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UNDERSTANDING REGULATORY REQUIREMENT FOR MANUFACTURING AND IMPORT OF ORTHOPEDIC IMPLANT

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ABSTRACT

In India, medical devices are regulated by the Drug Controller General of India (DCGI) under the Central Drugs Standard Control Organization (CDSCO), a part of the Ministry of Health and Family Welfare. While several medical device companies operate in India, only 7% of implants—classified as Class III medical devices—are manufactured domestically. With an import dependency of 75%, the European Union is the largest supplier. High-risk goods like orthopaedic implants, cardiac stents, and diagnostic equipment are frequently imported from the US. Orthopaedic implants, designed to replace or support damaged bones and joints, are defined as devices that help prevent musculoskeletal deformities and injuries. The regulation of imports aims to equip healthcare professionals to use these devices effectively, which in turn will enhance patient compliance and improve their quality of life. Additionally, various fiscal initiatives are in place to encourage the research, development, manufacturing, and import of medical devices in India, including specific standards for orthopaedic implants. The regulatory frameworks of European and international standards organizations differ in their approach, and new areas of work are also being developed to further strengthen these standards.

Keywords: Medical Devices, Regulations, Drug controller general of India (DCGI), Central drugs Organization of India (CDSCO), Class III medical devices, Implants, Orthopedic Implants, Regulatory Framework.

I. INTRODUCTION

1] MEDICAL DEVICE

Any tool, apparatus, implement, machine, appliance, implant, in vitro reagent, software, substance, or other comparable or related item that the producer intends to be used, either solo or in combination, for medical purposes is considered a medical device. Over 7000 generic device groups comprise the estimated 2 million distinct types of medical devices currently available on the global market.

Classification of Medical Devices:

1. Low Risk - Class A
2. Low Moderate Risk- Class B
3. Moderate High Risk- Class C
4. High Risk- Class D

Medical Device Classification in India (IMDRF)

CLASS	RISK	DEVICE EXAMPLES
A	Low	Bandages /tongue depressors, Absorbent-Cotton wools, Surgical dressing, alcohol swabs, Tongue depressor
B	Low-moderate	Hypodermic Needles / suction equipment, Thermometer, BP monitoring device, disinfectants.
C	Moderate-high	Lung ventilator / bone fixation plate, haemodialysis catheter
D	High Hazard	Heart valves / implantable defibrillator

2] ORTHOPEDIC IMPLANT

In human orthopaedic devices, bandages, splints, prostheses, and specialized equipment are used to prevent and treat injuries and deformities of the musculoskeletal system. There are several different kinds of orthopaedic devices. Fixing devices, such as hinged splints, which maintain a specific range of motion in a joint, and stiff splints, are made to either totally or partially limit joint movements. Corrective devices, such as corsets, splints, orthopaedic footwear, insoles, and other devices to correct abnormal foot positions, are used to gradually correct a deformity, while relieving devices transfer support to healthy parts of an extremity to relieve pressure on an ailing part.

Compression distraction devices fix inherent or acquired abnormalities of the extremities, such as pseudarthrosis, shortening, and curvature.

Bones are dissected using chisels, osteotomes, electric and pneumatic saws, and ultrasonics to connect bone fragments or remove abnormalities.

In osteosynthesis, rods, pins, plates, and screws are employed. Internal prosthesis made of metal and plastic are used to replace joint abnormalities. Orthopaedic implants are materials used to replace bones and joints in hard tissue applications. Fixation plates, which are implanted to stabilize shattered bones, are also included in this category.

There are two categories for orthopaedic implants, which include:

a) Permanent Joint Replacements: Shoulder, elbow, wrist, finger, ankle, hip, knee, and joint.

b) Temporary Fracture Fixation Devices: For the purpose of repairing broken or fractured bones, plates, screws, pins, wires, and intramedullary nails are required. These devices are meant to be used for a brief period of time, just long enough for the bones to recover.

2.1] TYPES OF ORTHOPEDIC IMPLANT

1] SCREWS

Orthopaedic screws are used to tighten injured areas, including a torn labrum or rotator cuff. They look almost exactly like the screws you may purchase at a hardware store and might have a flat or Phillips head. Don't anticipate to have screws taken out; instead, expect your orthopaedist to use them to fix broken bones or stabilize weak spots. Your screws are usually there to stay.

2]PLATES

Long bone fractures were first repaired using orthopaedic plates in 1886, more than 50 years after Mary Shelley's Frankenstein. Perhaps this masterwork of horror served as inspiration for these doctors. Plates were and are still a very effective treatment for fractures, stability, and reconstruction, thus it is unlikely. Plates come in five main varieties:

1) Buttress plates: In order to stabilize fractures at the ends of long bones, especially those at the knee and ankle, where the fracture site is subjected to significant compressive and other deforming stresses, buttress plates are utilized. Some of these plates may be L- or T-shaped, but they are curved to move with the body.

2) Neutralization plates: Neutralization plates are a class of plates that span the cracked area and balance the weight so that screws or other devices can stabilize and secure it. They are not a single plate.

3) Bridging plates: Bridging plates provide length and alignment while stabilizing the area. Furthermore, because bridging plates do not disturb the injured area, they maintain the blood supply to the fracture pieces, which aids in subsequent bone healing.

4) Tension plates: Wires called tension plates are typically used to hold an area in place as it heals.

5) Compression plates: Compression plates are made of metal and are used to mend broken bones by applying dynamic pressure between them.

3] PROSTHESES

To replace missing joints or bones, or to support a damaged bone, orthopaedists employ a range of orthopaedic prosthetic implants. Orthopaedists most frequently utilize knee and hip prosthesis, which enable patients to quickly regain their complete range of motion without experiencing any pain. In certain situations, the prosthetic material can be used in conjunction with healthy bone to repair damaged or diseased bone, or it can completely replace certain joint bone components. Orthopaedic implants provide the best surgical result for patients seeking to alleviate joint discomfort and regain mobility, so it's not just science fiction.

2.2] CLASSIFICATION

Orthopaedic Implant Classification as per India:

Sr.No.	Notified Device	Device Name	Class	General Intended Use
1	Orthopaedic implant	Intra Osseous Fixation Wire	**Class B**	Stabilization of fractured bony parts by direct fixation to one another with surgical wires
2	Orthopaedic implant	Cortical on Implant /Rigid loop Adjustable Cortical fixation system	**Class C**	Cortical Fixation System is a machined titanium implant designed to provide fixation in the repair of tendons and ligaments
3	Orthopaedic implant	Intervertebral Body Fusion Device / Fuse Spinal System	**Class C**	It is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels
4	Orthopaedic implant	Bone Wire	**Class B**	Intended to be used for bone stabilization in the hand and wrist
5	Orthopaedic implant	Bone cap	**Class B**	Intended to be implanted to cover the end of a bone
6	Orthopaedic implant	Orthopaedic implant & accessories	**Class C**	Intended to replace a missing joint or bone or to support a damaged bone
7	Orthopaedic implant	Intervertebral body fusion device	**Class D**	The device is inserted into the intervertebral body's sake of the cervical or lumbosacral spine, and is intended for intervertebral body fusion

8	Orthopaedic implant	Pedicle screw spinal system	**Class C**	It is used to intended to provide immobilization and stabilization of spinal segments
9	Orthopaedic implant	Ankle joint metal/composite semi-constrained cemented prosthesis	**Class C**	An ankle joint metal/composite semi constrained cemented prosthesis is a Device intended to be implanted replace
10	Orthopaedic implant	Ankle joint metal/ polymer non-constrained cemented prosthesis	**Class C**	A device intended to be implanted to replace an ankle joint. The device limits minimally translation in one or more planes. It has no linkage across-the-joint
11	Orthopaedic implant	Elbow joint metal/ polymer constrained cemented prosthesis	**Class C**	An elbow joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint
12	Orthopaedic implant	Elbow joint radial (hemi-elbow) polymer	**Class C**	An elbow joint radial (hemi-elbow) polymer prosthesis is a device intended to be implanted made of medical grade silicone elastomer used to replace the proximal end of the radius.
13	Orthopaedic implant	Elbow joint radial (hemi-elbow) metallic uncemented prosthesis	**Class C**	A device intended to be implanted made of alloys, such as cobalt chromium-molybdenum, that is used to replace the distal end of the humerus formed by the trochlea humeri and the capitulumhumeri.
14	Orthopaedic implant	Finger joint metal/ metal constrained uncemented prosthesis	**Class C**	A device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint.

15	Orthopaedic implant	Finger joint metal/ metal constrained cemented prosthesis	**Class C**	A finger joint metal/metal constrained cemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal (finger) joint.
16	Orthopaedic implant	Finger joint polymer constrained prosthesis	**Class C**	A device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint
17	Orthopaedic implant	Hip joint metal constrained cemented or uncemented prosthesis	**Class D**	A hip joint metal constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint.
18	Orthopaedic implant	Hip joint metal/polymer constrained cemented or uncemented prosthesis	**Class D**	A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint.
19	Orthopaedic implant	Hip joint metal/metal semi constrained, with a cemented acetabular component, prosthesis	**Class D**	It is a prosthesis intended to be implanted to replace a hip joint
20	Orthopaedic implant	Hip joint metal/metal semi constrained, with an uncemented acetabular component, prosthesis	**Class C**	Intended to be implanted to replace a hip joint.
21	Orthopaedic implant	hip joint metal/ composite semi-constrained cemented prosthesis	**Class C**	A hip joint metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace a hip joint.

22	Orthopaedic implant	Hip joint metal / ceramic/ polymer semi constrained cemented or nonporous uncemented prosthesis	**Class C**	Intended to be implanted to replace a hip joint
23	Orthopaedic implant	Hip joint metal/ polymer/ metal semi-constrained porous-coated uncemented prosthesis	**Class C**	Intended to be implanted to replace a hip joint
24	Orthopaedic implant	A knee joint femorotibial metallic constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint	**Class C**	Intended to be implanted to replace part of a knee joint
25	Orthopaedic implant	Shoulder joint metal/ metal or metal/polymer constrained cemented prosthesis	**Class C**	Intended to be implanted to replace a shoulder joint
26	Orthopaedic implant	Wrist joint carpal lunate polymer prosthesis	**Class C**	Intended to be implanted to replace the carpal lunate bone of the wrist.
27	Orthopaedic implant	Wrist joint metal/ polymer semi constrained cemented prosthesis	**Class C**	Intended to be implanted to replace a wrist joint
28	Orthopaedic implant	Wrist joint metal constrained cemented prosthesis	**Class C**	Intended to be implanted to replace a wrist joint
29	Orthopaedic implant	Wrist joint polymer constrained prosthesis	**Class C**	Intended to be implanted to replace a wrist joint

30	Orthopaedic implant	Wrist joint carpal trapezium polymer prosthesis	**Class C**	Intended to be implanted to replace the carpal trapezium bone of the wrist bone of the wrist
31	Orthopaedic implant	Wrist joint carpal scaphoid polymer prosthesis	**Class C**	Intended to be implanted to replace the carpal scaphoid bone of the wrist.
32	Orthopaedic implant	Toe joint phalangeal (hemi-toe) polymer prosthesis	**Class C**	Intended to be implanted to replace the base of the proximal phalanx of the toe

3] MANUFACTURING

Manufacturing of Medical Devices as per D&C Act:

• A Form 27 application and the required payment must be submitted to the State Licensing Authority in order to get a license to manufacture the notified devices.

• When manufacturing new medical devices or ones without any benchmark certification, Expert Committees will thoroughly review the data submitted by the applicant for the device's evaluation and provide the relevant authority with their assessment of the device's sustainability.

• Following Joint Inspection and verification, the State Licensing Authority sends the license to CLAA for approval.

•Form 28 is used to issue the license following CLAA Manufacturing of Medical Devices' proper approval.

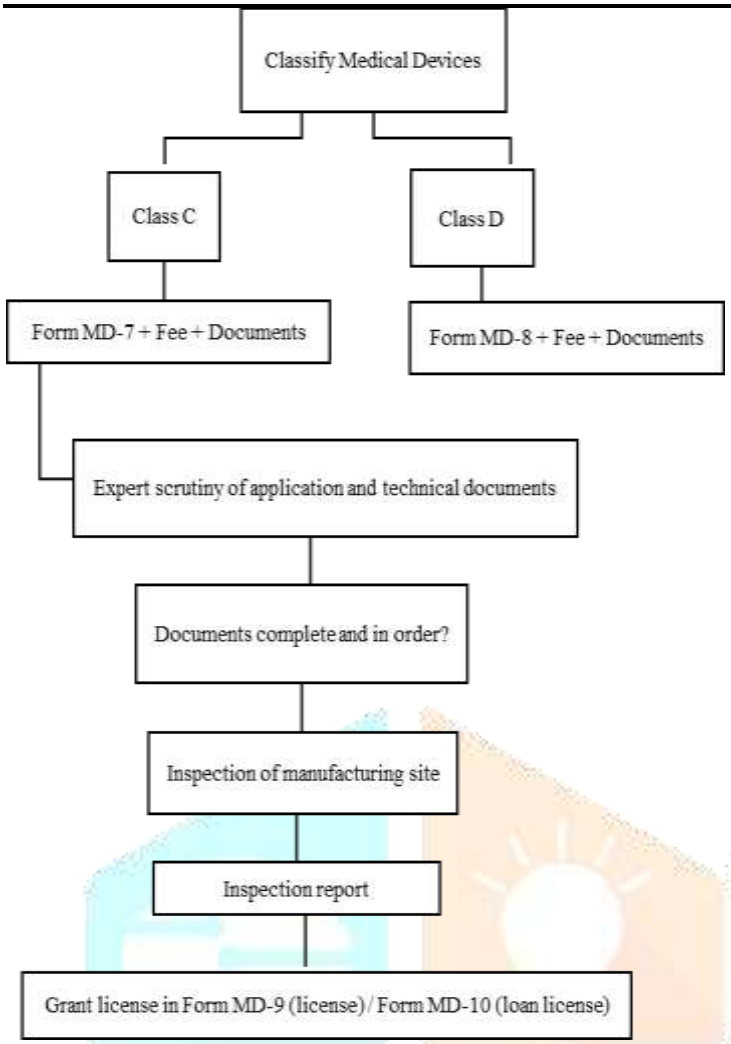

Fig. 1: Application for manufacture for sale or for distribution of Class C or Class D medical device

3.1] Clinical Evaluation of Medical Devices as per D & C

Rules 122A, 122D, 122D 122DAA, 122DAB, 122DAC, and 122DD of Part X-A declare that clinical evaluations for medical devices were undertaken in the same manner as clinical trials for medications, even though the Drug and Cosmetics Act 1940 and Rules 1945 make no mention of doing so.

According to MDR 2017, clinical evaluation of medical devices:

The sponsor must submit an application on Form MD-22 to the Central Licensing Authority for authorization to conduct clinical research on an investigational medical device. The application must include the papers listed in the Seventh Schedule and the cost listed in the Second Schedule. Only with the Ethics Committee's approval, filed under Rule 122DD of the Drugs and Cosmetics Rules 1945, may a clinical trial of medical devices begin.

3.2] The Central Licensing Authority will receive the fee.

- Authorization to carry out a pilot clinical study: Rs. 100,000.00
- Authorization to carry out a key clinical study: Rs. 100,000.00

The following documents must be sent with the application form in accordance with the Seventh Schedule:

- Data from design analyses
- Research on Animal Performance and Biocompatibility.
- The contract between the coordinating investigator (s), sponsor, and principal.
- If applicable, a proof of insurance.
- Reporting forms for significant adverse events and any other adverse occurrence.
- A summary report and study conclusion, as well as the report of biocompatibility tests and the justification for their selection.
- The risk analysis's findings.
- Data from studies on animal performance.
- CIP, or Clinical Investigational Plan.
- The Investigator's Brochure.
- The Case Report Form.
- The investigator's commitment and Ethics Committee approval;
- The Informed Consent Form.
- Information from pilot and pivotal clinical investigations, including any conducted abroad.
- The regulatory status and any restrictions on use in other nations where the product is marketed or authorized. Suggested labelling and usage instructions.

4] DESIGN

4.1] INTRODUCTION

To protect patients and healthcare professionals, the design process for medical equipment is strictly regulated. To control medical devices in Europe, the Medical Device Directive was created. It is a legally binding document with penalties for noncompliance and legal enforcement. Outside of Europe, regulations differ. For instance, the Food and Drug Administration (FDA) is in charge of ensuring the safety of medical equipment in the United States. Companies must have a quality management system in place to guarantee that the entire design process is planned and managed in a methodical and repeatable way in order to comply with the standards.Maintaining a Design History File (also called a Technical File or Design Dossier) that details a product's design history and is kept up to date after the product is released to include any changes made to it and pertinent post-market surveillance data is required to demonstrate compliance with the regulatory aspects. An overview of the design process for implantable orthopaedic medical devices is the goal of this research.

4.2] DESIGN PROCESS

4.2.1] Overview

Similar to other design processes, the medical device design process can be roughly categorized into six areas:

1.The market

2.The design specification

3.Design concept

4.Detailed design

5.Production

6.Offer for sale

4.2.2] Inputs for Design

Surgeons, other medical professionals, sales teams, or medical engineers—possibly collaborating as an interdisciplinary team—will provide ideas for new or enhanced medical equipment. The fundamental goals and therapeutic indications for the device will be established at the start of the project. To help direct the design and guarantee that the instrument is appropriate for the surgeon to use and that the gadget operates appropriately during surgery, a surgical review panel may be established.

4.2.3] Commercial Aspects

For a medical device to be conceived and manufactured, there must be a market or consumer need. Designing a device with a small market, whether because of competition from established products or a small patient base, is not commercially feasible. To determine the possible market share, comparable devices made by rival firms, and the potential market value of devices, a feasibility study for a novel device idea must be conducted. To ascertain whether the design can be protected and does not violate any other patents, an intellectual property examination is also necessary.

4.2.4] Planning

Throughout the Product Life Cycle, each stage of the design process must be handled as a project with well-defined and achievable goals. Establishing milestones should enable the project manager to keep an eye on the project's progress and guarantee that it is completed on time and within budget. The milestone definition should outline the requirements that must be met in order for the project to pass each milestone, such as completing the market feasibility report and project objectives. The project plan should outline the financial and human resources required to successfully implement a design. It should also contain frequent project meetings and milestones to facilitate planning. Additionally, it should detect issues and allow for prompt response to avoid delays in the project.

Objectives: To help with the planning process, the project plan should include regular milestones and project meetings. It should also identify the financial and human resources needed to successfully realize a design identification of problems and enable early action to counteract project delays. A risk management plan should be part of the planning process as well. It should outline the pertinent tactics that will be used to lower and control project risks. Finally, the planning process should identify the human and financial resources required to be in place to successfully realise a design.

4.2.5] Regulatory Requirements

Prior to their distribution onto the market, all medical devices must receive regulatory approval. Medical devices are required to comply with a number of nationally and globally approved regulations. There are discrepancies between the regulations in the US and Europe, and these standards are not currently harmonized. The degree of risk that a medical equipment poses to both the user and the patient must also be taken into consideration when classifying it. The appropriate approved path to market will be determined by the medical device's classification procedure. Therefore, it is crucial to identify early in the design process the restrictions that will affect a product's design. It is necessary to consult a Regulatory Authority, Conformity Assessment Body, or other authorized third party for independent counsel on this matter.

Global standards, which apply to all medical devices, semiglobal standards, which apply to a certain family of devices, and specific standards, which apply to specific devices or pieces of equipment, must all be identified during the product's design process. Complications in the later phases of the design process can be prevented by recognizing these norms. Even though not all of the requirements must be followed, doing so will frequently speed up the approval process.

4.2.6] Design Requirements

Before a medical device can be designed, the design requirements (also known as the product design specification) must be met. It lays out precisely what the design must include in order for each step of the process to be validated. A comprehensive requirement capture method is necessary to guarantee that all of the functional performance demands are identified early in the design phase, even though the project's start will highlight some of the technical requirements. To avoid limiting the potential design possibilities, it is crucial to keep in mind that the requirements are independent of the solution. The design requirements can be ascertained with the aid of a broad standard. Numerous medical device kinds, including joint replacement implants and osteosynthesis implants, also have specific needs.

Furthermore, certain devices, like hip and knee replacement implants, can have particular specifications. created to assist in determining the needs for surgical instruments. Since the packing, sterilization, and labelling are essential components of the entire device, it is also crucial to take these factors into account early on. The device's design specifications will comprise.

The following will be among the device's design requirements:

1. Design for Intended Performance
2. Features of Material Design
3. Assessment Manufacturing
4. Sterilization of Test Instruments is Necessary Packing

4.3] Evaluations of Designs

At every step of the design process, a design review is necessary to formally record a thorough, methodical analysis of a design in order to: assess design needs evaluate the design's potential and pinpoint issues.

4.4] Design

In order to decide which concept to pursue in the detail design stage, the design team can then systematically rate the variety of concept designs. There are numerous approaches to concept selection, including the Six Thinking Hats and the usage of matrices, in which ideas are rated in relation to a set of design requirements.

4.5] Production

Before putting the design into production, it is essential to make sure that the manufacturing techniques selected are reliable and reproducible. The following factors influence the preferred production method: Surface finish that needs to be attained following the necessary post-machining cleaning processes sterilizing procedure (if necessary).

In addition to the production of the devices and the surgical equipment required to implant the devices, the finalization of the device and tool packaging, sterilization protocols, operating manual requirements, and label printing specifications must be completed.

4.7] Design Validation

Validation of the device is performed under actual or simulated conditions for use. While verification is answering the question "are we building the thing right", validation is asking "have we built the right thing". Validation is to ensure that the medical device meets the user requirements and the intended use. Validation can include: mechanical testing of prototypes evidence that similar medical devices are clinically safe.

4.8] Design Transfer

It is vital to confirm that all paperwork and training related to the device are in place before a design is put into production. Transferring a design may involve:

Creation of usage instructions finalising the surgical plan and planning the surgeons' training finalising the packaging and labelling audits, first article inspections, and surveys that the vendor was required to conduct Completed inspection plans and procedure spreadsheets, total cost of materials establishing the master device record. To guarantee the safety of patients and healthcare professionals once a medical device is on the market, the producer must have a post-market surveillance process in place. Surgeons' suggestions could influence design.

4.9]. Design Changes

Once a medical device is on the market, the manufacturer is required to have a post-market surveillance procedure in place to ensure the safety of patients and medical personnel.

In response to surgeons' input, the gadget or surgical equipment may be redesigned. The changes made in response to this feedback must be fully recorded, and the effect on the device must be carefully considered. A significant amount of the verification and validation procedures may need to be repeated in this latter round, depending on the size of the change. Every design alteration must be accompanied by an updated risk assessment to ensure that the full impact of the change has been acknowledged.

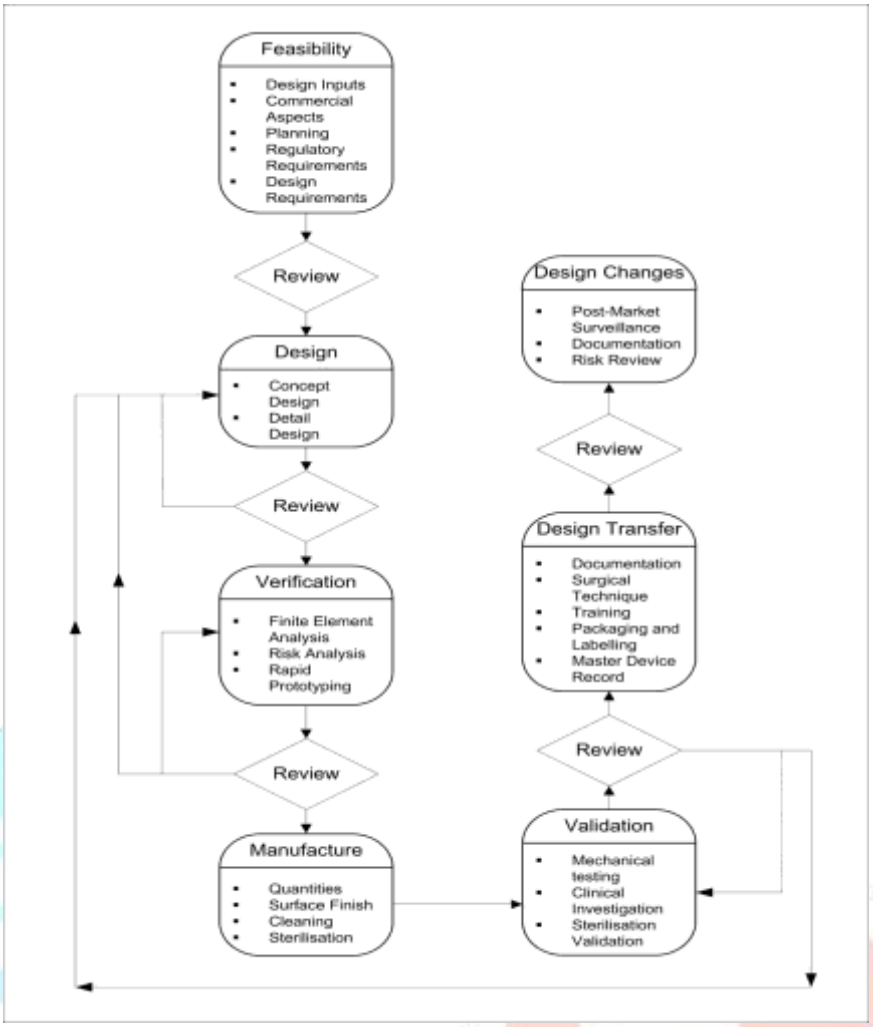

Fig. [2]. The medical device design process

5] DOCUMENT

List of Documents Needed to Complete the Class A MD Application:

1. Description, application, and specifications of the product (accessories)

2. The substance utilized in building

3.Operation and use of new machinery

4. User manuals, labels, and packaging inserts

5.Serious negative consequences

6. The plant and site master files

7. Firm rules and structure specifics

8.A checklist of essential principals

9. An initiative by the manufacturer

Steps for filling the application for import in India

Submit Application form MD 14 to CLA

⬇

Submit fee with application

⬇

i.e. 1000$ for one site and 50$ for each distinct

⬇

medical device of class A. For class B, 2000$ for one site & 1000$ for each distinct site and for class C and class D, 3000$ for one

⬇

CLA inspect the overseas manufacturing site

⬇

Applicant is liable to pay fee to one who visit overseas manufacturing site.

⬇

Submitted documents are examined, on the basis of inspection report, CLA decides the grant of above application CLA satisfied

⬇

Grant the license for import of MD in Form MD 15Valid until it is cancelled or surrendered.

5.1] IMPORT OF MEDICAL DEVICE

The import of every MD class is the responsibility of CLA. "Form MD 14" must be submitted with the necessary fees and documentation by the CLA in order for the import of MD to be approved in India. If it is denied, the applicant has 45 days to make an urgent request to the central Goi, and if an inquiry is made, the Goi has 90 days to issue an order. If "free sale certificate" has already been issued with respect to MD by the NRA or a competent authority of any country (USA, Australia, Japan, Canada, European Union Countries) then the licence should be provided to the petitioner without carrying out any clinical investigation.
Until it is Revoked or relinquished, the import License is good for a very long period. the authorized agent is required to pay the license renewal fee to the CLA (for each licensed medical devices and each overseas manufacturing site) Only after five years have passed since the date of issuance.

Table 1. Documents Required with the application form for import in India

Sr. no.	List of documents required with the application form for import in India
1	Quality Management System
2	Plant Registration System
3	Latest Inspection Report
4	Fee

5.2] DOCUMENTS REQUIRED FOR THE APPLICATION OF PERMIT OF THE LICENSE TO IMPORT OR MANUFACTURE CLASS B, CLASS C AND CLASS D MD

- The domestic manufacturer's or authorized agent's rules and organizational information.
- Plant/site master file.
- DMF, or device master file.
- A checklist of essential principles.
- Domestic manufacturers submitting a "Test license" for testing and quality control data generation.
- The petitioner's submission of an undertaking attesting to the compliance of all manufacturing facilities.
- The petitioner must submit a notarized copy of the registration of foreign manufacturing sites under the name that the relevant authority has designated (in the country of origin) as well as the "free sale certificate" that the petitioner obtained from the NRA.
- A certified copy of the manufacturing site's Quality Management System (QMS) or Quality Assurance certificate, notarized.
- A self-attested copy with legitimate manufacturing and wholesale licenses.
- A copy of the most recent Audit/Inspection Report completed by the Competent Authority (CA), Notified Body (NB), or NRA.
- A self-attested copy with legitimate manufacturing and wholesale licenses.
- A copy of the most recent Audit/Inspection Report completed by the Competent Authority (CA), Notified Body (NB), or NRA.

6] CONCLUSION

Medical equipment manufacturers are expected to switch from the traditional business model to new digital AI techniques by 2030. The potential for future medical AI development will assist humanity in tackling urgent problems such as chronic illnesses, infectious pandemics, and aging populations. International standards on AI in MDs are currently needed to facilitate market unification and the adoption of the regulatory framework. Data quality management and AI applications that impact people's health are being standardized

by organizations such as IEEE, ISO, and IEC. Despite acknowledged challenges, one may claim that AI has already significantly enhanced the standard for medical treatment, changed the way traditional medicine is conducted, and ensured everyone's health.

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