

What Does an MD 42 Licence Mean for Medical Device Importers?

For businesses importing medical devices into India, regulatory compliance is an important part of the import process. Medical devices are regulated products, and importers need to follow the requirements prescribed by the Central Drugs Standard Control Organization (CDSCO).

An MD 42 Licence is relevant to certain medical device import activities in India. Understanding what it means, who needs it, what documents are required, and how the application process works can help an importer avoid unnecessary delays.

This guide explains the MD 42 framework in simple terms, including eligibility, documentation, fees, application steps, and common questions.



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What Is an MD 42 Licence?

The [MD 42 Licence](#) is an import licence issued under India's Medical Devices Rules, 2017 for the import of medical devices, subject to the applicable regulatory requirements.

For an importer, the licence provides regulatory authorization to import specified medical devices into India. The exact requirements can depend on the type and classification of the device, its intended use, manufacturer details, and other regulatory factors.

Before starting the application, an importer should identify the correct regulatory category and ensure that the proposed products fall within the scope of the applicable licence.

Why Is MD 42 Important for Medical Device Importers?

Importing medical devices involves more than purchasing products from an overseas manufacturer and bringing them into India. The importer must meet applicable CDSCO requirements and maintain supporting documentation.

The licence helps establish that the importer has completed the relevant regulatory process for the products being imported.

For businesses, this can be particularly important when dealing with customs clearance, product documentation, distribution, and regulatory inspections.

A proper application also reduces the possibility of errors caused by incomplete documents or incorrect product information.

Who May Need an MD 42 Licence?

The requirement depends on the nature of the medical device import activity and the applicable provisions under the Medical Devices Rules.

Businesses should assess their products before applying. Important factors include:

- Classification of the medical device
- Intended use of the product
- Manufacturer and manufacturing-site details
- Product specifications
- Regulatory status of the manufacturer
- Importer information
- Applicable CDSCO requirements

An importer should not assume that every medical device follows exactly the same approval route. Product classification and regulatory category can affect the documentation and process.

MD 42 Registration Process

The [MD 42 registration](#) process generally involves preparing the required information and submitting the application through the applicable CDSCO regulatory system.

A typical process includes:

1. Identify the Medical Device

Start by identifying the products that will be imported. Product names, intended uses, models, variants, and specifications should be reviewed carefully.

2. Determine the Applicable Classification

Medical devices are regulated according to their risk classification. The classification can influence the regulatory requirements applicable to the product.

3. Prepare the Documents

The importer and foreign manufacturer need to provide the relevant documents required for the application. Documents should be consistent across the application, manufacturer records, product information, and supporting certificates.

4. Submit the Application

The application is submitted through the applicable CDSCO online regulatory process with the required information and supporting documents.

5. Regulatory Review

The submitted information may be reviewed by the relevant authority. If clarification or additional information is required, the applicant may need to respond accordingly.

6. Licence Issuance

Once the application satisfies the applicable requirements, the relevant licence can be issued to the applicant.

Because regulatory requirements can change, applicants should verify the current requirements before submitting an application.

Documents Commonly Required

The exact documentation depends on the product and application category.

However, an importer may need documents such as:

- Details of the Indian importer
- Manufacturer authorization documents
- Manufacturer details and address
- Device details and product information

- Intended use of the device
- Product specifications
- Free Sale Certificate or equivalent supporting documentation, where applicable
- Quality and manufacturing-related documents, where applicable
- Existing approvals or certificates from the country of origin, where applicable
- Labels and packaging information
- Declaration and other regulatory documents

One important point is consistency. The product name, manufacturer details, model numbers, and other information should match across the supporting documents.

MD 42 Certificate: What Should Importers Know?

Businesses sometimes use the term [MD 42 certificate](#) when referring to their regulatory authorization or licence documentation.

However, it is important to use the correct regulatory terminology for the specific approval involved. An importer should not rely only on a document name when determining compliance.

Before using an MD 42 certificate for commercial or import purposes, businesses should verify the scope of the authorization, the listed products, manufacturer information, and validity requirements.

MD 42 Licence Fees and Other Costs

The government fee associated with a medical device import application depends on the applicable regulatory category and current fee structure.

Apart from statutory fees, businesses may also have professional costs if they engage a regulatory consultant to manage documentation and application support.

The overall cost can therefore include:

- Applicable government application fee
- Product-related regulatory fees, where applicable
- Documentation and certification expenses
- Testing or evaluation costs, if applicable
- Professional consultancy charges
- Additional compliance expenses depending on the product

There is no single fixed cost that applies to every importer. The final amount should be confirmed after reviewing the product category, number of devices, manufacturer details, and applicable CDSCO requirements.

MD 42 Licence vs Wholesale License for Medical Devices

An import authorization and a domestic distribution authorization are not necessarily the same regulatory requirement.

A business involved in importing medical devices should first understand its complete business activity. If the company will also distribute or sell products within India, it may need to consider the applicable [wholesale license for medical devices](#) or other permissions depending on the nature of its operations.

This distinction is important because obtaining one authorization does not automatically mean that every other regulatory obligation has been fulfilled.

Common Mistakes Importers Should Avoid

Several avoidable mistakes can make a regulatory application more complicated than necessary.

Incorrect Product Classification

Using the wrong classification can lead to incorrect documentation or an unsuitable application route.

Mismatched Manufacturer Details

The manufacturer's name and address should be consistent across supporting documents.

Incomplete Product Information

Missing model numbers, specifications, intended use, or other product details can create clarification requirements.

Outdated Documents

Applicants should check whether supporting certificates and manufacturer documents are current and acceptable for the relevant application.

Applying Without Reviewing the Complete Requirements

Submitting an application before checking all requirements can result in additional queries and delays.

How Agile Regulatory Can Help

Medical device regulations involve technical documentation and regulatory procedures that can be difficult to manage without prior experience.

[Agile Regulatory](#) provides regulatory and compliance support for businesses dealing with medical device registrations and approvals in India. The support can include understanding the applicable requirements, reviewing documentation, preparing application information, and assisting with regulatory communication.

The exact requirements are assessed according to the product and business activity rather than using the same process for every applicant.

For importers, this approach can help create a more organized application and reduce avoidable documentation issues.

Frequently Asked Questions

1. What is an MD 42 Licence?

It is an import licence under the applicable Indian medical device regulatory framework for importing specified medical devices, subject to the relevant requirements.

2. Who issues the MD 42 Licence?

The applicable medical device import authorization is regulated through India's CDSCO framework under the Medical Devices Rules.

3. Is MD 42 required for every medical device?

Not necessarily. The applicable regulatory requirement depends on the device, classification, intended use, and nature of the import activity.

4. How long does the MD 42 process take?

The processing time can vary depending on the application, completeness of documents, product category, and whether the regulator requests additional information.

5. What documents are required for MD 42?

Requirements vary by product and application. Importer details, manufacturer documents, product information, labels, certificates, and other regulatory documents may be required.

6. Can an importer also sell medical devices in India?

Importing and selling are separate aspects of a business operation. The importer should review the applicable requirements for storage, distribution, wholesale, and sale of the relevant medical devices.

7. Can Agile Regulatory assist with MD 42 requirements?

Yes. Agile Regulatory can assist businesses with regulatory documentation, application support, and compliance requirements related to medical device registrations and approvals.

Final Thoughts

For medical device importers, understanding the applicable CDSCO requirements before starting an application is essential. Product classification, manufacturer documentation, importer details, labelling, and supporting certificates all need careful attention.

The MD 42 process should therefore be approached as a regulatory compliance exercise rather than simply an online form submission. Reviewing the requirements in advance and keeping documentation consistent can make the process more organized and help businesses manage their medical device import activities responsibly.