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RECENT ADVANCEMENT AND RULES REGULATIONS RELATED TO MEDICAL DEVICES AS PER CENTRAL DRUGS STANDARD CONTROLORGANIZATION (CDSCO) IN INDIA IN COMPARISION WITH SOUTH KOREA

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ABSTRACT

Medical device in India are regulated as drugs by the Central Drugs standard & control organization (CDSCO) as per the provisions of Medical device rules 2017 issued by the Govt under the Drug and cosmetics Act 1940, which are the new regulations for medical device in India, keeping pace with the requirements. These rules cover various aspects of device related regulations, advancement, including classification, registration, manufacturing and import, labelling, sales, and post market requirements, etc. The rules are a positive step and encompass most of the CDSCO approval process, which mandates that the devices are safe and performs its intended function. However, with rapid advancements in medical device technology, much is desired in clarity and revamping of the current regulatory system to harmonize standards to be in-line with advanced regulations. In vitro diagnostic medical device is an important segment in the global health care industry at a value for treatment medical diagnosis of general well being of public.

INTRODUCTION

Medical devices have been used to treat and diagnose disease since antiquity. There is evidence oftrephination having been performed in Neolithic times and instruments have been excavated in Jericho from 2000BC

1. Today devices are widely used in all branches of medicine, surgery and community care.
2. The device industry is a major one, with worldwide sells of more than 110 billion per year.

A medical device is defined according to schedule M-III creates a specific definition of medical devices as separate from drugs, unlike a drug, a medical device is defined as a medical tool"which does not achieve its primary intended action in or on the human body by pharmacological,immunological, or metabolic means".

Medical products covered by the Drugs and Cosmetics Act (DCA) will not fall under schedule-M.

If there is any uncertainty about whether the product falls under the drug or medical device category of the DCA under this schedule, regulators will consider the principal mode of action of the product.

AIM AND OBJECTIVES

The aim of work is to study about recent advancement in Indian medical rules and regulation concerning or related to medical devices including.

OBJECTIVES

The objective of the work as follows;

- To evaluate the rules and regulation/regulation requirements required for medical devices and Drugs and cosmetic act 1940 and rules 1945, devices rules 2017.
- To list out major changes in the regulation of medical devices with implementation of medical devices rules 2017.

Definition and Application

Medical devices: - (WHO definition)

These are the instruments, apparatus or machine which are used for diagnosis, treatment, prevention of illness or diseases or detecting, measuring, restoring, correcting or modifying the structure or function of the body for health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.

Classification

Medical devices are classified as per the risk level and intended uses.Classification by CDSCO and MDD

1. Class A -Devices involving low risks levels (Thermometer)
2. Class B -Devices involving low to medium risk (Hypodermic Needle)
3. Class C -Devices involving moderate to high risk (Lung ventilator)
4. Class D -devices involving high risk (Heart valve,

implantable device)

Fig. no. 1

Regulatory Authorities

Device Class / Activity	Class A	Class B	Class C	Class D
IMPORT	CLA	CLA	CLA	CLA
MANUFACTURE	SLA	SLA	CLA	CLA
Permission to conduct CI	Permission from CLA			
SALE	**SLA**			
QMS Verification by	*Notified Body	*Notified Body	CLA	CLA

***Note:** **Notified Bodies shall be registered with Central Licencing Authority. Prior inspection shall not be required before the grant of manufacturing of Class A devices.**

Table no. 1

Regulation in india

In India medical devices are governed by CDSCO (Central Drugs Standard Control Organization) which is regulated by Directorate general of health services, Ministry of health and Family Welfare, Government of India.

India's medical device regulation structure;

⬇

Ministry of health and welfare

⬇

Drug controller general of India

⬇

Central drugs standard control organization (CDSCO)-medical devices division

Import of medical devices

The import of medical devices in the country has seen an increase in the past three years amid Central and State government's efforts to promote local manufacturing of medical equipment. In 2020-21, India imported $6.24 billion worth of medical devices, up from $5.84 billion in 2019-20 and $5.7 billion in 2018-19.

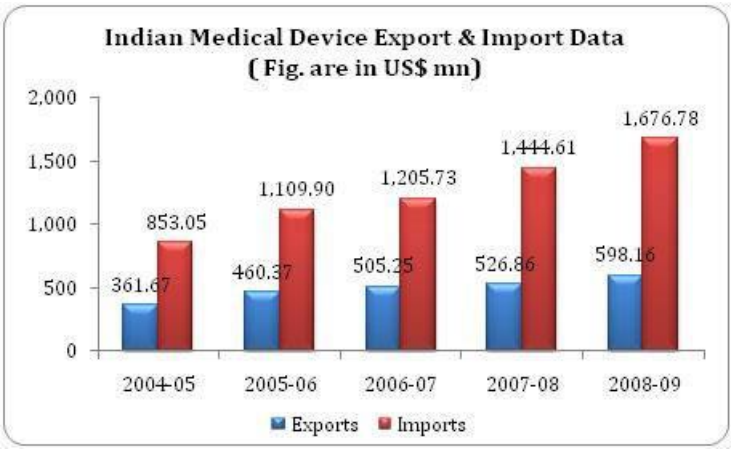


Fig. no. 1.1

Personal and Hospital of medical devices:-Personal use

Personal protective equipment: Wearing a protective gear, including gloves, aprons, and gowns, and eye protection, is a crucial component of infection prevention and control for nurses and other healthcare workers. Effective assessment, knowledge of how different PPE type work in difference clinical settings, and an appropriate application are all necessary for its use. Understanding the purpose of PPE can help nurses use it effectively, cut down on wasteful spending, and maintain the nurse-patient relationship as the foundation of care. This article describes PPE, its components, when it should be used, and how it should be utilized.

Blood pressure monitor

A sphygmomanometer, also called as a blood pressure monitor, or blood pressure gauge, is a device used to measure blood pressure composed of an inflatable cuff to collapse and then release the artery under the cuff in a controlled manner, and a mercury or aneroid manometer to measure the pressure. Manual sphygmomanometers are used with a stethoscope when using the auscultatory technique.

Fig. no. 1.2

Labeling requirements for registration of medical devices in india

Medical device manufacturer must follow the labeling requirements and must be done on every medical device packaging.

The CDSCO is the INDIAN FDA which handles all the regulation for the medical devices in India.

On September, 2014 the CDSCO issued amendments to the Drugs and Cosmetic rules, 1945. An important amendment for the medical devices manufacturer to observe is Rule 109A-

Labelling requrements

Medical devices which require registration in India includes;

- Spinal needles
- Surgical sealants
- Cardiac stents

- Dental implants
- Surgical sealants
- Heart valves

Clinical Investigation of Medical Device and Clinical Performance evaluation of New in vitro Diagnostic Medical Device

Conduct of clinical investigation

No person or sponsor shall conduct any clinical investigation in respect of investigational medical device in human participants except in accordance with these rules and in accordance with the permission granted by the Central Licensing Authority.

Duties of medical device officer

- Subject to the instructions of the Central Licensing Authority or State Licensing Authority, as the case may be, it shall be the duty of Medical Device Officer
- Provided that in case of large sized medical device, wherein the opinion of the Medical Device Officer drawing samples of such a device may not be physically practical, such large sized medical device shall be inspected at the place where these are kept by the Medical Device Officer with or without expert and evaluated or tested by the Medical Device Testing Officer

Duties of notified body

A registered Notified Body, referred to in rule 13, shall carry out its duties and functions, in respect of Class A or Class B medical devices as specified in Part II of the Third Schedule

Procedure to be adopted by notified body

A registered Notified Body shall carry out its duties and functions either by itself or by any other qualified person on its behalf as per specified procedure as detailed in Part II of the Third Schedule.

Fees to be charged by notified body

A registered Notified Body may charge fee from the applicant for the services rendered by it as may be determined by the Central Government.

Sale of medical devices

- The Indian Medical Devices market is expected to be worth $11 billion by 2023.
- Global medical devices market is around 252 billion US dollars
- In 2011, the Indian medical devices market generated $3 billion in sales.
- The opportunities lie in the emerging regions of the country. With the market relying largely on imports, the country provides significant opportunities for multinational medicaldevice manufacturers.
- The domestic manufacturers are mostly engaged in low-value products like syringes, needles, catheters, blood collection tubes, medical electronics, medical equipmentand implants.
- The Indian medical devices market will benefit from the expansion of health Insurance.
- Future growth in the medical devices market is also expected to be driven by patient demographics, particularly with the rise in the country's aging population, which has increased incidence of age-related diseases, such as cardiovascular disease and Alzheimer's disease.

Rules and Regulation related to medical devices in india comparision with south korea

	India	**South Korea**
Regulatory Body	CDSCO Central Drug Standard Control Organisation	KFDA Korea Food And Drug Administration or MFDS Ministry Of Food And Drug Safety
License	Shall be issued in the form 28	KMLE Korean medical licensing examination
Classification	Class A: Low Risk Class B: Low to medium risk Class C: Medium to high risk Class D: High risk	Class A: Low Risk Class B: Low to medium risk Class C: Medium to high risk Class D: High risk
Clinical trial application	Trial form 44 is an application for strating clinical	Filling submission pre and post approval registration forms through online
Application Fee	Phase I : 50000 Phase II : 25000 Phase III: 25000	Class I : US $ 73 Class II : US $ 112 Class III: US $ 617 With SE
Application Submission	Form 44 have to be submitted	KLH Korea Liecnse Holder
Approval Timeline	16-18 weeks	Class I : 0 Days Class II : 25 Days

		Class III: 65 Days With SE
Institutional review board	DCGI and ethics committe approval requirement	MFDI Minstry of food and drug safety
Post market clinical evidence	Vigilance reporting	Medical device manufacture conduct a through assumption of a device performance in real life comparing through an ideal clinical situation

Micellaneous regulations

Exemption from provisions related to medical devices

The medical devices specified in the Eighth Schedule shall be exempt from the provisions of theserules to the extent and subject to the conditions specified in that Schedule.

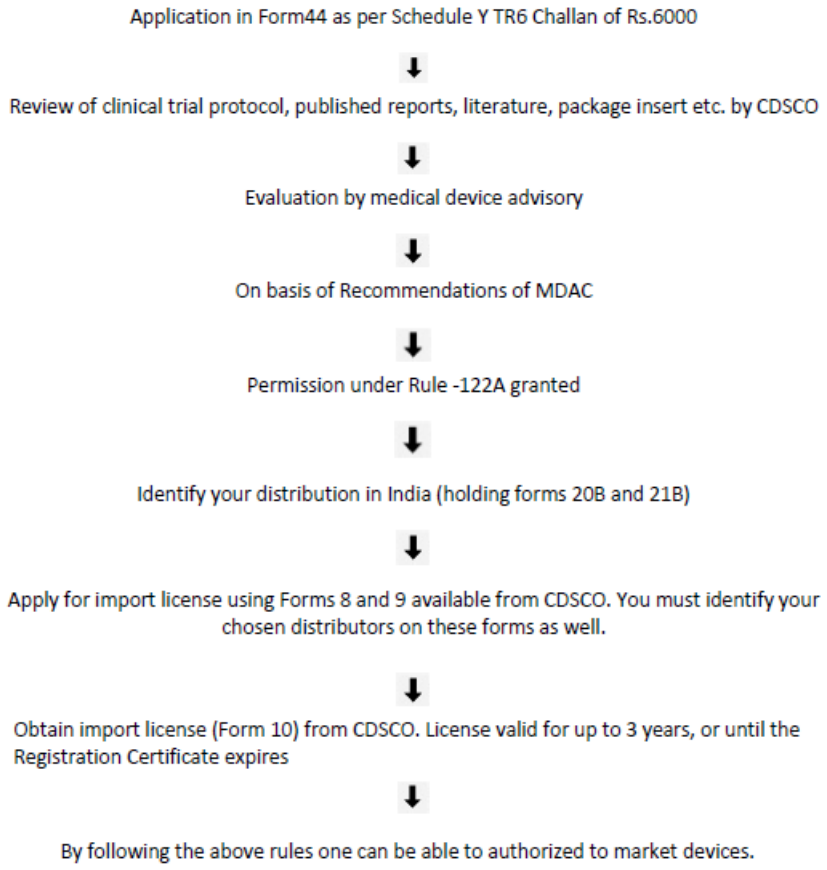
Export of medical devices

Where a person intends to export any medical device, manufactured in India, and for that purpose, requests a certificate in the nature of free sale certificate or a certificate about quality, safety and performance in relation to that medical device as required by the authority concerned of the importing country, such person, may apply to the Central Licensing Authority for the purpose along with a fee as specified in the Second Schedule and the said authority shall, if the requirements are fulfilled, issue a certificate to the applicant.

Rejection of application

If any document submitted by an applicant for grant of licence for import /manufacture/ test licence/ permit for personal use or permission to import /manufacture investigational medical device or new in vitro diagnostic medical device or permission to conduct of clinical investigation or clinical performance evaluation is found to be misleading, fake/fabricated, the application, after giving an opportunity to the applicant of being heard shall be summarily rejected.

Approval of new medical devices



Registration of medical devices in india

The following steps are followed to register and/or import medical devices in India.

1. Appoint a local agent in India to be the applicant and license holder.
2. Prepare a Device Master File (DMF)

3. Prepare a Plant Master File (PMF)
4. Prepare application Form /supporting documents
5. Submit above documents to DCGI with fees
6. DCGI reviews and sends back an enquiry letter
7. Applicant responds and addresses inquiries made by the DCGI
8. DCGI may request technical presentation
9. Approval granted, if the information provided by applicant suffices the requirements

New medical devices rules (2020)

As medical devices deal with the health and safety of the patients, their manufacturing is done in a strictly regulated environment, and they fulfill stringent regulatory environment, and they fulfill stringent regulatory requirements and guidelines.

While the drug regulations in India are well defined regulations for medical devices was missing for long. Nevertheless, Indian regulatory regime for medical devices has recently been very active.

Medical devices and Diagnostic division of Central Drug Standard Control Organization (CDSCO) has developed structured regulations for medical devices, IMDR which was released in January 2017 and came into force from January 2018.

"IMDR was amended in February 2020 as 'Medical Devices Rules 2020' and came into force in April 2020."

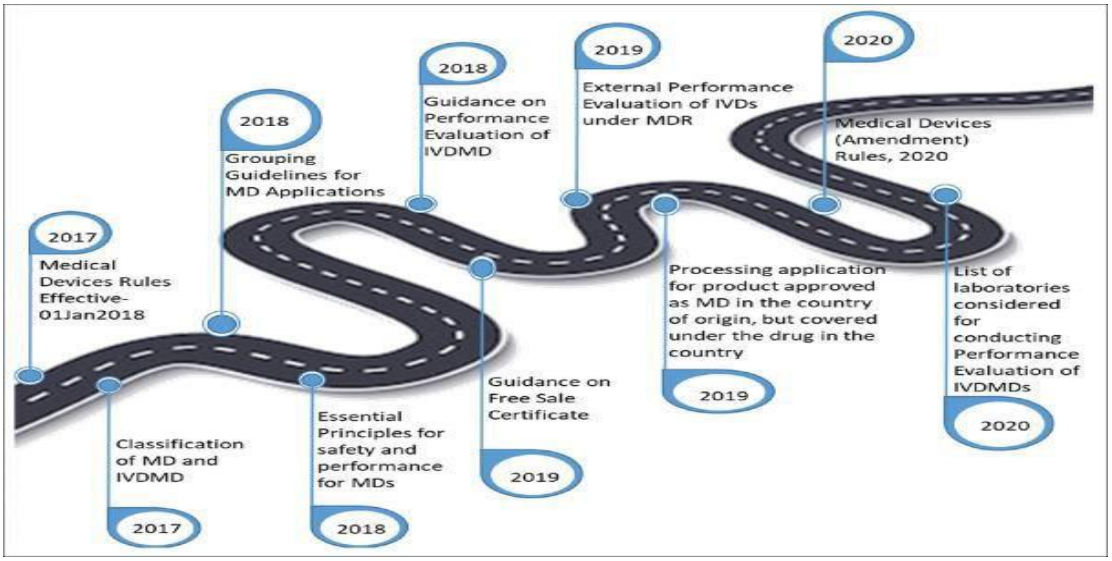


Fig. no. 1.3

Top medical device companies (2021)

- Abbott Laboratories
- Medtronic PLC
- Baxter International
- Danaher Corporation
- General Electric
- Stryker Corporation
- Johnson & Johnson

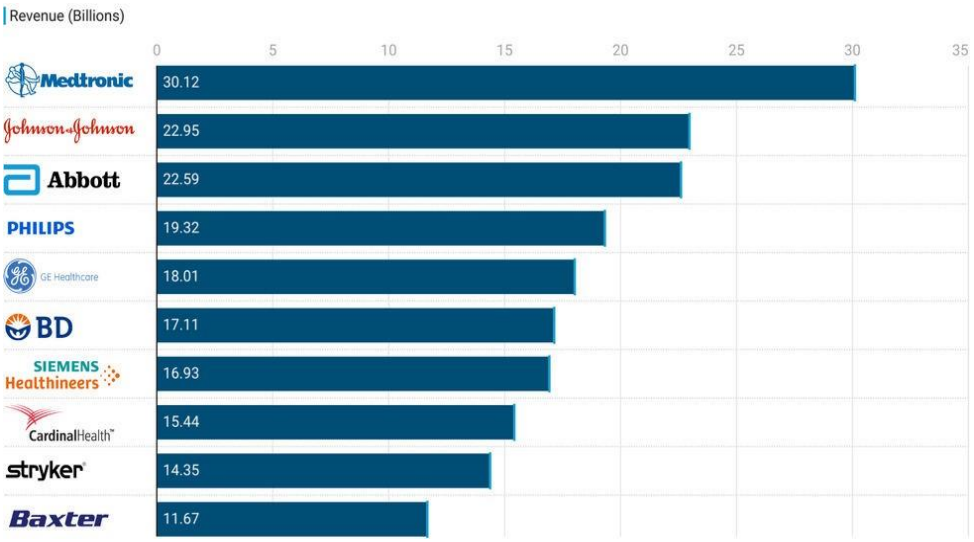


Fig. no. 1.4

RESULTS AND DISCUSSION

Safety, Quality and Efficacy of medical devices under Drugs andCosmetics act

Essential principles of Safety and Performance of medical Devices

A medical device is said to be clinically effective when it exhibits the effect intended by the manufacturer according to the medical condition, for instance, a pain relief medical device should relieve pain as per the manufacturer's intended use. In such a scenario, the manufacturer needs to have clear objectives and a scientific proof such as results from the clinical tests which assures that the pain has relived when using the device.

A medical device is to be devised and developed by assuring that: -

- Any risk related to the utilization of the device are compatible with a high level of health and safety and acceptable risks must be omitted when weighed alongside the aimedadvantage to the patient.
- The clinical condition or patient safety, or the health and safety of the user or any other individual will not be compromised under the circumstances and for the objectives for which the device was aimed for.

Central licensing authority

Funtions

- Approval of new drug and clinical trials
- Banning of drug and cosmetics
- Grant of test license, personal license
- Import registration, licensing and approaching of blood banks, vaccines, medical devices.

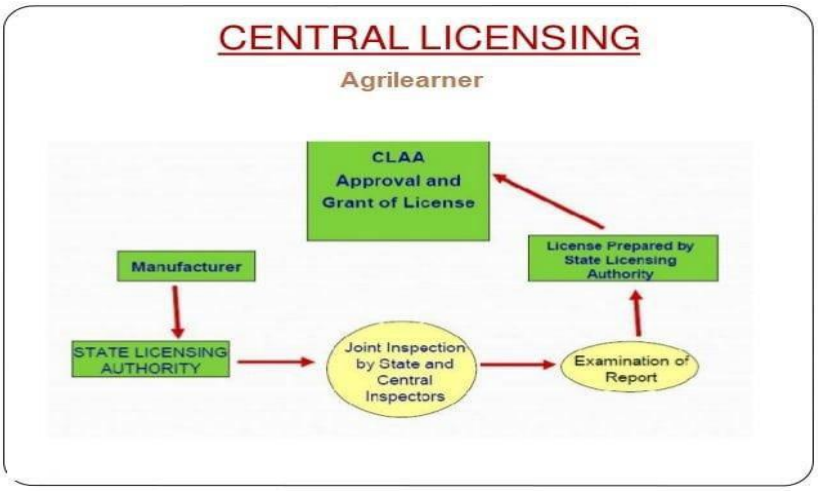


Fig. no. 1.5

Quality management system based on iso

ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that will meet customer and regulatory requirements. Such organization can also be involved in different stages like design development, production, storage, and distribution, installation, or serving of a medicaldevice.

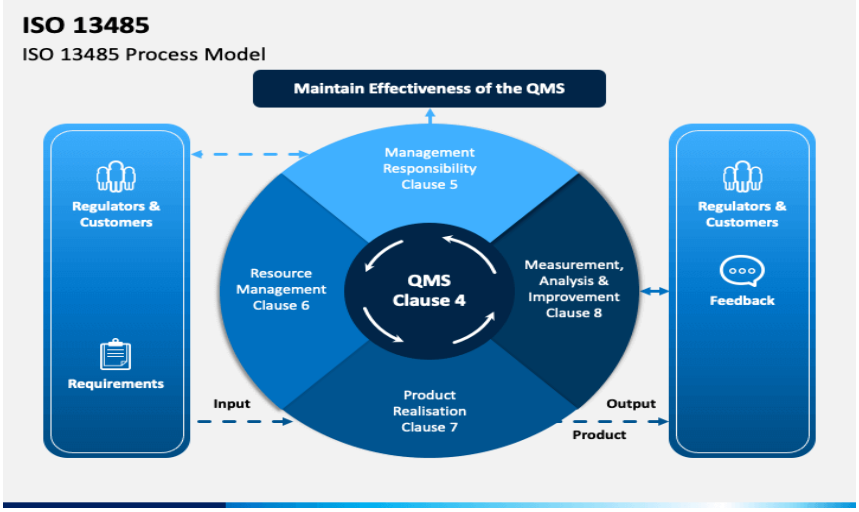


Fig. no. 1.6

Drug controller general of india (DCGI)
Drug Controller General of India (DCGI) is the head of department of the Central Drugs Standard Control Organization of the government of India responsible for approval of license of specified categories of drugs such as blood and blood products, IV fluids, vaccines, and sera in India. DCGIcomes under the Ministry Of Health and Family Welfare. It also set standard for manufacturing, sales, import, and distribution of drugs of India.

Drug master files
Good manufacturing practice regulations for medical devices
Organizations or persons who submit IDEs, 510(k)s, or PMAs, or other device-related submissions to FDA may use contract manufacturers, sterilizers, packagers, etc., in the manufacture of their devices. The latter, for trade secret or confidentiality purposes, may submit a description of its facilities, manufacturing procedures and processes, and quality control procedures in an MAF rather than provide this information directly to the client for inclusion in itssubmission.

Roles and Responsibility of medical device officers
The establishment of a medical device officer (MDO) role is integral to improving medical device incident reporting and learning within organizations. One of the Medical Device Officer's key roles is to promote the safe use of medical devices across their organization and provide expert device. As well as improving the quality of reporting, the Medical Device Officer will be the essential link between the identification and implementation of medical device safety initiatives and the daily operations to improve the safety of medical devices.

Clinical trials for medical devices
- Detection, diagnosis, prevention, monitoring.
- Treatment or alleviation of any physiological condition or state of health, or illness.
- Replacement or modification or support of the anatomy or congenital deformity.
- Supporting or sustaining life.
- Disinfection of medical devices.
- Control of conception.

Post-Marketing approval
The permission holder of Form MD-27 shall inform the date of launch of a medical device in the market to the CLA and shall submit Periodic Safety Update Report from the date of launch in the market and such report shall be submitted every six months for first two years followed by submission of the said report annually for the two more successive years.

The expansion of the definition of medical devices and the requirement to obtain registration for medical devices should not come as a surprise because the Government had published a draft of these notifications in October 2019. It was covered extensively at the time, including by us.

Risk Analysis and Control memory on medical devices
- Risk analysis is now required by law.
- Identification of device design problems prior to distribution eliminates costs associatedwith recalls.
- It offers a measure of protection from product liability damage awards.
- Regulatory submissions checklists used by the FDA now call for inclusion of risk analysis.
- It is the right thing to do.
- Product Liability.
- To ensure safety of the device.
- To ensure that any unsafe device that do reach the market are promptly identified and efficiently corrected.
- Risk management system demonstrates that the manufacture providing safe device.

Risk control
Process through which decisions are reached and protective measures are implemented for reducing or maintaining risk within the specified level.

Risk control measures
Protective measures, e.g., default operating modes Information for safety, e.g., warnings in labelling Many measures require intervention
- The correct response for the circumstances, e.g., a patient-specific response
- Timeliness

CONCLUSION
- The regulations of medical devices focuse on overall improvement of patient treatment and appropriate use of medical devices.
- The number of medical devices are growing rapidly, therefore a great need for increase awareness of potentially involve a medical device of technology not only to the health care practitioners but also to the patient and their families.
- Increasing appropriate use of medical devices and monitoring adverse effects of medical products will decrease adverse events and harmful reactions by focusing on safety efforts, improve the overall effectiveness of the treatment.

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