CDSCO CERTIFICATE

Medical Device Import License Guidelines

Medical Devices entering to India must be in compliance with the Indian Medical Device Regulation set forth by the CDSCO. The CDSCO is responsible for the approval and regulation of New Drugs and Clinical Trials in the Country, laying down the standards for Drugs, control over the quality of imported drugs, coordination of the activity of State Drug Control Organizations.

As per the new Guidance of CDSCO, suspension and cancellation of the Class A & B medical devices may happen if importer fails to meet the deadline specified by CDSCO. CDSCO has set a complete procedure for granting license for medical devices imported in the country. This procedure is applicable when we import medical devices from other countries to India. However, they need to be classified according to CDSCO notified devices list, Earlier manufacturer were able to sell their medical device in India without following any specific rules and regulations but from 2006, medical devices entering to India need to follow specific import guidelines set by CDSCO.

Medical Device Import License Process

Pre-requisites for registration process:

- Generic Name / Brand Name
- Intended Use
- Material of construction
- Mode of application
- Study of device details and Classification of medical device on the basis of notified product list of

Import License Registration Phases

CDSCO Import license for medical devices is regulated in India that any industry or an individual having license (wholesale and/or manufacturing license issued under

central drug standard control organization (CDSCO), Drugs and cosmetics act, 1940 and can import medical devices into India.

Under the new dispensation, foreign manufacturers have to apply for registration certificate for their manufacturing premises and the individual drugs to be imported. The applications can be made by authorized agents of foreign firms in India. The documents required for registration certificates have been clearly specified in the amendments. The validity of registration certificates will be 3 years from the date on which these are issued.

Phase I – Applicant Registration:

After applying Client will have an active account on CDSCO online registration portal. An authorized agent (who must have wholesale license for local distribution) having license to manufacture for sale or distribution or wholesale license for sale or distribution under these rules, shall make an application for grant of import license for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a license.

Procedure of phase 1

- Online form
- Submission of required
- Approval from
- If rejected, CDSCO will communicate the reason behind rejection or reapplication if

Phase II – Import License application

This license is required to have permission to import medical device for commercial purpose.

Procedure of Phase 2

- Submission of online form with necessary details like classification of device, brand name, intended use, product description,
- Uploading the

- Fees to be paid
- Change in the status of the
- If any query raised, then proper justification or revised documents needs to be

How Lockene Will Help You in Import License for Medical Device?

Lockene is the leading medical device regulatory consulting company. We help our clients in making technical dossier for the import licensing of medical devices in India, we also solve the queries raised by the regulators, and we also providie turnkey services, system implementation, training, licensing, regulatory approvals and certifications.

Our Competencies

- We reduce our client's costs and
- We have Strong relations with regulated
- We also have dedicated and experienced regulatory
- We represent on behalf of our clients for Audits of FDA, ISO & CE
- Competent Technical

Many times, rejections or need of re-submission has been seen due to incomplete information or wrongly submission, to avoid rejections and delay in projects get expert guidance and follow a correct procedure for better results.

An Overview of CDSCO Cosmetic Import Registration

In India, the cosmetic industry is rapidly growing, with a massive market for cosmetic and personal care products. The import of cosmetics in India should be regulated to ensure the quality, safety, and performance of cosmetics being imported into India needs CDSCO Cosmetic Import Registration Certificate from the Ministry of Health & Family Welfare as prescribed under Rule 21 Of Drugs And Cosmetics Rule 1945. The certificate is required from the primary regulatory authority for CDSCO Cosmetic Import Registration in India, which is obtained from the Central Drug Standard Control Organisation (CDSCO). With this registration,

import activities and sales of cosmetic items can be carried out in India without any hassle. In India, CDSCO Cosmetic Import Registration in India is governed under the Drugs and Cosmetics Act, 1940.

What is the meaning of Cosmetic?

Cosmetic means any substance which is aimed to be scrubbed, sprayed, poured, or introduced into the human body which is used for altering, cleansing, or beautifying the appearance, which also includes any article used as a part of cosmetic products.

What is the Role of CDSCO for Cosmetic Import in India?

1. Amendment of the Cosmetic Rules, 2020 regarding the import and registration of cosmetic products;
2. Examination of various applications for NOC (No Objection Certificate) or clarification regarding the import of cosmetic products;
3. Handling of NGOs or public or Consumer forums complaints regarding the standard of cosmetic products;
4. Replying to the Government correspondences or BIS as and when needed;
5. Examining applications for CDSCO Cosmetic Import Registration into the nation as per the requirements of the Drugs & Cosmetics Act, 1940 and Rules;
6. Handling of public inquiries or PMOPGs or hearing regarding the CDSCO Cosmetic Import Registration process & providing guidance thereto;
7. Preparation of draft replies to RTI, VIP references, court cases, and Parliament questions related to

Who can apply for CDSCO Cosmetic Import Registration in India?

According to the Drugs & Cosmetic Act, 1945, CDSCO has listed the applicants who are eligible to apply for CDSCO Cosmetic Import Registration in India:

1. Authorised Agent: In case the manufacturer has authorised an agent on their behalf to import
2. A subsidiary of the Manufacturer: For any foreign cosmetic manufacturer, the Indian subsidiary firm can apply on their behalf for the CDSCO Cosmetic Import
3. Manufacturer: The manufacturer can also apply for the grant of CDSCO Cosmetic Import Registration in
4. Any Other Importer: Any Indian importer willing to import cosmetics to India from a foreign manufacturer can apply for this license or

Documents required for CDSCO Cosmetic Import Registration

Following are some vital documents required at the time of CDSCO Cosmetic Import Registration:

- Covering Letter: Purpose (Fresh/Endorsement of Products or Pack Size or Manufacturing site or Additional Sourcing Location or Re-Registration) must be clearly mentioned along with the information of earlier issued Import Registration Certificate (if any) and product or product category (whether registered or not).
- Part-1 Of Second Schedule: Details & undertaking required to be provided by the manufacturer or his authorised distributor or importer, or agent with the application form for Import Registration Certificate. The format should be properly filled in for each application in Form COS-1.

List Of Composition Or Ingredients:

1. Cosmetic name and ingredients name in the nomenclature of standard reference along with percentage contained in the Cosmetic signed by authorised person along with the stamp from the
2. No cosmetic shall be manufactured or imported which contains Colours, Pigments, and Dyes other than the one specified by the BIS and includes the 10th
3. The allowed synthetic organic colours and natural organic colours used in the Cosmetic shall not contain more than:

- 20 parts/million of lead calculated as lead;
- 2 parts/million of Arsenic calculated as Arsenic Trioxide;
- 100 parts/million of Heavy Metals other than lead are calculated as the total of the respective

1. Raw material stated in ANNEX A of the IS: 4707 Part 2, as amended from time to time, shall not be added to the cosmetic
2. No cosmetic containing Hexachlorophene shall be manufactured. In the case of soaps, Hexachlorophene may be used in concentrations not exceeding 1% weight by weight with a cautionary note be shown & shall appear in a conspicuous manner on the wrapper of a package of each
3. Cosmetics manufactured or imported into the country shall contain mercury in the following proportions:
4. In cosmetics aimed for use only in the area of the eye, the level of mercury not exceeding 70 parts per million (0,007 per cent) of mercury, calculated as the metal, as a preservative;
5. In other finished cosmetic products, unplanned mercury shall not exceed one part/million (1 ppm).
6. The use of arsenic & lead compounds for the purpose of colouring cosmetics is

- Labels Of Proposed Products: Original label for the proposed cosmetic product or item along with their variant (if any) as per the Chapter VI Of The Cosmetics Rules, 2020, which comprised the following:
    1. Cosmetic name;
    2. Manufacturer name and complete address of the manufacturer's premises where the Cosmetic has been manufactured. If the product hasn't been manufactured in a factory owned by the manufacturer, the name & address of the manufacturer or the country name where it has actually been manufactured as "Made in (Country Name)" should be there on the label;
    3. Date of expiry or use before or use by or expiry XX months from manufactured date or date of manufacturing;
    4. A unique Lot Number or Batch Number;
    5. Manufacturing License Number, the number is preceded by the letter M or L. No or Mfg. Lic. No. shall carry on outer/inner labels;
    6. A declaration of the net contents stated in terms of weight for solids, fluid measure/weight for semi-solids, fluid measure for liquids, combined with numerical count if the content is sub-divided;

7. In the case of cosmetics, where a hazard exists; every inner label must clearly indicate enough directors for safe use, caution or any special direction required to be observed by the customer;
8. In the instance of imported cosmetics to be marketed in India, the CDSCO Cosmetic Import Registration number shall be cited in the unit pack label preceded by the letter RC or Cert. No. or RC No, along with the address & name of the importer;
9. If a cosmetic package has only one label, such label must contain all the details required to be displayed on both the inner and the other outer labels under the prescribed rules;
10. In all instances, the ingredients list, present in a concentration of more than 1% must be listed in the descending order of volume or weight during they are added, followed by those in a concentration of equal/less than 1%, in any order and preceded by the words "INGREDIENTS";
11. The Cosmetic must comply with all the labelling requirements, if any, specified in the relevant Indian standard as set by BIS for the cosmetics covered under the 9th Schedule;
12. No Cosmetic shall be imported unless it is packed & labelled in conformity with these rules & label of imported cosmetics shall bear the Registration Certificate Number of the product & name and address of the owner of the CDSCO Cosmetic Import Registration for marketing the concerned product in

- Specification & Testing Methods: The specification of document is required from the manufacturer's The protocol for testing of cosmetics & specifications are as per the standards specified in the Cosmetics Rules, 2020 for the applied product.
- Pack Insert (If Any).
- Manufacturing Licenses: Original certified copy of Manufacturing Registration or License or Marketing Authorisation regarding applied products issued by the Regulatory Authority from the country of origin or
- Free Sale Certificate: This certificate is issued by the National Regulatory Authority of the country for the applied products or from the Indian Embassy of the country of origin. List of products of Free Sale Certificate should be signed & stamped by issuing authority. A Free Sale Certificate (FSC) should contain the statement that in which nation the applied product is freely
- Declaration Of Non-Animal
- Declaration For Heavy Metal &
    - Application COS-I
    - TR-6 Challan (In Original).

*Note: All The Documents Are In The English Language.

Procedure for CDSCO Cosmetic Import Registration in India

Following is the step by step procedure for CDSCO Cosmetic Import Registration in India:

Step 1: Determination Of Cosmetics Classification: When a manufacturer decides to register their products in India, then the manufacturer must check the Gazette Notification of CDSCO prior to making a final determination of a device's regulatory status & classification.

Step 2: Appointment Of An Indian Agent: The manufacturer should appoint an authorised Indian agent to interact with the CDSCO. The agent will be granted a Power of Attorney to assist in cosmetic approvals and manage registration & importation in India.

Step 3: Fill Out The Application Form For CDSCO Cosmetic Import Registration: After appointing an agent, the importer or manufacturer of cosmetics shall be required to submit the Registration Form along with all the documents and prescribed fee on the CDSCO website to the Drug Controller General Of India (DGCI) by simply logging on to the online website of CDSCO and signing into the website.

Step 4: Issuance Of CDSCO Cosmetic Import Registration Certificate: Once the application form along with documents & fee is submitted on the website of CDSCO, the DGCI Registration Authority may send a query via an inquiry letter to the manufacturer or from the certified representative of the importer. Once the authority is fully satisfied with the application, then they may issue a Cosmetic Import License.