ATMA NIRBHAR BHARAT WITH MEDICAL DEVICES RULES IMPLEMENTATION

NEHU – 15TH
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MEDICAL DEVICES RULES 2017 IMPLEMENTATION

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THERE WILL BE CHAOS IF WE DON'T FOLLOW THE RULES. WE WILL MOVE SLOWER

GOING WILL BE SMOOTH IF WE FOLLOW THE RULES WE CAN MOVE FASTER

WHY REGULATIONS

- Patient Safety
- Global Acceptance
- Level Playing Field for Imported as well as Indigenous Manufacturers

WHAT IS QUALITY STANDARD

Quality standards are defined as **documents that provide requirements, specifications, guidelines, or characteristics** that can be used consistently to ensure that materials, products, processes, and services are fit for their purpose.

We have ISO Standard, BIS Standard etc. for Medical Devices.

The standards are there as Voluntary Standards in the beginning but when Regulators come into force the standards are made mandatory and every MD is required to follow these regulations.

MDR-2017

Medical Devices Rules 2017 were introduced in 2017 AND are required to be complied with effective Jan 2018.

List of Regulated Devices were released in pieces.

However the regulators defined the MD and all the Medical Devices were required to comply with the regulations in phases.

Phase-1- All the MD are required to be registered with CDSCO till 1st Oct 2021.

Phase-2- All the Devices in Class A and B are required to get Manufacturing or Import License till 1st Oct 2022

Phase-3- All the Devices in Class C & D are required to get Manufacturing OR Import License till 1st Oct 2023.

STATUS OF THE MD IMPLEMENTATION

37 Devices have been notified as below out of which 15 are Medical Equipment as below:

These devices can no longer be sold or imported or manufactured without registration

Name of MD	Class	Name of MD	Class	Name of MD	Class
CT Scan	C	Nebulizer	C	Bone Marrow Cell Separator	C
MRI	C	BP Monitors	B	PET	C
Defibrilators	C	Digital Thermometers	B	X-Ray	C
Dialysis M/C	C	Glucometers	C		

STATUS UPDATE CONT..

All other MD will be regulated phase wise as below:

1. All the devices and firm required to be registered on VOLUNTARY basis till 1st Oct 2021.

2. All the devices and firm to be registered on mandatory basis after 1st Oct 2021. No imports can take place without registration.

3. All the devices and firm to get either manufacturing license or import license till 1st Oct 2022 for A and B devices and till 1st Oct 2023 for Class C and D devices failing which manufacture, sale and imports will be illegal. There will be a penalty of Rs 1 lakhs or 3 times the value of drugs confiscated and an imprisonment of 3-5 years.

WHAT WE NEED TO DO

We need to get registered as manufactures, as importers or as distributors till 1st Oct 2021

After registration till 1st Oct 2021 we need to apply for Manufacturing License, Import License or distributors license.

For reselling of imported goods under the Indian brand name you need to get a Loan Manufacturing License and get the items manufactured and sold at the loaned premises of any manufacturer which already has got a manufacturing license.

PROCEDURE FOR DISTRIBUTORS

Apply for a Drug License with state authorities.

Get a user name and password within 1-2 days

After getting user name and password apply for Wholesale or retail license to authorities with the documents including Trade License, Firm registration certificate, site ownership or rent agreement in Form 19 A which doesn't require any pharmacist. However a Biomedical Engineer CV may be required. Time to get the License 37 days

The space requirement is 10 sqm for Wholesale and 15 sqm for Wholesale and retail combined license.

Fees will be vary from state to state but it is less than rs 5000/-

DOCUMENTS FOR DISTRIBUTORS

1. Blueprint of the premises with signatures of owners and tenant.
2. Supervisor and 2 Directors photograph.
3. Non conviction affidavits by two directors and supervisor.
4. Address proof of Directors and Supervisor.
5. Rent receipts / ownership certificates for operating from premises.
6. Affidavit of Authorised Signatory attested by notary.

PROCEDURES FOR MANUFACTURERS

- Get the firm and devices registered till 1st Oct 2021.
- After 1st Oct apply for Manufacturing License.
- Fees for Site Registration for Class A & B Devices- Rs 5,000
- Fees for each device Rs 500
- Fees for Site Registration of Class C&D Devices -Rs 50,000
- Fees for each Device - Rs 1,000

DOCUMENTS FOR MANUFACTURING LICENSE CLASS A & B MD

- Form MD-3 Duly filled in.
- Time frame -45 days for class A Device.
- No audits will be required for Class A Device. However after the license is granted within 120 days an audit by SLA may take place.
- For Class B devices audits will take place by NB within 90 days prior to grant of License. The NB will send the report within 30 days. The SLA will either reject the application with reasons recorded in writing or grant the License.
- The appeal for rejection can be made within 45 days and will be disposed off within 60 days with hearings.

DOCUMENTS FOR MANUFACTURING LICENSE C&D

- Form MD-7 for Class C & Class D Duly filled in.
- Fees details
- Scrutiny period 45 days by CLA with help of experts.
- Inspection within 60 days from the date of application.
- License or rejection with reasoning to be issued within 45 days of inspection.
- Appeal within 45 days and disposal within 60 days.
- License validity period is 5 years for all devices and renewed annually thereafter.

DOCUMENTS FOR CLASS A DEVICE SCH 4

1. Device details, intended use and description.
2. Material of construction.
3. Working principle.
4. Label, package and inserts, IFU and User Manual.
5. Summary of serious AER and action taken by authorities.
6. Site or plant master file.
7. Constitution details of the firm.
8. Essential performance and safety checklists.
9. Undertaking for compliance to fifth schedule(QMS ISO 13485)

DOCUMENTS FOR CLASS B.C&D DEVICE SCH 4

1. Constitution of the firm.
2. Site/ Plant Master File.
3. Device Master File. With BIS standard conformity assessment report for EACH Device
4. Essential Checklists for compliance to safety and Performance of MD.
5. Test License if any .
6. Undertaking of compliance to QMS.

REQUIREMENTS FOR IMPORTERS CLASS A DEVICE

Power of Attorney by Foreign Manufacturer in Favour of Authorised Indian Agent (Authenticated by First Class magistrate in India OR Indian Embassy in the Originating Country of Apostile Services recognized in the originating Country) on Standard Format Provided.

All the documents required for Manufacturing License.

In addition the Authorised agent will submit the following to get the import license.

MD-14 Duly filled in.

THE FOREIGN MANUFACTURERS CAN'T REGISTER DIRECTLY.

REQUIREMENTS FOR IMPORTERS CLASS A DEVICE

- Notarized copy of overseas Plant or Site registration., and Free sale Certificate of the Manufacturer.
- Notarized copy of QMS Certificate issued by competent authority in respect of the manufacturing site.
- Self attested copy of Manufacturing License or Wholesale License.
- Copy of inspection report carried out by the Regulatory or Notified bodies within last three years.

FEES FOR IMPORT LICENSE

1

CLASS A MD- SITE FEES $1000 AND EACH DEVICE FEES $ 50

2

CLASS B MD- SITE FEES $2000 AND EACH DEVICE FEES $ 1000

3

CLASS A MD- SITE FEES $3000 AND EACH DEVICE FEES $ 1500

REQUIREMENTS FOR IMPORTERS CLASS B,C AND D DEVICES TO BE SUBMITTED BY AUTHORIZED AGENT

1. Constitution of the manufacturing firm.
2. Site/ Plant Master File of manufacturing firm
3. Device Master File for EACH Device with test reports on compliance to standards.
4. Essential Checklists for compliance to safety and Performance of MD.
5. Undertaking of compliance to QMS.
6. MD-14 Duly filled in.

SITE OR PLANT MASTER FILE CONTENTS

1. General information- Name and addres of company and site, number of employees, type of Medical Devices handled, any other activities in the site, QMS Description summary.

2. Personnels- Qualifications and designations and responsibility, training and hygiene.

3.Equipment- List of equipment for Quality Control, maintenance and Calibration procedures and records.

4.Sanitation requirements.

5. Production process, quality validations and rejections handling.

SITE OR PLANT MASTER FILE CONTENTS

6. Premises and facilities- Ventilation, handling of hazardous materials, fixtures, water handling schematics.

7. Quality assurance and release of finished products.

8. Storage of raw materials and finished goods condituons.

9. Documentation storage and control.

10. MD Complaints handling procedures.

11.Internal Audits procedures and records.

12.Contract activities.

DEVICE MASTER FILE

1. Executive Summary-

A. Device Descriptions, intended use etc.

B. Sterilization requirement, process details if sterilization is required.

C. Risk management.

D. Clinical evidence for new equipment.

E. Regulatory status of similar devices in India(approved or not approved)

F. Declaration of conformity.

G. Domestic pricing of the device.

DEVICE MASTER FILE

H. List of regulatory approvals in other countries.

I. AER and corrective actions and other safety evaluations.

2. **Device description and product specification, including variants and accessories**

3.Labelling , IFU , Catalogues and Manual

4. Design and manufacturing informations

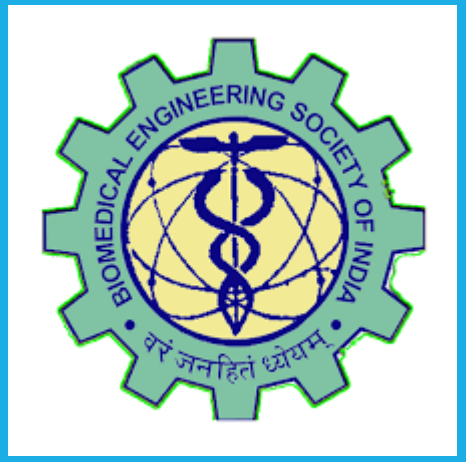
5. Essential principal checklists.

6. Risk analysis and control summary.

7. Verification and validation information

8.Biocomatibility, stability

QUALITY MANAGEMENT SYSTEM



1. General requirement.
2. Applicability
3. Terms and definitions
4. General QMS
5. Documentation and control
6. Quality Manual
7. Management responsibility
8. Quality Policy

QUALITY MANAGEMENT SYSTEM

9. Planning
10. Management review.
11. Resource management.
12. Product realization.
13. Customer management.
14. Design and development.
15. Purchasing
16. Service and installation.

QUALITY MANAGEMENT SYSTEM

17. Measurement and analysis

18. Internal Audit and feedback.

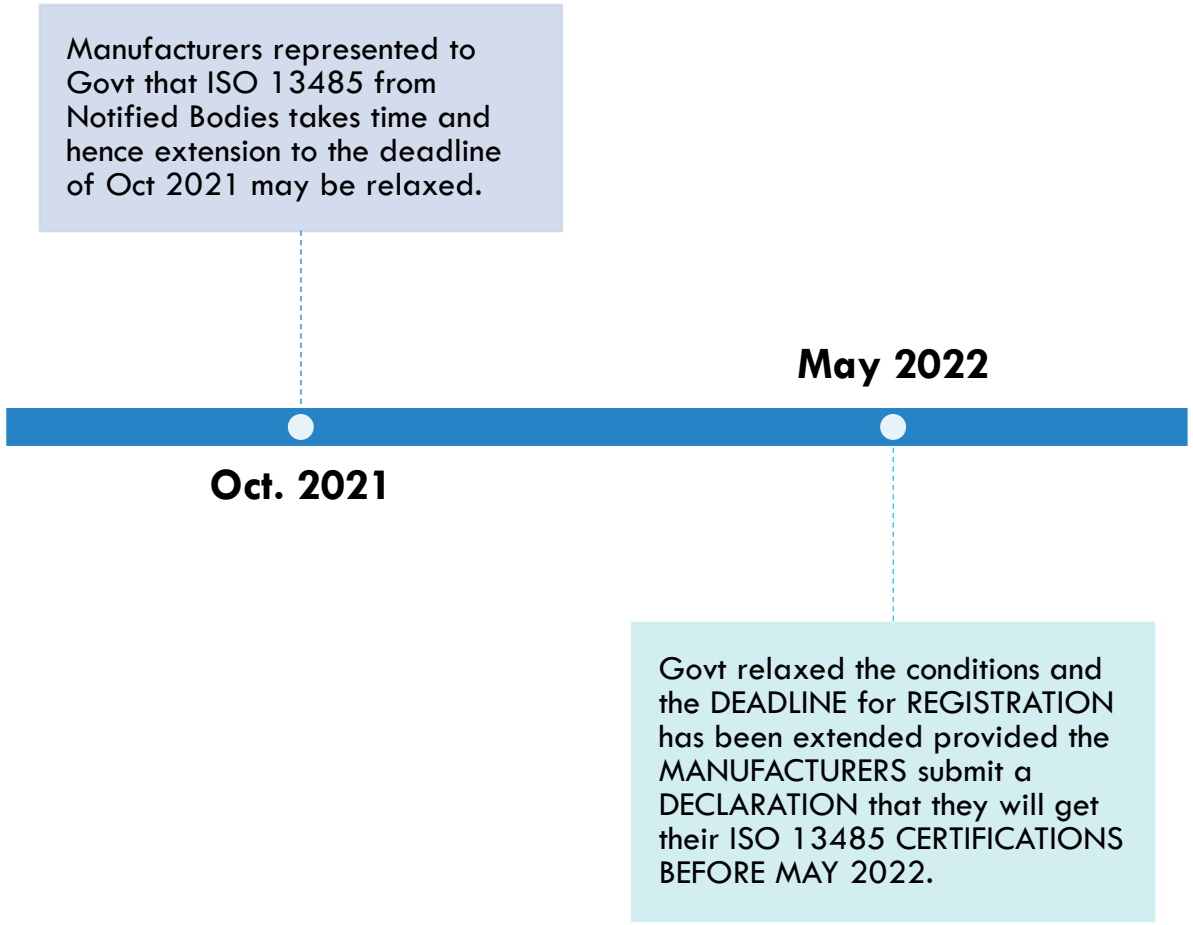
19. Control of non conforming products

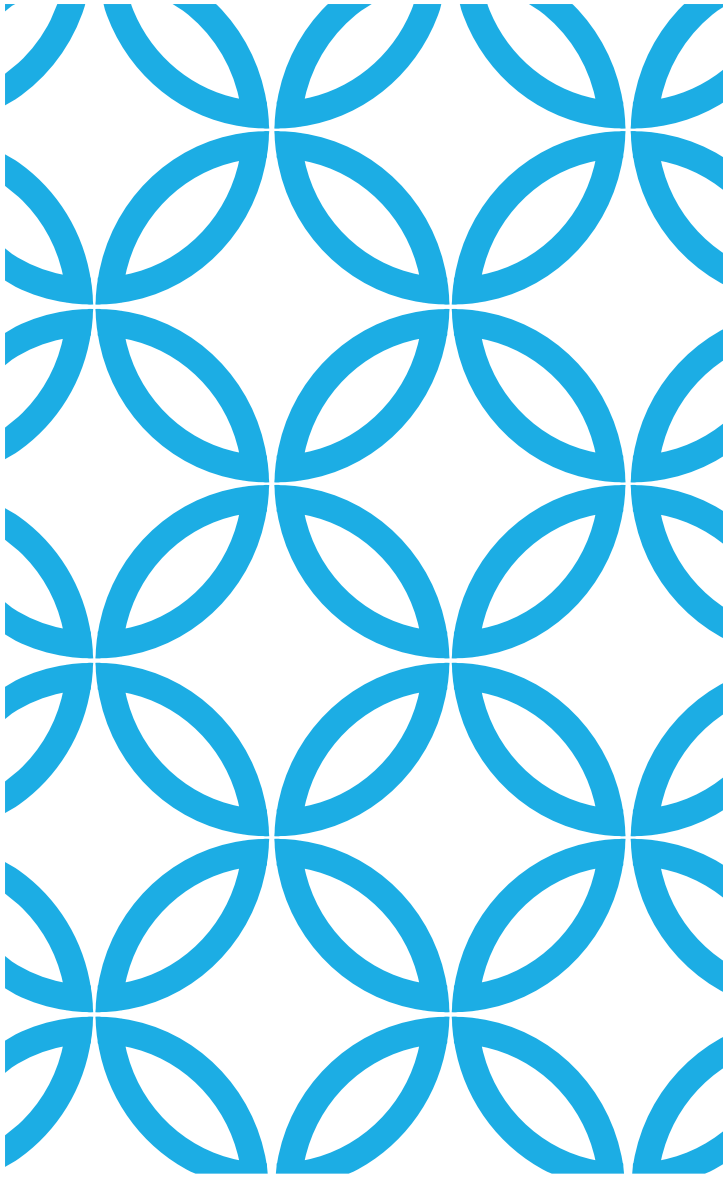
20.Corrective and preventive actions

LIST OF FORMS

- MD-3- Grant of Manufacturing license for Class A & B Devices.
- MD-4- Grant of Loan manufacturing license for Class A&B MD
- MD-7-Grant of Manufacturing license for Class C&D MD
- MD-8- Grant of loan manufacturing for Class C&D MD
- MD-14- Application for import of MD

STATUS UPDATE





THANKS FOR WATCHING

Q/A