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Labeling Requirement for Dental Devices as Per CDSCO Guidelines

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Abstract: *The labelling of medical and dental devices plays a vital role in ensuring their safe use, effective performance, and regulatory compliance. In India, the Central Drugs Standard Control Organization (CDSCO), under the Medical Device Rules, 2017, regulates the labelling requirements for all categories of medical and dental devices. This study focuses on understanding the mandatory labelling components for dental devices as specified by CDSCO, such as device name, manufacturing details, batch or serial number, manufacturing and expiry dates, storage conditions, and intended use. . It also emphasizes the importance of including information related to safety warnings, precautions, and directions for use. The objective of this report is to analyse how these labelling standards ensure product traceability, patient safety, and regulatory compliance. Proper labelling not only helps healthcare professionals in correct device usage but also supports post-market surveillance and quality assurance. This paper highlights the significance of following CDSCO's labelling norms for maintaining uniformity and ensuring that only safe and effective dental devices are available in the Indian market.*

Keywords: Dental devices, CDSCO, labelling requirements, Medical Device Rules 2017, regulatory compliance, patient safety

I. INTRODUCTION

Medical devices are instruments or apparatus used for diagnosis, treatment, or prevention of diseases. Dental devices are a specific category of medical devices used for oral health care, including instruments, materials, and equipment. Dental devices are a specialised category of medical devices designed for the diagnosis, prevention, monitoring, treatment, and alleviation of oral and dental disorders.

Scope

• Covers a wide range of products, from simple consumables to advanced machinery.
• Includes devices that come into direct contact with oral tissues or are indirectly used in oral care.
• Can be single-use (disposable) or reusable.

Examples of dental devices:

Dental mirrors, Periodontal probes, Dental headpieces and drills, Mouthguards , Sealants applicators, Filling materials.

1.1 CLASSIFICATION OF DENTAL DEVICE IN INDIA

Under the medical device rules, 2017, dental devices in India are categorised by risk level.

Risk Level	Class	Examples
Class A	Low risk	Mouth Mirrors, Cotton Holders
Class B	Low-moderate risk	Dental Handpieces, Sunction Tips
Class C	Moderate-high risk	Dental X-ray units, Intraoral Scanners
Class D	High risk	Heart Valves, Implantable Defibrillators

Risk Level Class Examples

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II. CDSCO (INDIA)

Aim

To study and understand the labelling requirements for dental devices as per the Central Drugs Standard Control Organization (CDSCO) guidelines, and to ensure that all necessary information related to safety, identification, and regulatory compliance is appropriately displayed on the labels of dental devices.

Objectives

1. To understand the CDSCO guidelines related to the labelling of dental devices.
2. To identify the essential information that must appear on dental device labels.
3. To study the regulatory requirements ensuring safety and quality compliance.
4. To highlight the importance of accurate and clear labelling for user safety and regulatory approval.
5. To compare labelling elements of dental devices with other medical devices.
6. To evaluate the role of proper labelling in preventing misuse and ensuring traceability of dental devices.

3.1 Indian Regulatory Framework

There are two main sets of regulations that medical device companies must comply with for labelling their products in India: -

A. Legal Metrology Act, 2009

The Legal Metrology Act 2009, ensures standardization in weights and measures and governs the labelling requirements for packaged commodities. Medical devices, when sold as packaged commodities, must carry essential declaration such as the manufacturer's details, product quantity, pricing, and other consumer-relevant information. This ensures transparency, consumer protection, and fair-trade practices.

B. Medical Devices Rules, 2017

Formulated under the Drugs and Cosmetics Act, 1940, these rules are dedicated specifically to medical devices. The medical devices Rules, 2017, detail requirements regarding classification, registration, quality management, and especially labelling. These rules aim to ensure that medical devices available in the Indian market meet necessary safety and performance standards.

3.2 Contents of Medical/Dental Devices Labelling

The labelling of medical device in India must include detailed and standardized information that helps in identifying, handling, storing, and using the device appropriately. These labelling contents are grouped into three major categories: -

3.2.1 General

A. Requirements Identification and Manufacturer Information: - Each label must clearly state the name or trade name of the device along with the name and address of the manufacturer. For imported devices, the name and address of the authorized representative or importer in India must also be included.

B. Device Details:

Labels must provide enough information for users to understand what the device is and what it contains. This includes the common name of the device and a description that can help distinguish it from other similar products.

C. Tracking information:

Medical devices must carry batch numbers, lot numbers, or serial numbers. This information is vital for traceability and is used when recalls or quality control actions are necessary. It ensures that any faulty or compromised device can be quickly identified and addressed.

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D. Usage Timeline and Manufacturing Date

Labels must clearly state the expiration date or the period until which the device can be used safely. This date should be expressed as a combination of the month and year.

E. Storage and Handling Instructions

Proper storage and handling are important to maintain a device's efficacy and safely. Labels must specify any conditions that need to be maintained, such as temperature range, humidity, or protection from light. This information helps uses store the product correctly until use.

F. Safety Information

Each label must include safety- related details such as warnings, potential side effects, and precautions. These elements are vital to inform the user about any risk factors or necessary protective measures while using the device.

G. Operational Assurance

To ensure correct installation and operation, labels must include essential maintenance instruction. This may involve component replacement or calibration needs to ensure that the device performs as intended throughout its lifecycles.

H. Preparation requirements

For certain devices, specific pre-use preparations may be required. For example, if the device needs sterilization or calibration before use, this information must be clearly stated on the label.

3.2.2 Applications

A. Sterilization instructions: - If the device is supplied sterile, it must include handling instructions, especially what to do if the sterile packaging is damaged. Methods for re- sterilization should be included, if applicable.

B. Usage Restrictions: - If a device is for single use only, it must be prominently mentioned on the label. Similarly, custom-made devices, devices for clinical investigation, or those intended only for demonstrations must carry appropriate labelling statements.

C. Compatibility and Interference: - Labels must indicate compatibility with other devices and highlights any potential interference risks. For Examples: - Electromagnetic interference risk should be noted if the device is used near MRI machines or other electronic devices.

D. Reusability: - Reusable devices should come with detailed cleaning, disinfection, and sterilization procedures. The label must also mention how many time the devices can be reused safely.

F. Radiation Emission: - If the device emits any kind of radiation, the nature, type, intensity, and distribution of the radiation must be clearly described on the label. This helps users take necessary precautions.

3.2.2 Instructions

A. Device Performance: - Monitoring Instructions must explain how to monitor changes in device performance. If any sign indicates that the device is malfunctioning, users should know what action to take.

B. Environmental Exposure: - Labels should include precautions against magnetic fields, electrical interferences, and other environmental conditions that may affect the device's functionality.

C. Medicinal Interactions: - If the device administers any medicinal substance, the label includes information about the medicine, its quantity, and any usage restrictions.

D. Disposal Risks: - Proper disposal is essential to avoid harm to health or the environment labels must include guidelines on how to safely dispose of the device after use.

E. Incorporated Substances: - If the device includes any medicinal substances or other materials, they must be listed along with any usage limitations.

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F. Accuracy and Usage Requirements: - Devices with measuring functions must specify their accuracy limits. Moreover, labels should mention if any special training, qualifications, or facilities are required for correct usage.

IV.0 ADDITIONAL CDSCO GUIDELINES FROM MEDICAL/ DENTAL DEVICES RULES, 2017

The following are some additional CDSCO guidelines from Medical Devices Rules, 2017:

1. Indelible Ink: - Requirement all labelling information must be printed using indelible ink to prevent tampering and ensure durability throughout the device's shelf life.
2. Shelf Life and Expiry: - Medical devices must display both the date of manufacture and the date of expiry. For devices that are sterile, the date of sterilization may serve as the manufacturing date. In certain cases, like stainless steel or titanium non-sterile devices, expiry dates may not be required.
3. Batch/Lot Numbers: - Each device must carry a unique batch or lot number to maintain accountability and support any future corrective actions.
4. Sterile State and Sterilization Method: - If the device is sterile, the label must indicate its sterile state and specify the method of sterilization, whether it be EO gas, gamma radiation, or steam.
5. Warning and precautions: - All necessary warnings and precautions, especially those pertaining to safe usage, must be highlighted clearly on the label.
6. Single-Use Indication: - Devices that are meant for single use must be labelled with statements like "Single Use Only" or "Do Not Reuse."
7. Labelling of Physician Samples: - Medical devices provided as free samples must be labelled as "Physician's Sample-Not to be sold."
8. License information: - For domestic devices, the manufacturing license number must be mentioned. For imported device, the import license number, name and address of the importer, and the overseas manufacturing facility must be included.
9. Use of Symbols: - Internationally accepted symbols can replace text if they are universally understood by the intended users. This allows for multilingual accessibility.
10. Labelling for Small Devices: - In cases where the device is too small to carry all the required information, only essential information such as product name and batch number should be included on the device, with dull details on the outer package.
11. Export Labelling: - Devices intended for export must comply with the labelling requirements of the importing country. However, Indian regulations still require labelling of critical elements such as device name, manufacture details, lot/batch/serial number, expiry date, and license number.
12. UDI (Unique Device Identification): - Compliance As of January 1, 2022, all registered medical devices in India must carry a Unique Device Identifier (UDI). This includes a Device Identifier (DI) specific to the product and a Production Identifier (PI) that provides traceability.
13. Shelf-Life Restrictions: - In general, medicinal devices should not have a shelf life exceeding 60 months unless justified with evidence. Shorter shelf-life devices may have additional import requirements.
14. Labelling for Clinical Evaluation Devices: - For devices used in clinical investigation or performance evaluation, the label must include specific information like product name, batch/lot number, date of manufacture, expiry date, storage conditions, and manufacturer's details.

4.1 Labelling Requirements as Per the Legal Metrology Act, 2009: -

The following are some important labelling requirements as per Legal Metrology Act, 2009: -

1. Principal Display Panel: - All essential labelling details should appear on the principal display panel of the device packaging. This ensures users can quickly access necessary information.
2. Mandatory Information: - Labels must include the manufacturers, packer, or importer's name and address, product's common or generic name, net quantity, manufacturing date, packaging date, and retail price.
3. Font Size and Placement: - The size of the letters and numerals used in labelling should meet visibility standards to ensure readability. The font should be clear and legible.

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4. Consumer Contact Details: - All packages must include contact details such as the manufacturers address, telephone number, and email for consumer complaints or queries.
5. Prohibition on Stickers: - The use of stickers to modify labelling content is strictly prohibited, except in cases where the MRP is being reduced. Such stickers must not cover any mandatory declarations.
6. Handling Multi-Component Packages: - If the product contains multiple items sold together, either the outer package should contain complete labelling information, or the inner packages should carry it with a note on the main package.
7. Old Packaging Material: - Manufacturers are allowed to use outdated packaging materials if corrections as per the latest labelling rules are made. However, this is only allowed until a specified deadline.
8. Penalties for Non-Compliance: - Violations of labelling regulations may attract a penalty of INR 2,000 under the Legal Metrology rules. This emphasizes the importance of accurate and honest labelling practices.
9. Language: - As per the CDSCO + Legal Metrology require label in ENGLISH, but, as per the new update the local language preference is rising. You can consider the following points: -
• Labels must be in English.
• Additionally, regional languages may be used for better understanding by patients (especially for over-the- counter devices or home-use devices).
• IFUs (Instruction for Use) must also be in a user- comprehensible format.
10. Barcodes: - As per CDSCO guidance must be included for class C& D devices. Helps in recalls, adverse event reporting, and inventory management.
11. Import: - Before sale in India, CDSCO mandates additional declarations for importers. Imported medical/dental devices must have: -
• Importer name & address
• Manufacturing Country
• Import license number
• MRP with all-inclusive taxes
12. Device-Specific labelling Requirements: - Not all medical/dental devices are a like- different classes and types serve unique functions and pose different risks. Hence, labelling requirements vary depending on the device's intended use, risk class, and mode of application. Symbols: - Internationally recognized symbols like: -
• "Do Not Reuse" – for single-use items.
• "Sterilized Using…" symbol- to specify sterilization method.
• "Keep Dry"- if moisture can compromise sterility.

V. CDSCO LABELLING CHECKLIST FOR IMPORTED MEDICAL/DENTAL DEVICE

The CDSCO labelling checklist for imported devices is a mandatory regulatory requirement that guarantees that all imported medical devices entering India follow the safety, quality, and transparency standards as fixed by the CDSCO. This checklist plays a vital role in protecting public health by making sure that the medical device labels carry all necessary information needed for their complete use, traceability, and regulatory compliance even if you're importer, distributor, or foreign manufacturer supplying to India, following these labelling guidelines is important to avoid clearance delays, penalties, or product rejections at customs. Let's get into the CDSCO Labelling Checklist for Imported Devices to understand this from the core, including what needs to be displayed, who should apply, and how you can stay compliant. The CDSCO Labelling Checklist for Imported Devices is a set of mandatory requirements that define what information must be present on the label of all medical devices imported into India. These guidelines are framed under the Medical Device Rules, 2017, and are appropriate to all classes of devices. This checklist ensures that:
1. The instrument is traceable to its manufacturer or importer.
2. Accurate and clear information is available to end users and authorities.
3. Imported devices meet Indian regulatory norms before reaching the market.

5.1 The CDSCO labelling checklist for imported medical devices is necessary because it makes sure: -

1. Patient Safety – Correct labels help medical professionals and users perceive product usage, expiry, and risk factors.

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2. Regulatory Compliance – Labels should follow Indian laws to avoid rejection or customs delays.
3. Transparency – Details such as labels, country of origin, MRP, and manufacturing information have to be disclosed.
4. Custom Clearance – Non-compliant labelling can result in seizure of goods at ports.
5. Avoid Legal Issues – CDSCO can impose penalties or take legal action in case of misleading or improper declarations.

5.2 CDSCO Label Format Guidelines For imported Dental/Medical Devices: -

You should know that the CDSCO label format guidelines for imported devices don't prescribe a fixed template, however, you should follow the points we have mentioned below: -

• Information should be printed, not handwritten.
• Use standard symbols for sterilization, expiry, etc.
• Front size should be readable (minimum 1.5mm recommended).
• MRP should be in bold and labelled as "inclusive of all taxes."
• The CDSCO license number should be mentioned. If a label is modified in India, for example, to include MRP, it is required to be done using non removal stickers before clearance at the port.

VI. LABELLING REQUIREMENT UNDER CDSCO DEVICES

The important labelling requirement under CDSCO are provided in Rule 44 of the Medical Device Rules, 2017. Here we have mentioned a list of some important: -

Serial Number	Mandatory Information	Description
1.	Name of Device	Generic name, not only brand name
2.	Model Number	Applicable for electronic/variant devices
3.	Manufacturer's Name & Address	Must be as per the registered license.
4.	Country of Origin	Indian importer's registered address
5.	Manufacturing Date	Mandatory post- 2020 regulation
6.	Expiry Date (If Applicable)	Month and year of manufacture
7.	Batch or Lot Number	For consumables or sterile devices
8.	Net Quantity	Ensures Traceability
9.	Storage Conditions	Especially for items like bandages or packs
10.	Instruction for Use	Temperatures, humidity, etc
11.	MRP (inclusive for Use)	If not printed, must be included in a leaflet
12.	CDSCO Import License Number	As per Legal Metrology (Packaged Commodities) Rules

6.1 Labelling Compliance of Dental Devices as per CDSCO Guidelines

Labelling compliance ensures that dental devices are safe, traceable, and used correctly. CDSCO (Central Drug Standard Control Organization) regulates all medical and dental devices in India under the Medical devices Rules, 2017.

Compliance with these labelling requirements is mandatory for: -

• Manufacturers (domestic production)
• Importers (foreign-manufactured devices)

Proper Labelling is: -

• Dental professionals identify the correct device and its use.
• Ensure patient safety.
• Maintain traceability in case of complaints, defects, or recalls.

Mandatory Labelling Requirement: - CDSCO specifies that all dental devices must have clear and accurate labels containing the following information: -

Device Name: - Must be the commercial or generic name. Example: Plastic Filling Instrument.

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1. Manufacturer / Importer Details: - Name, address, and contact details of the manufacturer or authorized importer.
2. Country of Origin: - Required for imported devices.
3. Batch / Lot Number: - Helps in tracking the device in case of defects or recalls.
4. Manufacture Date & Expiry Date: - Applicable for devices with limited shelf life.
5. Sterilization Status / Method: - Indicate whether the device is sterile, non-sterile, or autoclavable.
6. Intended Use / Purpose: - Example: "For dental restorative procedures".
7. Precautions / Warnings: - Example: "Use under professional supervision only".
8. Instructions for Use (IFU): - Detailed instructions may be included on the label or as a package insert.
9. Reference Standards / Certification Marks: - ISO, CE, or other relevant certifications, if applicable.

A. Special Labelling Considerations: -

1. Small Devices: When labels cannot fit on the instrument itself, information may be provided on primary packaging or package inserts.
2. Language: Labels should be in English, and if marketed in regions requiring other languages, translations must be included.
3. Class-based Labelling: Higher-risk devices (Class B, C, D) may require more detailed instructions and warnings.

B. Importance of Labelling Compliance

- Patient Safety: Prevents misuse or errors in dental procedures.
- Regulatory Adherence: Ensures compliance with CDSCO and avoids legal penalties.
- Traceability: Batch numbers and manufacturing details allow tracking defective devices.
- Professional Guidance: Helps dentists use the devices correctly and safely.

6.2 Compliance Analysis

When mapped against the CDSCO labelling checklist, the following compliance status was identified:

6.3 Interpretation

- This case example highlights that while most of the mandatory labelling elements under CDSCO guidelines are present, certain aspects like clear intended use statement and UDI barcode are either missing or partially addressed.
- This reflects the current transition phase in Indian medical device labelling, where manufacturers are gradually adopting UDI and more detailed usage instructions.

VII.0 CASE EXAMPLES OF DENTAL DEVICES

To understand the practical implementation of CDSCO labelling guidelines, a case example of a Plastic Filling Instrument (a dental device) has been taken. The product label, as obtained from the market (see Figure3), demonstrates how manufacturers comply with the Medical Device rules, 2017.

7.1 Observations from the Label

On examination of the label, the following details were observed:

1. Name of device:- The label clearly mentions the product as plastic filling instrument, which is the generic name recognized under dental devices.
2. Manufacturers Details:- The name and complete address of the manufacturers are displayed, which is mandatory under CDSCO guidelines.
3. Batch / Lot Number:- A unique batch number is provided for traceability. This helps in product recall, if required.
4. Date of Manufacture and Expiry:- The label contains the manufacturing date and a "use before'' date, ensuring the device is not used beyond its validated shelf life.
5. Sterility status:- The label specifies whether the device is sterile or non-sterile. If sterile, the method of sterilization is indicated.

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6. Quantity / Pack Size:- The packaging clearly states the number of instruments included in the park.
7. Instructions/ Warnings:- The label carries precautionary statements such as “For Dental use Only” and Use by qualifies professionals”.
8. Import/ manufacturing License Number:- As per CDSCO requirement, the relevant license number is displayed.
9. Storage conditions:- directions such as “Store in a cool and Dry Place” are included.
10. Symbols:- Internationally recognized symbols are present making the product acceptable for global markets.

VIII. CONCLUSION

Proper labelling of dental devices is a key requirement under the Medical Device Rules, 2017 issued by the Central Drugs Standard Control Organization (CDSCO). It ensures patient safety, supports regulatory adherence, and allows effective traceability of products in case of complaints or recalls. The mandatory labelling elements—such as device name, manufacturer details, batch number, sterilization status, instructions for use, warnings, and certification marks—help dental professionals handle devices safely and appropriately. Special considerations, like language requirements, class- based instructions, and labelling of small instruments through packaging or inserts, further enhance clarity and safety. The case example of the Plastic Filling Instrument demonstrates how these regulatory requirements can be practically implemented on a real device label. By following CDSCO’s guidelines, manufacturers and importers can maintain high standards of quality, protect patients, and comply with Indian regulations for dental devices.

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