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Review

Catchment of the Test License for the Regulation of Medical Devices in India

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ABSTRACT

The medical device industry in India is gaining momentum and is expected to grow rapidly. Given the significant impact of medical devices (MD) on patient health, a robust regulatory framework that combines policies, laws, regulations, and approvals is necessary to ensure adherence to standards before market entry. To initiate regulatory approval, test license is the preliminary step. It is required to manufacture or import materials in small quantities for specified purposes; for example, testing, training, examination, evaluation, demonstration, and clinical investigation under India's Medical Devices Rules (MDR) 2017. In general, as the associated risk of the device increases, the testing or evaluation parameters required to establish its safety and efficacy also increases. In this regard, test license is introduced so that manufacturers or importers must navigate to ensure compliance for the generation of data, particularly in the context of quality aspects of a MD or *in vitro* diagnostics (IVD), such as its design verification and validation, material of construction, testing, functionality, durability, sterility, biocompatibility, electrical safety, usability, and many more. Therefore, the present paper deals with the basic requirement and the details of the requisite documents for the grant of test license for the aforementioned purposes. It also aims to address the challenges so as to reduce the time-lapsed, effort, and financial burden to the applicant.

Keywords—*Medical device, In vitro diagnostics, Test license, Medical device rules, Testing, Evaluation.*

INTRODUCTION

The medical device sector in India is the fourth largest medical devices (MD) market in Asia after Japan, China, and South Korea, and is among the top twenty globally because of its growth potential driven by the country's increasing healthcare demands, technological advancement, innovations, and government support through various initiatives or incentive opportunities.[1] As MD have a significant potential for hazards, it should be ensured that they are safe and effective before being marketed. Thus, Govt. of India (GOI), Ministry of Health and Family Welfare's Central Drugs Standard Control Organization (CDSCO) headed by the Drug Controller General of India (DCGI), who is the central licensing authority (CLA), has notified Medical Devices Rules (MDR), 2017, vide GSR 78(E), dated 31st January 2017, effective from 1st January, 2018, and its amendment came into effect as Medical Devices (Amendment) Rules, 2020 vide GSR 777(E) dated 14th October, 2022, effective from 14th October, 2022, to have specific requirements for MD that have been framed in conformity with the Global Harmonization Task Force (GHTF) framework in order to align with the best international practices wherein the requirements for import, manufacture, clinical investigation/performance, sale and distribution of MD including *in vitro* diagnostics (IVD) have been prescribed.[2] As India recently joined the International Medical Device Regulators Forum (IMDRF) on 3rd October, 2024, as an affiliate member to accelerate global collaboration, harmonization, and convergence in medical device regulations, the importance of test license significantly helps to protect public health.[3]

At present, 38 categories of MD have been notified and regulated; the current regulatory practices in India are fully geared to meet the requirements to introduce in the country.[4] The present study provides a critical explanation and significance of the regulatory framework's initiation, that is, commencement of test license governing MD, aiming to annotate how such pivotal approvals have shaped the current regulatory landscape and influenced the MD industry in India. It is mandatory that, an applicant shall apply for test license for manufacturing or importing a small quantity of MD/IVD (in case of both availability and unavailability of predicate device in India) to manufacture/import three consecutive test batches accompanied with a fee, as specified in the second schedule of MDR-2017 having a validity of three years. A predicate device is an approved MD (manufacture/import) that may be legally marketed in the country of origin or globally and used as a point of comparison for new IVD/investigational MD seeking approval through CDSCO. An applicant can choose the right predicate device that is similar/ subsequent equivalence to the subject device with regard to indications for use (disease treatment/screening/diagnosis/management), material of construction (MoC), design and technological characteristics/underlying principle, and types of specimen. Any remarkable change in the said features that does not come under the predicate device are supposed to be investigational MD/new IVD. Moreover, if no such predicate device is available in India against the proposed device, meaning that it comes under the scope of investigational MD or new IVD, the applicant must also initiate the regulatory approval by applying for test license.

INITIATION OF TEST LICENSE

A test license is required to ensure that MD/IVD is safe, effective, and meets quality standards before they are sold or used. Test license is a type of approval from CLA that allows an applicant (person/firm/organization/startup/innovator/institute/sole proprietor/limited liability partnership/others) as manufacturer or importer for all risk-based classification to make or import a test device or IVD in a small quantity (Figures 1a and 1b) on the digital platform—a government initiative of National Single Window System (NSWS) for any of the following conditions in Form MD-12 (for manufacture) or Form MD-16 (for import).[5]

- Proof of concept is validated with working prototype, and the design is finalized.
- MD/IVD should be already approved (either manufacture/imported) in India.
- Investigational MD/new IVD in case no such approved devices are available in India.
- For all risk-based classification of MD/IVD (except risk-based class A—non sterile and non measuring).

• Before conducting any preclinical/clinical studies, it is mandatory to obtain the approval for test license. All data obtained prior to granting of test license is not considered for regulatory approval of MD/IVD.

The specific process for obtaining a test license for the proposed MD/IVD in India involves several steps, as outlined in Figure 1c (for manufacture in Form MD-12) and Figure 1d (for import in Form MD-16).

PURPOSE OF TEST LICENSE

Test license is granted (Form MD-13) in order to manufacture and import small quantities of MD or IVD (either earlier approved/investigational medical device/new IVD) for any of the following purposes at a time: testing, evaluation, clinical investigation, examination, demonstration, and training. The purpose of applying for the test license should be very specific in nature, as only one option of purpose is available while filling the Form MD-12 on the NSWS portal. In addition, when a particular purpose of applying the test license is changed, a fresh application must be submitted. A brief illustration of a specific purpose for the grant of test license is given below.

Demonstration

The proposed device (either earlier approved/investigational/new) is manufactured or imported for the purpose of showcasing the said device at a national or international platform/forum.

Training

The proposed device (either earlier approved/investigational/new) is manufactured or imported for the purpose of training for process/method or learning any skills on the said device.

Examination

The proposed device (either earlier approved/investigational/new) is manufactured or imported for the purpose of conducting an examination to understand the technology, familiarity, or proficiency on the said device.

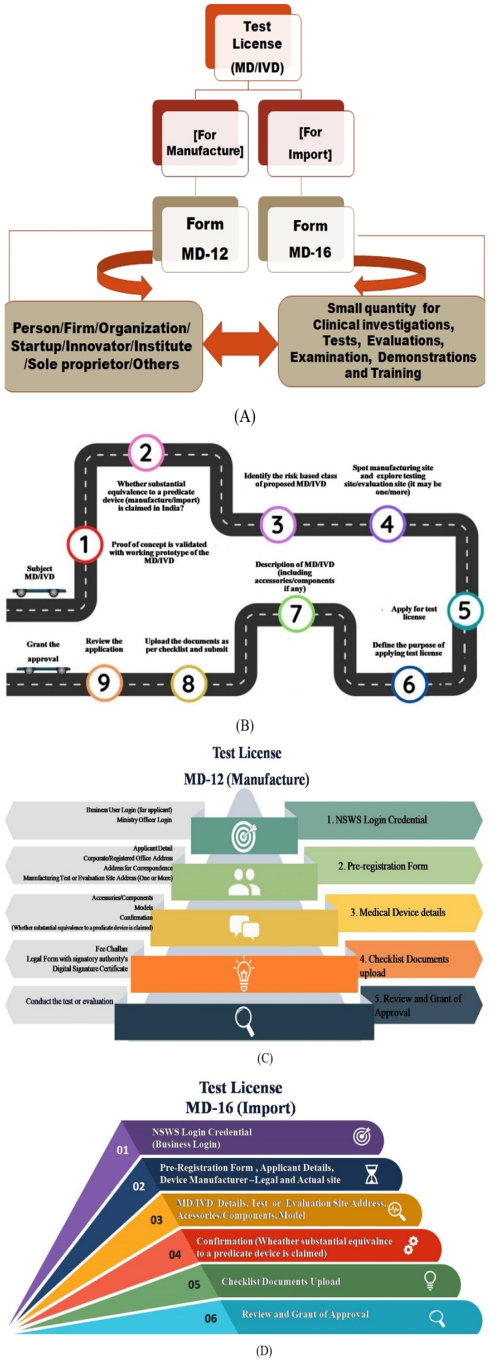

FIGURE 1. (A) An overview to apply for a test license for the manufacture or import of MD/IVD. (B) A process flow to grant a test license. Serial numbers 1 to 4 indicate the prerequisites to apply for test license, and serial numbers 5 to 9 mention the respective steps to grant approval for test license. (C) The process of obtaining manufacture test license (Form MD-12) in India. (D) The process of obtaining import test license (Form MD-16) in India.

Testing

In general, medical device testing is the process of demonstrating that the device will reliably perform safely in use. It is used if the proposed device (either approved/investigational/new) is manufactured or imported for the purpose of assessing various quality aspects of a device, such as its design verification and validation, material testing, mechanical test, reliability test, functionality, durability, sterility, stability, biocompatibility (ISO-International Organization for Standardization 10993 standard for evaluating the biocompatibility of MD), electrical safety and usability, *ex vivo* (animal performance study), and software verification and validation (for any software components).

Evaluation/Performance Evaluation

Predominantly, it is the theoretical assessment of evaluating the safety, effectiveness, and performance of MD that should start even before the product is marketed. If the proposed device (whether approved, investigational, or new) is manufactured or imported for the said purpose that include physical (mechanical, electrical), analytical (sensitivity, specificity, toxicity, stability, linearity, limit of detection, positive predictive value-PPV, negative predictive value-NPV), biological (biocompatibility) and other parameters (sometimes, clinical samples/left over samples are also used) assessment to evaluate its functions as intended use and doesn't provide any faulty information.

Particularly, performance evaluation is carried out specifically for IVD, irrespective of either new or earlier approved devices at CDSCO designated lab under sub-rule (1) of rule 19 of MDR-2017/ National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited lab/Govt. Lab/In-house lab (in case of unavailability of these labs with prior approval from CDSCO).[6] It mainly covers three major parameters, namely, scientific validity, analytical performance, and clinical performance (Figure 2).[7] Scientific validity covers the degree to which a study or test accurately measures what it is intended to measure in a broader population. It is achieved by defining research objectives (to accomplish), choosing appropriate methods (to collect and analyze data), using rigorous methods (to apply strict techniques to ensure the data are accurate), and evaluating the results (to assess the validity of the finding). Analytical performance of an IVD is the ability to measure or detect a specific analyte accurately and reliably. These studies demonstrate the analytical performance of an IVD that includes device specification, accuracy, precision, linearity, detection limit, quantitation limit, cross reactivity, specificity, sensitivity, either qualitative or quantitative, and range. However, clinical performance is the output of a device to yield results that are correlated with a particular clinical condition based on sample size, diagnostic sensitivity, diagnostic accuracy, diagnostic specificity, PPV, NPV, likelihood ratio, and expected values in normal and affected populations.[8] Performance Evaluation Reports (PER), which are essential technical documents for the regulatory approval of the subject IVD, include clinical performance reports as a key component.

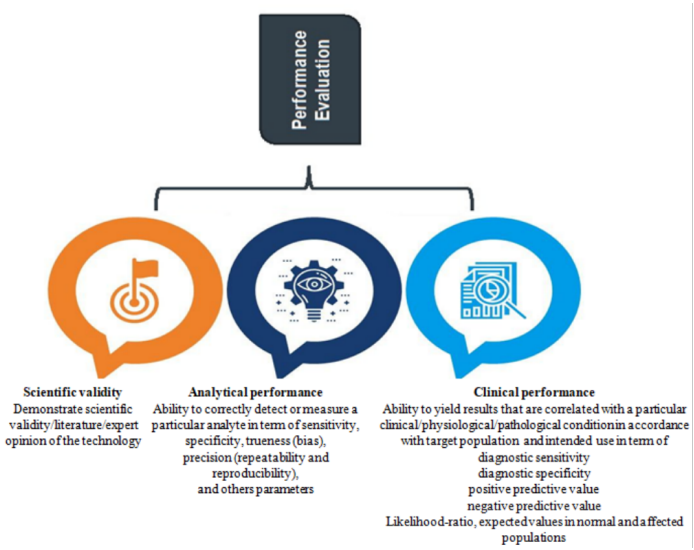

FIGURE 2. Performance evaluation of the IVD with three major parameters.

Clinical Investigation/Clinical Performance Evaluation

Clinical trials using MD are referred as clinical investigations. The purpose of a clinical investigation is to answer important scientific questions. It must follow strict scientific standards (ISO-International Organization for Standardization 14155:2020—clinical investigation of MD for human subjects), which can protect patients and produce reliable scientific outcomes. One of the purposes of a clinical investigation could be to establish and verify clinical safety, meaning to understand how

to prevent and reduce risks, errors, and harm that may happen to patients/end users. Furthermore, the purpose of a clinical investigation is to establish and verify the performance of a device in human subjects. Broadly, it focuses on good clinical practice (GCP) for the design, conduct, recording, and reporting of the adverse events of clinical investigations carried out on human subjects to assess the clinical effectiveness and safety of MD as per the seventh schedule of MDR-2017. This means checking the ability (or capability) of a device to perform as per intended use until the specified period/duration. It needs to be verified whether it enables the manufacturer to achieve the intended purpose of the device leading to clinical benefits for patients.[9]

Moreover, evaluation of clinical performance is the systematic study that can be used to diagnose and treat diseases *in vitro*. Broadly speaking, it is the assessment of an IVD using a specimen taken from humans to evaluate its performance when used as intended by the manufacturer. IVDs are designed to extract information from human samples, such as blood, tissues, and biological fluids that can allow for drawing of conclusions, such as physiological or pathological changes in the body. Clinical performance evaluations may include:

- Testing for sensitivity, specificity, accuracy, precision, and clinical validity.
- Using clinical performance evaluation plan in human specimens.
- Analyzing and summarizing clinical data.
- Demonstrating scientific validity.
- Demonstrating analytical performance.

For applying for a test license (manufacturer) for clinical investigation of MD, a copy of the grant of permission is to be provided (in Form MD-23, whether it is for pilot/pivotal/post-marketing clinical study). Conditional approval of test license may be granted in absentia of Form MD-23. However, for permission to conduct clinical investigation for an earlier approved medical device, valid approval from the ethics committee is required (Table 1).

On the other hand, for applying for a test license (manufacturer) for the evaluation of the clinical performance of a new IVD, a copy of the grant of permission is required (in Form MD-25). Conditional approval of test license may be granted in absentia of Form MD-25 with prior submission of the clinical investigation plan and approval from the institutional ethics committee (IEC).

However, for permission to conduct evaluation of clinical performance of an earlier approved IVD, valid approval from the ethics committee is required (Table 2). In addition, if a certain medical device/IVD is imported for the purpose of clinical investigation/clinical performance evaluation from the USA, Britain, the United Kingdom, Japan, the European Union, Australia, and Canada (with a condition that the product has already been marketed for at least 2 years in these territories, and the CLA is satisfied with the data of safety, performance, and pharmacovigilance of the said device), the requirement to apply for test license to conduct clinical investigation/evaluation of clinical performance is waived off. However, if medical device/IVD is approved and marketed in places other than these territories, proof of grant of permission to conduct clinical investigation/evaluation of clinical performance (Form MD-23/ Form MD-25) is required in accordance with the test license (Table 1).

CONSEQUENT ATTRIBUTES AFTER TEST LICENSE

Once test license has been granted for any of the aforesaid purposes, the applicant may prepare/import at least three test batches of the said device in statistically significant quantities at the manufacturing site (in-house) to generate quality control (QC) data that comply with the essential principles of safety and performance of the proposed device. In addition, these data should also be generated at the testing site that may be comparable enough with the in-house data. However, in the case of manufacture/import of IVD, PER that would be generated at designated labs (specific for a particular IVD) should be compared with the in-house data generated. These data are further used in the next regulatory application in order to get the final approval of the device/IVD for sale and distribution in the market.

TABLE 1. Requirement for the application of test license with the purpose of clinical investigation/evaluation of clinical performance.

Objective		Test License for MD/IVD
Manufacture	Investigational MD/new IVD	Proof of grant of permission to conduct clinical investigation/evaluation of clinical performance (Form MD-23 for MD), (Form MD-25 for IVD).
	Earlier approved in India	Ethics committee (EC) approval
Import	Investigational MD/new IVD in the country of origin	• Waive off if: • Medical device imported from the United States, Britain, the United Kingdom, Japan, the European Union, Australia, and Canada. • Already marketed for at least 2 years in these territories. • CLA is satisfied with the data of safety, performance, and pharmacovigilance of the said device[*,2] However, if medical device/IVD is approved and marketed in places other than these countries, proof of grant of permission to conduct clinical investigation/evaluation of clinical performance (Form MD-23 for MD), (Form MD-25 for IVD) is required.
	Earlier approved in the country of origin	

MD: Medical device, IVD: *In vitro* diagnostics. [*]Subject to approval from the CLA.

Moreover, it has been noticed that at the time of applying for the test license, it is not mandatory that the manufacturing site should comply with the quality management system (QMS) as per the fifth schedule of MDR-2017 and the subject device should adhere with applicable Bureau of Indian Standards (BIS)/ISO/International Electrotechnical Commission (IEC)/pharmacopeial standards). But, while applying for the commercial manufacturing license, the manufacturing facility must comply with QMS or have ISO 13485, which may be audited later by the concern notified body (in the case of risk-based class of A and B by the state licensing authority) or by a medical device officer (in the case of risk-based class of C and D by the CLA), and the proposed device must follow the respective standards.

All the data obtained prior to granting of the test license is not to be considered for regulatory approval of medical device/IVD (Figures 3 and 4). In this regard, it is advisable that the innovator may refer to the regulatory pathway for MD/IVD given on the CDSCO website.[10]

DOCUMENT UNDERLYING FOR APPLYING THE TEST LICENSE

There are a certain set of documents for applying for test license against the proposed device/IVD as per Form MDR-2017.2 A brief overview of each document is herewith discussed and summarized in Table 2.

1. Covering letter mentioning the objective of the test license specifically details the purpose, intended use, justification of quantity, and regulatory status (i.e., availability of predicate device in India and approval status in other countries), and detail of manufacturing and testing/evaluation site.

2. Brief description of applied MD/IVD including intended use, material of construction (MoC, design, label, specimen used for testing (human/animal), type of specimen (blood, serum, plasma, etc.). If a predicate device is available, the applicant needs to submit the substantial equivalence evaluation along with relevant published literature, that is, comparative analysis to prove substantial equivalence to the predicate device(s) as claimed with respect to intended use, MoC, design characteristics, mechanism, principal of operation, etc.

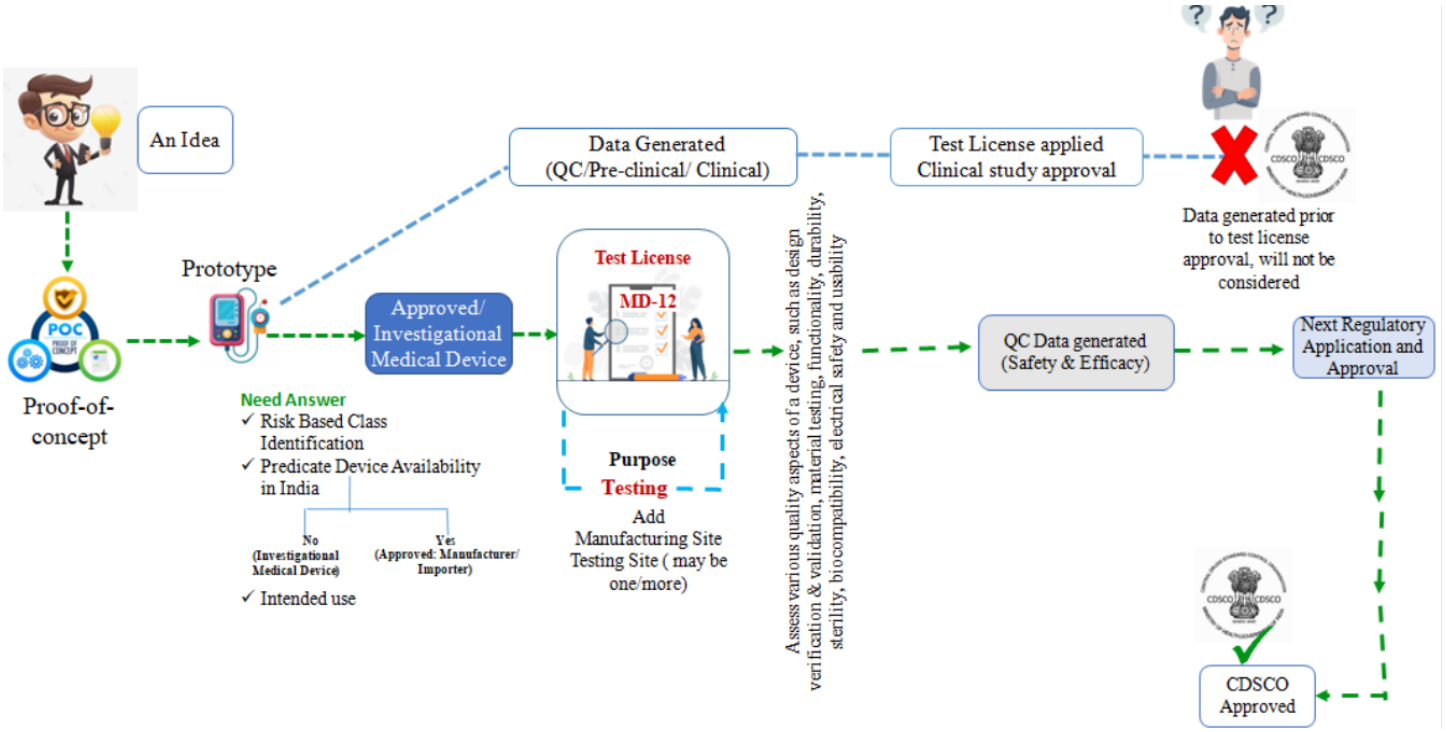

FIGURE 3. Road map to apply test license (Form MD-12) for MD with the purpose of testing.

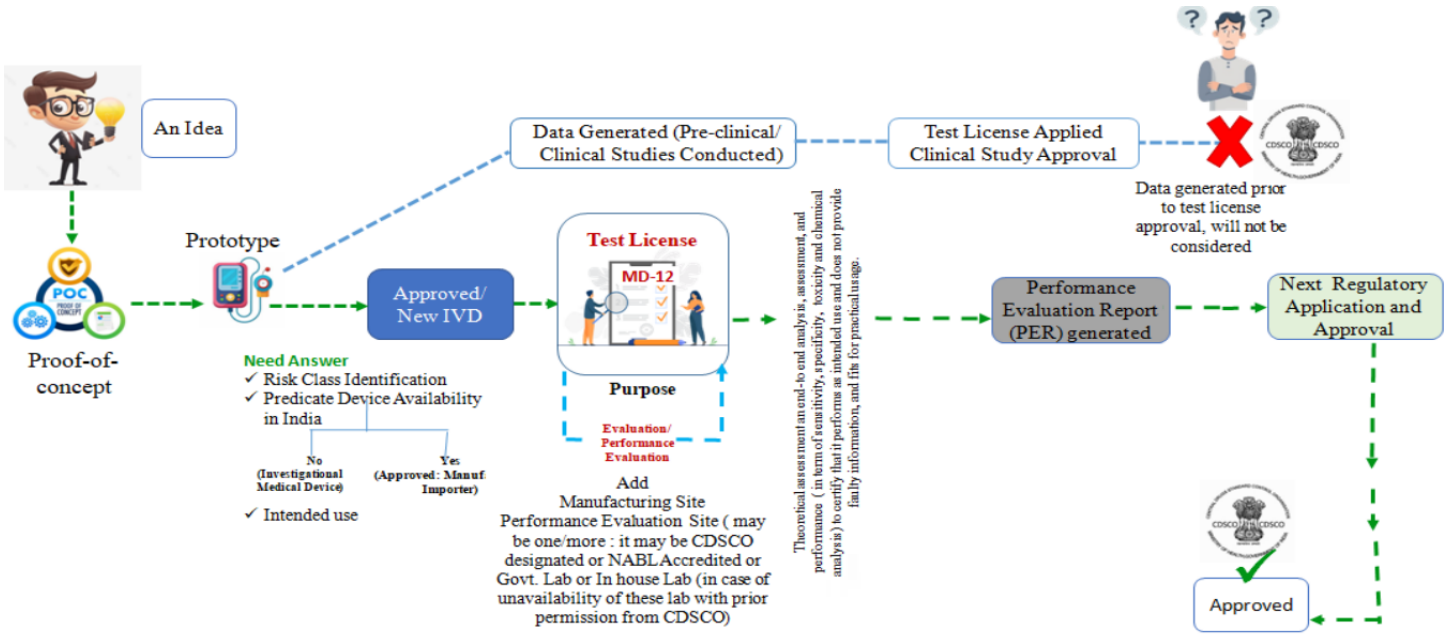

FIGURE 4. Road map to apply test license (Form MD-12) for IVD with the purpose of evaluation/performance evaluation.

3. Undertaking stating that the required facilities including equipment, instruments, and personnel have been provided to manufacture such MD/IVD on the letterhead with a stamp and signed. However, in the case of import of MD/IVD in small quantities, 2 undertakings are required, namely:

• An undertaking stating that the MD/IVD proposed to be imported is to be used exclusively for the specified purpose and not for commercial purpose.

• An undertaking stating that required facilities including equipment, instrument, and personnel will be provided to test or evaluate the medical device.

4. List of equipment, instruments for manufacturing and testing/evaluation of applied MD/IVD (not applicable for the import of MD/IVD).

5. List of qualified personnel for manufacturing and testing of applied MD/IVD in tabular form under whose direction and supervision the test batches' manufacturing activity, testing, and evaluation of a medical device shall be undertaken (not applicable for the import of MD/IVD)

6. Justification of quantity proposed to be manufactured along with its utilization breakup mentioning testing parameters with quantity required for the applied quantity, mentioning both internal and external evaluations (if applicable). Moreover, the same implies for IVD with quantity required for evaluating at both internal and external evaluation sites (if applicable). However, in the case of import of MD/IVD in small quantities, the applicant can give the proper justification of the quantity proposed to be imported with its utilization breakup.

7. Test specification and protocol along with applicable standards that provide the testing protocol or any other protocol specific to the device/IVD. Approved clinical study protocol or approval copy of Form MD-23 or Form MD-25 will be required if the selected purpose of applying for the test license is for clinical investigation or evaluation of clinical performance. It is also applicable for the import of MD/IVD in small quantities.

8. Brief description of the manufacturing and testing process and flowchart that includes each process step of manufacturing of the subject device/IVD.

9. Copy of the manufacturing license of the premises where the development/testing activity is to be carried out, under these rules, if any. It is applicable only to existing manufacturers who have been previously issued a license; otherwise, this does not apply. Please upload a declaration confirming this.

10. Approval letter authorizing to undertake research and development activities issued by a government organization, if any. Any approval from agencies funding research internally or externally

11. Other documents, if any. It may include publication/research paper in support of intended claims, design, principal of operation, MoC, etc.

12. Fee challan that will be paid online via the Bharat Kosh portal (https://bharatkosh.gov.in/) directed through the NSWS portal. The fee amount is subjective and is calculated automatically by the system based on the device applied (as per second schedule of MDR-2017). It is advisable not to pay the respective amount directly through the Bharat Kosh portal.

13. Legal form. It is a system-generated filled form of MD-12 application that should be submitted after being digitally signed with the digital signature certificate (DSC) of an authorized signatory.

In addition, the following documents are used exclusively for the import of MD/IVD in small quantities:

• Quality certificates like QMS, etc., of the manufacturer, if any. Manufacturing site should comply with QMS as per the fifth schedule of MDR-2017 or ISO 13485.

• Labels and instructions for use (IFU), as per Rule 44 of MDR-2017. Labelling of MD needs particulars such as name of the medical device; the details necessary for the user to identify the device and its use; the name of the manufacturer and the address of the manufacturing premises; the correct statement about the net quantity in terms of weight, measure, volume, number of units, as the case may be; and the number of the devices contained in the package expressed in the metric system; the month and year of manufacture and expiry (the label may indicate the product's shelf life. For sterile devices composed of stable materials such as stainless steel or

titanium, and supplied non-sterile, the date of sterilization may be treated as the manufacturing date. In the case of medical equipment, instruments, or apparatus, it may not be necessary to specify an expiry date) on the shelf pack of the MD or on the outer cover of the MD that shall be printed in indelible ink on the label, whereas the intended use of a medical device is clearly communicated in the IFU. The IFU (or electronic IFU) is a set of instructions that are legally required for MD to be sold and are intended to ensure the safe and effective use of the device. It should include:

- Intended use: The specific intended use of the device.
- Precautions: Any precautions or warnings that should be considered while using the device.
- Preparation: How to prepare the device for use, such as sterilization, assembly, or calibration.
- Disposal: How to dispose of the device.
- Other information: The name of the device, manufacturer's address, shelf-life, storage requirements, and technical specifications.

In cases where certain requisite documents are not applicable to a particular device or IVD, the applicant must provide a proper justification and upload the same on the portal.

EXCLUSION OF THE TEST LICENSE

A test license is not required to apply for all MD in India, but it depends on the risk-based class of device, usability, and the purpose in certain conditions as follows:

Manufacture/Import of Class A Nonsterile and Nonmeasuring device

Consequent to the implementation of the notification G.S.R. 102 (E) dated 11th Feb, 2020, all MD are under the licensing regime (except for class A—non-sterile and non-measuring MD), and license is required for the import/manufacture of MD in the country.[11] These devices such as scalpels, scissors, walking sticks, eyeglasses, and wheelchairs do not require a license, but they do need to be registered on "online system for medical devices" established by CDSCO for this purpose.[12] The registration number obtained shall not be considered as a regulatory approval for the manufacture/import of devices.

Import of MD/IVD from the Founding Member Countries of the GHTF

Clinical investigation will be waived off for the subject device if it is imported from the United States, Britain, the United Kingdom, Japan, the European Union, Australia, and Canada and remains marketed for at least 2 years in these territories (Table 1). In addition, the CLA is satisfied with the data of safety, performance and pharmacovigilance of the said device as per rule 63 of MDR-2017.[2] However, it is subject to approval from the CDSCO on a case basis.

Imported for Personal Use

Test license is not required for the import of small quantities of MD/IVD for personal use (by a person or by a government hospital or statutory medical institution for the treatment of a patient), which is otherwise prohibited under Section 10 of the Act. MD/IVD may be imported for personal use subject to prior approval in Form MD-20 as per rule 43 of MDR-2017 accompanied by requisite documents and the fee as specified in the second schedule of MDR-2017 on the cited portal.[12] On the other hand, small quantities of an investigational medical device, the import of which is not allowed, but approved in the country of origin, may be allowed to be imported by the CLA for the treatment of a patient suffering from a life-threatening disease, or disease causing serious permanent disability, or disease requiring therapy for an unmet medical need, on an application made by a medical officer through the medical superintendent of a government hospital or a statutory medical institution in Form MD-18 as per rule 42 of MDR-2017 accompanied by requisite documents required and the fee as specified in the second schedule of MDR-2017 on the cited portal for this purpose.[12]

Manufacturing of Custom-Made Device

MD that are made specifically in accordance with a written prescription of a registered medical practitioner, specialized in the relevant area, under his/her responsibility in accordance with a specific design, characteristics, and

the same is intended for the sole use of a particular patient, and the label mentions "for the sole use of a particular patient," and does not include the mass production of such a device. All provisions of chapter IV (manufacture of MD for sale or for distribution and chapter V (Import of MD) are exempted as per the eighth schedule of MDR-2017.

WITHDRAWAL, REJECTION, AND CANCELLATION OF TEST LICENSE

Once the test license application is submitted successfully, there is no option to withdraw/amend the submitted test license application on the NSWS portal. However, an applicant can request the CLA for cancellation with a proper justification for the same. In addition, after obtaining the test license in Form MD-13, if an applicant fails to comply with relevant provisions of the MDR-2017 against the proposed device/IVD, the CLA may issue a show cause notice for cancellation giving an opportunity to explain in writing the licensee's defense against an order for cancellation. The licensee has the right to appeal to the central government within 45 days from the date of cancellation of the order.[2]

The CLA may reject the grant of a test license in Form MD-17, and the reasons, such as the requirements of these rules are not satisfied by the applicant, are to be recorded in writing within a period of thirty days from the date of the application under sub-rule (2) of rule 40 of MDR-2017.[2]

SIGNIFICANCE OF TEST LICENSE

The importance of test license significantly implies a quality of MD/IVD that should make it worthy of global acceptance. Within a functioning healthcare system, initiating the regulatory application process—beginning with the issuance of a test license—is a crucial first step for any subject device intended for widespread use in the prevention, diagnosis, treatment, monitoring, and rehabilitation of a broad range of diseases and medical conditions. In addition, it can also be used to monitor vital signs, deliver medications, remove biological waste, and support or replace damaged body parts. The important aspects of test license are herewith outlined below:

• Role in regulatory compliance: Obtaining test license is an important step which helps in ensuring adherence with the existing regulatory framework so that it can be of help to protect public health. It also ensures that products that are manufactured/imported in small quantities after obtaining test license shall be used only for specified purposes and not for commercial purposes.

• Safety measures: Test license granted against manufacturing/importing the MD/IVD for the purpose of testing/evaluation ensures that testing/evaluation carried out with respect to applicable gold standards will establish that the products are safe and effective for human use.

• Commercial manufacturing preparedness: The grant of a test license is the preliminary step for the preparedness of commercial manufacturing license for sale and distribution of MD/IVD in the Indian market, as it helps to prevent the marketing of unsafe or ineffective devices. Usually, it is applied for once the working prototype is ready, and its design is finalized in the case of investigational MD/new IVD.

• Build trust: The end user can build trust in the company's various products of MD/IVD for which the license has been granted.

• Adverse event surveillance: Test license encompasses the compliance of regulatory approval, identification of all quality-related issues, investigation of the root cause, and implementation of necessary legal actions in case of adverse events reported (if any) of the subject device. This ensures that such problems do not arise again and develops the confidence of users on device potentially, safety, and effectiveness of use in humans.

KEY CHALLENGES AND SUGGESTIONS FOR AMELIORATION

Test license permits the manufacturer/importer to make/import a limited quantity of MD/IVD falling within class A (except non-sterile and non-measuring)/B/C/D for any of the aforesaid purposes before being put into commercial use. There are certain challenges with regard to applying the test license and possible suggestions, which are summarized below.

Challenges Faced

The dynamic and complexity of regulatory compliance:

With ongoing amendments and regular updates to MDR-2017 in India, usually the applicants often face the following challenges in fully understanding the nuances related to device/IVD:

• Class of MD/IVD: Correct identification of a risk-based class of the device.

• Laboratory for conducting performance evaluation: Availability and identification of CDSCO designated labs under sub-rule (1) of rule 19 of MDR-2017 for IVD.

• Identification of predicate device: It is essential for confirmation that it either falls under investigational MD or New IVD or subsequent equivalent of the approved device/IVD.

• Understanding of different components/accessories/consumables: It includes a basic overview of the device and its parts, whether or not consumable items are included—along with their respective risk-based classification and intended use, is not clearly explained in the remarks. Justification of quantity to be manufactured/imported for different purposes and their breakups utilization.

• Clarity on grouping of MD/IVD; either it falls under the category of single, system, group, family, or cluster.

• Identification of test batch manufacturing sites/testing sites.

Technical Barriers on the NSWS Portal

The NSWS platform, while designed to simplify regulatory processes, can present technical barriers, such as slow response times, connectivity issues, or errors in uploading required documents along with login credential requirements of mandatory DSC, which is linked to the permanent account number (PAN) of the business entity or signatory authority for its validation to submit the application as well as approval.

Extended application review period

In general, 30 working days are allocated to review the application and grant approval. However, long extended time has been utilized to review the application because of a large volume of applications or insufficient information/incorrect documents submitted by the applicants.

POSSIBLE SUGGESTIONS

Inconsistent Testing Standards

There may be inconsistencies in how different laboratories apply the standards, leading to variability in testing/performance outcomes. There is no harmonization of the analytical parameter, which is established to conduct the performance evaluation of the subject IVD that varies across designated labs. Aligning the harmonized results with MDR-2017 is critical for approval.

Emergence of New Technologies:

Emergence of new technologies for health solutions require new risk-based classification under either software integrated medical device (SiMD) or software as medical device (SaMD) for addressing efficacy/intended use in ways that are not previously covered.

An Awareness-Strengthening Regulation

Since, there is an overall trend to cover all MD/IVD under the license regime, it is primarily recommended as safety concern grows, to be aware about increased regulation over previously non-notified category of MD/IVD.

CONCLUSION

MedTech industry is not just a component of healthcare but is the catalyst that links patients, payors, service providers, and regulators to create a stronger and more equitable system in a fast-paced environment globally. In this regard, MD/IVD is the unique positioning of the MedTech sector that holds the promise of revolutionizing healthcare delivery and outcomes, both in India and globally. The wide spectrum MD/IVD, from simple technologies to complex high-throughput systems, presents varying degrees of risk that may directly influence patient health

and safety. On the other end, the regulatory compliances in accordance of risk-based classification of MD/IVD vary. However, test license is an important principal requirement to get the necessary approval for manufacture/import of a small quantity of MD/IVD for the purpose of clinical investigation, testing, evaluation, examination, demonstration, or training. The process of obtaining test license under the MDR-2017 in India via the NSWS portal involves navigating complex regulations and ensuring compliance with testing standards. The objective of the current study is to provide a significant overview of the regulatory framework that brings test license approval of the MD in India. These approvals facilitate ease of doing business, remove regulatory bottlenecks to make in India, while ensuring availability of better MD for patient care and safety. Conversely, there are certain challenges that significantly present opportunities for improvement in regulatory frameworks and quality standards, potentially leading to a more robust medical device market in India. These insights may be relevant when considering the broader context of MD/IVD testing and licensing under MDR-2017.

AUTHOR CONTRIBUTIONS

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We have no conflicts of interest to disclose.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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