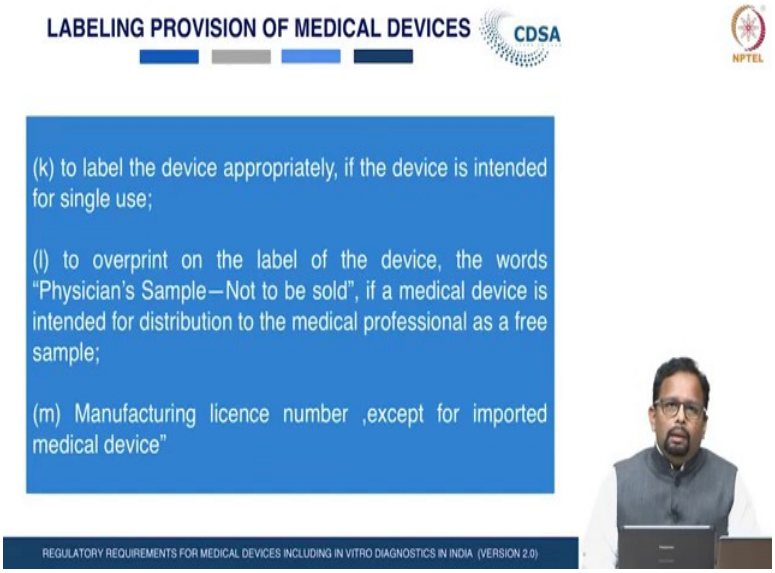

If the devices is intended for the single use, it has to be clearly mentioned. There is International recognized symbols applicable for the medical devices, the standard is there that ISO 15223 that recognized symbols should be provided if possible. If the devices or the in vitro diagnostic devices are intended for distribution to the medical professional as a free sample, it should be clearly mentioned on the label that it is a physician simple not to be sold. Except for the imported devices, the manufacturing license number should be mentioned on the label of the medical devices or in vitro diagnostics.

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For imported medical devices or in vitro diagnostic kits, the information by way of the sticking where the details have not already printed on the label, the name of the importers, import license number, name and address of the actual manufacturers and date of the manufacture that information has to be mentioned on the label by way of the stickering.

And, for which the necessary approval is required to be obtained from the licensing authority. As already informed you the symbols to be used with the medical devices labels, labelings as per the ISO 15223 part 1 2017 the general requirement.

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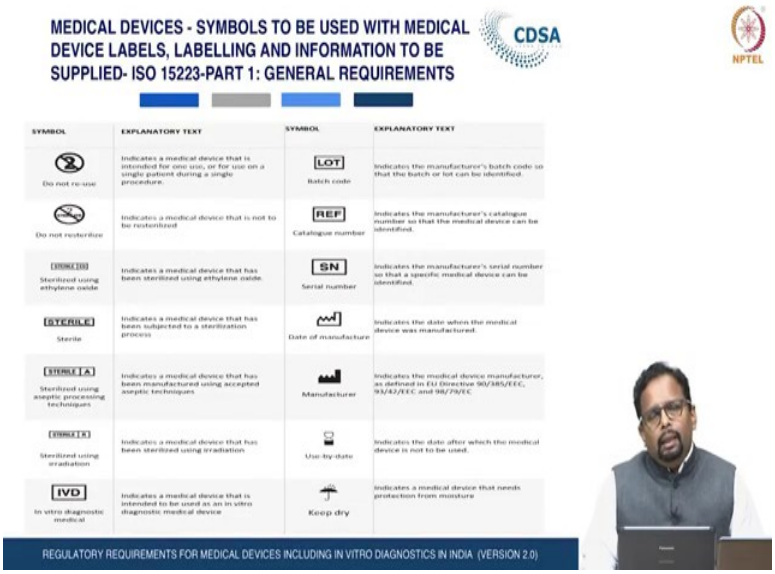

The manufacturers can also use these symbols on the labels of the medical devices. In case of the small size of the medical devices where the detailed information cannot be printed, the certain information necessary for the product information, product identification and safety shall be labeled on such devices. These are the mandatory requirement, labeling requirement for import, manufacture and marketing of the medical devices into the country.

This is the sample label, the information which we have discussed this is this specimen lable of the medical devices. The label should have the information as shown in the presentations, the name of the medical devices, sizes, lot number, catalog number.

If it is a single use symbol can be used, used by that symbol also can be used for such informations if it has to be keep in the dry places either a symbol or the statement should be provided on the label of the product, quantity, name of the manufacturer address. And, this label also include the UDI system, UDI identification number though it is not mandatory as far as MDR 2017 is concerned.

So, these are the minimum mandated requirement that has to be mentioned on the label of the devices which has to be imported, manufactured for sale and distribution in to the country. If the information as provided in the Medical Device Rule 2017 under chapter 6 has not been mentioned on the label, there is a violation and the necessary action will be taken in such cases by the licensing authority.

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The rule 45 of the Medical Device Rule 2017 which has the provision for exemptions of the labeling requirement for export of the medical devices. The devices, which is meant for export shall meet the specific requirement of law of the country to which the device is to be exported. However, the certain minimum information that has to be mentioned on the label of such devices should be there.

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The information is like name of the device they should be mentioned, batch number or lot number or serial number, date of expiry if any, name and address of the actual premises where the device has been manufactured, license number. And, internationally recognized symbols can be used in addition to the specific requirement of the law of the country to which the devices is to be exported, Unique Device Identification(UDI) of the medical devices as already discussed.

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This will be effective from January 2020, five years time has been given to the stakeholders for implementation of this provisions this UDI number. In this UDI number composed of device identifiers and the production identifiers. The device identifier means the Global Trade Item Number(GTIN) which is the fixed portion of the UDI systems wherein, the specific model serial number and name of the laborer has to be given.

This is the fixed portion of the UDI system. The production identifier which is a variables wherein the serial number, lot number, batch number, date of expiry, date of manufacturer all those number will be given. But, the detailed implementation of the system will be from January 2022, you can see that what information will be captured when that UDI system will be applicable, the label along with other information should have the UDI code also wherein the device identifier and the production identifier are there.

Though, this system will be implemented after January 2022, the shelf-life of the medical devices that provision has been made in the 6th chapter of the Medical Device Rule 2017.

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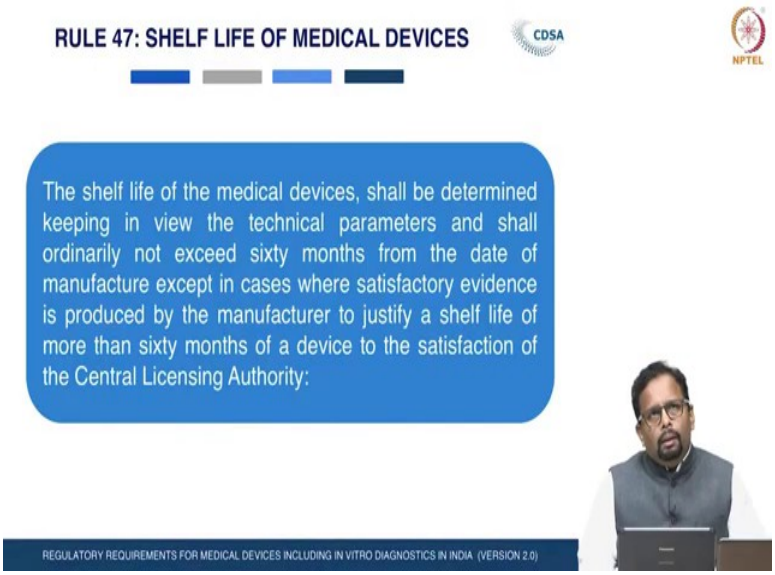

Under these rules the maximum shelf life will be given by the licensing authority to the manufacturer for the particular devices will be sixty month, 5 years time based on the document provided to the Central Licensing Authority(CLA) or the State Licensing

Authority(SLA). The maximum sixty month a time of the shelf life is provided in the Medical Device Rule 2017.

However, if the devices have if the manufacturer claimed their devices more than the sixty month of the shelf life, they have to submit the satisfactory evidence to justify the shelf life. And, if it is satisfied to the Central Licensing Authority(CLA) or the State Licensing Authority(SLA), the shelf life beyond the sixty month will also be considered and given for the specific medical devices.

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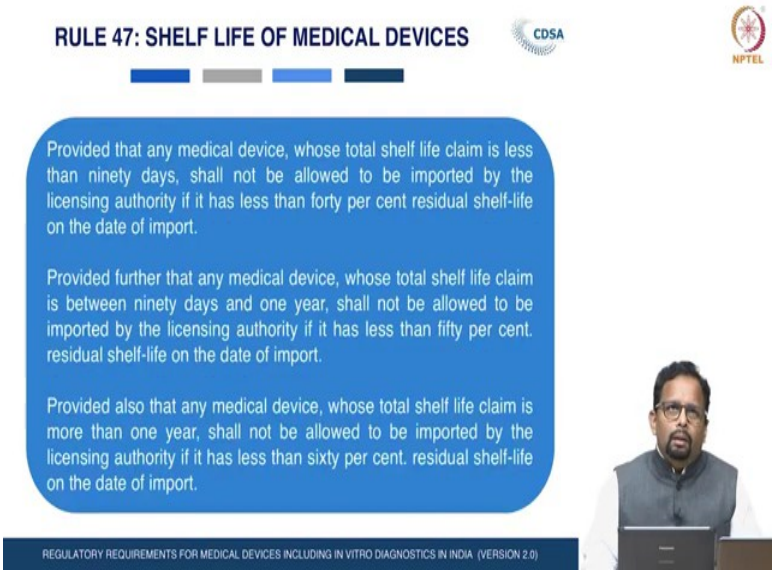

Also, in under this rules the provisions for import of the medical devices, the provision of residual shelf life of imported devices has been given. If the medical devices which is imported into the country have ninety days or less than ninety days of shelf life. And, if its residual shelf life is more than forty percent that can be allowed to be imported into the country.

If the shelf life claimed shelf life of the medical devices or in vitro diagnostic kits is between ninety days to one year, then the residual shelf life of the date of import of that particular devices should not be less than fifty percent. Then it if it is more than fifty percent, it can be allowed or imported to the country for sale and distribution.

If the residual shelf life of the product having shelf life of one year or more than one year, more than one year then the more than sixty percent residual shelf life should be

there on the date of import of the particular devices. Then it will be allowed to be sold into the country that provision has been given in the Medical Device Rule 2017.

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Rule 48 wherein the provisions for the labeling provisions for the medical devices or the new in vitro diagnostic medical devices for the purpose of test or evolution or clinical investigation has been given. In such devices the label should be at the name of the product, code number, batch number or serial number wherever is applicable.

Date of manufacturing of the devices, name and address of the manufacturers and the purpose for which it is manufactured. Only this information has to be mentioned on the devices which we meant for the purpose of test and analysis or the clinical investigation purpose. So, these are the labeling requirement which has to be fulfilled by the manufacturer or the importer on the product being marketed in the country.

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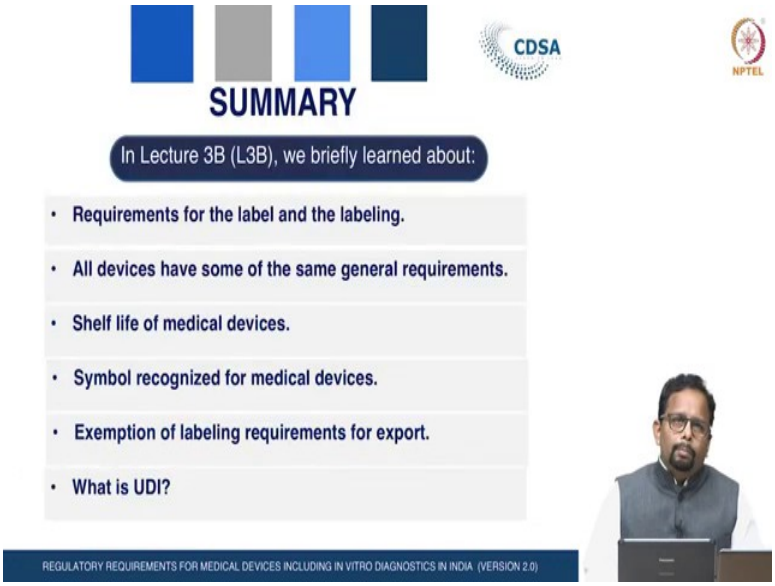

So, we have discussed, we have now understand what information should be mentioned on the label of the medical devices and in vitro diagnostics. What are the general requirement, what is the shelf life of the medical devices whether the symbol is recognized for the medical devices can be used in the label of the medical devices, we have discussed that.

And, what is the UDI system, when it will be applicable. This information we have covered in this lectures and other topic we will discuss in the forthcoming lectures.

Thank you very much.