This

Draft Bill

is hosted for inviting comments, suggestions etc. for improvement.

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THE MEDICAL DEVICES REGULATION BILL, 2006
No XX of 2006

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THE MEDICAL DEVICES REGULATION BILL, 2006

No XX of 2006

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BILL

To consolidate laws related to medical devices and to establish the Medical Device Regulatory Authority of India for establishing and maintaining a national system of controls relating to quality, safety, efficacy and availability of medical devices that are used in India, whether produced in India or elsewhere and exported from India.

Be enacted by the Parliament

in the Fifty Seventh Year of the Republic of India as follows:

	CHAPTER 1: PRELIMINARY	
AA	1) This Act may be called The Medical Device Regulation Act, 2006 2) It extends to whole of India 3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint, and different dates may be appointed for commencement of different provisions of this Act and any reference in any such provision to the commencement of this act shall be construed as reference to the coming into force of that provision only 4) The provisions of this Act which are not specifically notified under clause (3) above shall come into force by the 31st of December 2009 and thereafter the design, manufacture, packaging, labeling, import, sale, usage and disposal of medical devices in India shall be in accordance with the provisions of this Act. 5) Any reference in this Act to a law, which is not in force in the Sate of Jammu and Kashmir, shall, in relation to that State, be construed as a reference to the corresponding Law, if any, in force in that State.	Short title, extent and commencement

AB	6) Having regard to the proposal for ensuring the safety of the public in the use of medical devices, and the fact that the content and scope of the present laws of the country including the regulations and administrative provisions in force do not extend to and cover adequately the safety, health protection and performance characteristics of medical devices; and that in the amendments to the Drugs and Cosmetics Act, 1940, the scope of the definition of the expression 'drugs' has been extended to cover 'devices'; whereas this definition does not adequately cover all the products which are covered by the current internationally accepted definition of 'medical devices'; 7) Whereas it is clear from international experience in the regulation and use of medical devices, that the optimum assurance of medical device safety has several essential elements, viz.: • Absolute safety cannot be guaranteed • It is a risk management issue • It is closely aligned with device effectiveness / performance • It must be considered throughout the life span of the device • It requires shared responsibility among the stakeholders 8) Whereas a diverse range and multitude of medical devices are in use, which are manufactured using a wide variety of technologies with the result that for ensuring the safety of the public in the use of medical devices an entirely different system and method of regulation from the current national and international practices that are being applied for the regulation of drugs and cosmetics is required; 9) Whereas, the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonized with global provisions in order to guarantee the free movement of such devices within the country and into the global market; 10) Whereas, to ensure that medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; it is necessary to improve, the level of regulation, supervision and control over medical devices manufactured in or imported into the country;	Preamble

AC	11) Therefore, it is found expedient in the public interest, that the Union should enact a law to bring under its control the safety and performance of all medical devices.	Declaration as to expediency of control by the Union
AD	12) In this Act, unless the context otherwise requires: - a) 'accessory' means an article which though not being a device is intended specifically by its manufacturer to be used together with or as part of a device to achieve the intended use of the same by the manufacturer of the device; b) 'adverse event/incident' means possible fault(s) or failure(s) of the medical device, difficulties in using the medical device or an undesirable outcome associated with the use of the medical device, that can or does result in permanent impairment, injury or death to the patient or the user. a) 'advertisement' means any audio or visual publicity, representation or pronouncement made by means of any light, sound, smoke, gas, print, electronic media, internet or website and includes publication through any notice, circular, label, wrapper, invoice, books, magazines or other documents or other media; b) 'Authority' means the Medical Devices Regulatory Authority of India (also hereinafter referred as MDRA) established under this Act; c) 'CEO' means, the Chief Executive Officer of MDRA d) 'Conformity Assessment Certificate', means a certificate of conformity issued under this Act. e) 'Custom made device' means any medical device specifically made in accordance with a written prescription given by a person authorized for the same by virtue of his professional qualifications, or by a duly qualified medical practitioner, under his responsibility, and in accordance with specific design characteristics and is intended for the sole use of a particular patient or patients. Explanation: Mass produced devices which only need adaptation to meet the specific requirements of the medical practitioner or any other professional user are not considered to be custom made devices. f) 'date expired medical devices' means medical devices, which have exceeded its shelf life period or date of expiry, if any as indicated in the device label. g) 'efficacy' with reference medical device means, quality established through a valid scientific evidence that a medical device would produce an intended clinical effect on	Definitions

	a target population; h) ‘harm’ means any physical injury or damage to the health of people or damage to property or the environment; i) ‘hazard’ means a potential source of harm j) ‘health professional’ includes a person who is a medical practitioner, a dentist or any other health worker and would include a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, pharmacist, physiotherapist and any other paramedic; k) ‘Import’ means bringing into India any medical device by land, sea or air; l) 'intended purpose' means the use for which the medical device is intended according to the information provided by the manufacturer on the device, label, cover or packing material or in the instructions, booklet or leaflet and/or in promotional materials accompanying the product; m) ‘Label’ means any tag, brand, mark, pictorial or other descriptive matter, written, printed stenciled, marked, embossed, graphic drawn, perforated, stamped or impressed on or attached to the container, cover, lid of any medical device package and includes the literature or instruction provided by the manufacturer within the medical device package (usually known as product insert); n) "manufacturer" means - (a) the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, or in the name of a firm or company, regardless of whether these operations are carried out by that person by himself or on his behalf by a third party; or (b) any other person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name, apart from a person who assembles or adapts devices already on the market to their intended purpose for an individual patient; o) ‘Medical device' means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: i) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the	

	specific purpose(s) of: – diagnosis, prevention, monitoring, treatment or alleviation of disease, – diagnosis, monitoring, treatment, alleviation of or compensation for an injury, – investigation, replacement, modification, or support of the anatomy or of a physiological process, – supporting or sustaining life, – control of conception, – disinfection of medical devices, – providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; ***And*** ii) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means; p) 'Medical device intended for clinical investigation' means any medical device intended for use by a duly qualified medical practitioner or by a person authorized to use the same by virtue of his professional qualifications for conducting investigations in an adequate human clinical environment; q) 'medical device testing laboratory' means any medical device laboratory or Institute established by the Central or a State Government or any other agency and accredited to the National Accreditation Board for Testing and Calibration Laboratories (NABL) or an equivalent accreditation agency and/or recognized by MDRA; r) 'misbranded product' means an article of medical device of any of following categories where it purports, or is represented to be, or is being – (1) offered or promoted for sale with false, misleading or deceptive claims either upon the label of the package,	

		or through advertisement, or where it is sold by a name which belongs to or is misleadingly similar to another article of medical device or product ; or offered or promoted for sale under the name of a fictitious individual or company claiming to be the manufacturer or the producer of the article as borne on the package containing the article or the label on such package; (2) where it is sold in package which have been sealed or prepared by or at the instance of the manufacturer or producer bearing his name and address but the article is actually an imitation of, or is a substitute for, or resembles in a manner likely to deceive a person to believe that it is another article of medical device marketed under the name under which it is sold, and is not plainly and conspicuously labeled so as to indicate its true character; or the package containing the article or the label on the package bears any statement, design, or device regarding structure of the product contained therein, which is false or misleading in any material particular, or if the package is otherwise deceptive with respect to its contents; or the article is offered for sale as the product of any place or country which is false; (3) if the article with in the package contains any component which is not mentioned in the declarative label, or the package is not labeled in accordance with the requirements of this Act, or contravenes any of the provisions of this act, or the rules and regulations made thereunder; or is offered for sale for special uses, unless its label bears such information as may be specified by rules and regulations as might be prescribed , concerning its components in order sufficiently to inform its purchaser as to its value for such use; s) 'Notified Body' means a body corporate or other legal entity notified by the MDRA as competent to carry out the assessment, verification and certification of medical devices before they are placed on the market by manufacturers as being in conformity with the requirements of this Act, and the rules thereunder; t) 'package' means box, bottle, casket, case, pouch, receptacle, bag, wrapper, container, or other thing in pre-packed condition, in which the medical device is subsequently packed; u) 'patient' means and includes person and families purchasing and/or receiving medical devices in order to meet their	

	healthcare needs of themselves or their relatives; v) 'performance' means, satisfactory functioning of the medical device as intended and in accordance with the declarations in the associated labeling and in conformity with applicable technical specifications and relevant product standards; w) 'placing on the market' means the making available in stores, shops, or any other market place for sale or distribution of a product, whether in return for a price, or payment or even free of any such charges, of a medical device other than a medical device intended for clinical investigation, with a view to market the same in India regardless of whether the product or device is new or fully refurbished; x) 'putting into service' means the stage at which a medical device, ready for use, is introduced in India for the first time for use for intended purposes; y) 'Refurbished device' means a medical device, or a part of the device, which is substantially rebuilt from one or more used medical devices of that kind so as to create a medical device that is able to be used for the purpose originally intended by the manufacturer of the original device; z) 'Registration' means the registration of medical device manufacturers under this Act; aa) 'Regulations' means regulations made by the MDRA under this Act; bb) 'risk' is defined as the combination of the probability of occurrence of harm and the severity of that harm; cc) 'risk management' in relation to medical device means, systematic application of policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk; dd) 'Safety' means freedom from unacceptable risk; ee) 'sale' with its grammatical variations and conjugate expressions means, the transfer of possession of a medical device, whether for cash or on credit or by way of exchange and whether wholesale or retail, for human consumption or use, or for analysis, and includes not only an agreement for sale, an offer for sale, the exposing for sale or having in possession for sale of any such article, but also an attempt to sell any such article; ff) 'sample' means a sample of any article of medical device taken under the provisions of this Act or under the rules and regulations made thereunder; gg) 'standard' in relation to medical devices means, any	

	standard fixed by national or international standard making bodies and notified by the MDRA; hh) 'Sterile medical device' means medical device intended to meet the requirements for sterility; ii) 'Tribunal' means the Medical Device Safety Appellate Tribunal established under this Act; jj) 'variant' in relation to medical device means, a medical device, the design of which has been varied to accommodate different patient anatomical requirements (for example, relating to the shape, size, length, diameter or gauge of the device), or any other approved variation, provided the variation does not change the intended purpose of the device;	

	CHAPTER 2: MEDICAL DEVICE REGULATORY AUTHORITY OF INDIA	
AE	13) The Central Government shall, by notification, establish a body to be known as the Medical Device Regulatory Authority of India (hereinafter called as MDRA) to exercise the powers conferred on, and to perform the functions assigned to, it under this Act. 14) The MDRA shall be a body corporate by the name aforesaid, having perpetual succession and a common seal with power to acquire, hold and dispose of property, both movable and immovable, and to contract and shall, by the said name, sue or be sued. 15) The head office of the MDRA shall be at New Delhi. 16) The MDRA may, in its discretion, establish its regional offices at any other place in India also.	Establishment of Medical Device Regulatory Authority of India
AF	17) The MDRA shall consist of the following nine members to be appointed by the Central Government, namely i) Two Members, to be nominated by the central government, not below the rank of Additional Secretary to the Government of India or equivalent rank to represent the Ministries or Departments of the Central Government dealing with (1) Science & Technology (ex-officio) (2) Health (ex-officio) ii) One eminent jurist, to be nominated by the Central Government in the manner prescribed by rules iii) Two eminent medical practitioners, to be nominated by the Central Government in the manner prescribed by Rules iv) Two eminent medical device technologists or scientists, to be nominated by the Central Government in the manner prescribed by rules v) Secretary General of Quality Council of India (ex-officio) vi) Chief Executive Officer (CEO) of MDRA, (ex-officio) 18) There shall be a Chairperson of the MDRA who shall be nominated by the Central Government from among the members other than the CEO. The Chairperson shall exercise such powers and discharge such functions as are laid down in this Act or as may be prescribed by rules or	Composition of MDRA and appointment of the Chairperson, CEO and Members

	regulations. 19) The CEO of the MDRA shall be appointed by the Central Government on the recommendations of a selection committee to be constituted by it. The selection shall be made in such a manner as to ensure the highest standards of competence and broad range of relevant expertise; regards being had also to the aspect of geographic representation from within the country.	
AG	20) The Central Government shall, for the purpose of selection of the CEO, constitute a selection committee consisting of: a) Cabinet Secretary – Chairperson b) Secretary, Department of Science and Technology, Government of India as convener-member c) Secretaries from the Departments or Ministries of Health, Law and Personnel, Govt. of India– members d) Chairman of the Public Enterprises Selection Board – member e) An eminent medical device technologist to be nominated by the Central Government – member Explanation: For the purpose of the sub clause (e), the Central Government shall nominate a person from amongst persons holding the post of Director or the Head, by whatever name called, of any national research or technical institution in the area of medical devices. 21) The Central Government shall, within two months from the date of occurrence of any vacancy by reason of death, resignation or removal of the CEO of the MDRA and three months before the superannuation or completion of the of office of the CEO, make a reference to the Selection Committee for filling up the vacancy. 22) The Selection Committee shall finalise the selection of the CEO within two months from the date on which the reference is made to it. 23) The Selection Committee shall recommend a panel of two names for every vacancy referred to it. 24) Before recommending any person for appointment as a CEO of the MDRA, the Selection Committee shall satisfy itself that such person does not have any financial or other interest, which is likely to affect prejudicially his functions as a Member.	Selection committee for the selection of CEO of MDRA

	25) No appointment of the CEO shall be invalid merely by reason of any vacancy in the Selection Committee	
AH	26) The term of office of a Member of MDRA other than ex officio Members shall be five years from the date on which they enter upon their offices, and shall be eligible for re-appointment for a further period of three years. 27) The term of office of an ex officio member of MDRA shall continue so long as he holds the office by virtue of which he is such a member 28) The chairperson and other members shall receive such allowances, if any, from the MDRA as may be prescribed by rules. 29) The Chairperson of MDRA shall have a rank not below that of a Secretary to the Government of India and the CEO, not below the rank equivalent to that of Additional Secretary to the Government of India 30) The Chairperson, CEO and every Member shall, before entering upon his office, make and subscribe to an oath of office and of secrecy in such form and in such manner and before such authority as may be prescribed by the Central Government 31) Notwithstanding anything contained in clause26, the Chairperson, CEO or any Member may: a) Relinquish his office by giving in writing to the Central Government a notice of not less than three months; or b) Be removed from his office in accordance with the provisions of clause 33. 32) The Chairperson, CEO or any Member ceasing to hold office as such shall not represent the cause of any person, firm or company before the MDRA in any manner thereafter.	Term of office of members
AI	33) Notwithstanding anything contained in clause 26, the Central Government may, by order, remove from the MDRA, its Chairperson, or any other Member, if he a) has been adjudged an insolvent; or b) has been convicted of an offence which, in the opinion of the Central Government, involves moral turpitude: or c) has become physically or mentally incapable of acting effectively as a Member; or d) has acquired such financial or other interests as is likely	Removal of Chairperson and Members of MDRA

	to affect prejudicially the discharge of his functions as a Member; or e) has so abused his position as to render his continuance in office prejudicial to the public interest. 34) No Member shall be removed under sub clauses (d) and (e) of clause 33 unless he has been given a reasonable opportunity of being heard in the matter.	
AJ	35) It shall be the objective of the MDRA to regulate and monitor the design, testing & evaluation, manufacture, packaging, labeling, import, sale, usage and disposal of medical devices, to ensure availability of safe medical devices for human use in the country 36) With a view to the implementation of the objects specified in clause 35, the MDRA may- a) Provide for notification of essential principles of safety and performance of a medical device and the requirements for design and manufacturing b) Provide for risk based classification of medical devices c) Notify the standards and guidelines in relation to medical devices and specify an appropriate system for enforcing various standards notified under this Act; d) Provide for a mechanism for conformity assessment using direct or third party notified bodies e) Notify the method of conformity identification by assigning marks or other means f) Specify the requirements pertaining to conformity assessment of imported medical devices, refurbished devices, date expired devices, custom made devices and other special cases g) Stipulate the procedure and guidelines for testing laboratories and referral testing laboratories and notification of the same; h) Provide for the exchange of information among the notified bodies and other enforcement authorities;. i) Prescribe methodology for implementing and operating a vigilance and post-market surveillance system and taking preventive and pro-active measures j) Provide for enforcement of the various provisions stipulated in this Act and those relating to offences k) Stipulate the manner and procedures for risk management and risk benefit analysis.	Objects and functions of MDRA

	l) provide for all or any of the other matters as specified in this Act 37) It shall also be the duty of the MDRA to a) provide scientific advice and technical support to the Central Government and the State Governments in matters of policy and principles in areas which have a direct or indirect bearing on medical device safety and efficacy; b) search, collect, collate and analyze relevant scientific and technical data particularly relating to: i) hazards with the use of medical devices ii) the exposure of individuals to risks related to the use of medical devices ; iii) incidence and prevalence of risks associated with medical devices; iv) identification of emerging risks ;and v) introduction of effective alert system ; c) promote, co-ordinate and issue guidelines for the development of risk assessment methodologies and monitor, conduct and forward messages on the risks associated with medical devices to the Central Government, State Governments and other enforcement agencies; d) provide scientific and technical advice and assistance to the Central Government and the State Governments in implementation of crisis management procedures with regard to medical device safety and to draw up a general plan for crisis management and work in close co-operation with the crisis units set up by the Central Government in this regard. e) promote networking of national and international organizations within and outside India with the aim of facilitating scientific co-operation, co-ordination of activities, exchange of information, implementation of joint projects and exchange of expertise, within the areas of operation of MDRA; f) provide scientific and technical assistance to the Central Government and the State Governments for improving co-operation with international organizations ; g) take all such steps to ensure that the public, medical professionals and interested parties receive rapid, reliable, objective and comprehensive information	

	through appropriate methods and means; h) provide, whether within or outside their area, training in medical device safety and standards for persons who are or intending to become involved in medical device businesses, whether as entrepreneurs or employees or otherwise; i) contribute to the development of national / international technical standards for medical devices; j) contribute, where relevant and appropriate, to the development of agreements, national or international, aimed towards standardization of metrology relating to medical devices; k) support international efforts to improve and harmonize standards relating to medical devices and regulatory practices; l) promote consistency between international technical standards and national medical device standards while ensuring that the level of protection adopted in the country is not reduced; and m) promote general awareness as to medical device safety and medical device standards. n) undertake any other task assigned to it by the Central Government to carry out the objects of this Act; o) provide guidance and support to industry to understand and comply with the regulatory requirements 38) Subject to the provisions of the Right to Information Act 2005 and except where such disclosure is necessary to protect public health, the MDRA and its officers and employees shall not disclose or cause to be disclosed to third parties, information that it receives from others with liability to maintain confidentiality.	
AK	39) The MDRA shall make regulations prescribing procedures in regards to the transaction of business at its meetings, notice, quorum, place of sitting etc. and follow the principles of equity, justice and good conscience in its procedures. 40) If the Chairperson is unable to attend a meeting of the MDRA, any other member nominated by the Chairperson on his behalf and, in the absence of such nomination or where there is no Chairperson, any member chosen by the members present from amongst themselves, shall preside at the meeting. 41) No act or proceedings of the MDRA shall be questioned or	Proceedings of MDRA

	invalidated merely on the ground of existence of any vacancy or defect in the constitution of the MDRA. 42) The MDRA shall meet as frequently as is necessary and not less than four times a year. The meetings may be convened at the initiative of the CEO or on directions from the Chairperson.	
AL	43) The MDRA may, with the approval of the Central Government, determine the number, nature and categories of officers and other employees required by the MDRA for the discharge of its functions. 44) Subject to such rules as may be made in this behalf, the MDRA may appoint such number of officers and employees as may be necessary for the exercise of its powers and discharge of its functions and may determine the designations and grades of such officers and employees. 45) Subject to such rules as may be made in this behalf, the CEO and other officers and employees of the Institute shall be entitled to such salary and allowances and shall be governed by such conditions of service in respect of leave, pension, gratuity, provident fund and other conditions of service as may be prescribed by regulations made in this behalf.	Staff of MDRA
AM	46) The Chief Executive Officer shall be the secretary and convenor of the MDRA. CEO and shall be responsible for - a) convening the meetings of the MDRA, and other committees b) the day-to-day administration of the MDRA; c) drawing up of proposal for the MDRA's work programmes in consultation with the Advisory Committee ; d) implementing the work programmes and the decisions adopted by the MDRA; e) ensuring the provision of appropriate scientific, technical and administrative support for the MDRA; f) ensuring that the MDRA carries out its tasks in accordance with the requirements of its users, and in particular, with regard to the adequacy of the services provided and the time taken; g) the preparation of the statement of revenue and expenditure and the execution of the budget of the	Functions of the Chief Executive Officer

	MDRA ; and h) Developing and maintaining contact with the Central Government, and for ensuring a regular interaction with its Advisory Committee and Technical Panels. 47) Every year, the Chief Executive Officer shall submit to the MDRA for approval a) Annual report covering all the activities of the MDRA in the previous year; b) programmes of work for the next year,; c) the annual accounts for the previous year; and d) the budget for the coming year. 48) The MDRA, from time to time, may give directions, on matters relating to medical device safety and standards, to the CEO, who shall be bound by such directions while exercising his powers under this Act; 49) The Chief Executive Officer shall approve all expenditure of the MDRA and report on the MDRA's activities to the Central Government. 50) The Chief Executive Officer shall have administrative control over the officers and other employees of the MDRA.	
AN	51) The MDRA shall, by notification, establish an Advisory Committee consisting of the following members: a) Chairperson of MDRA (Ex-officio) who shall be the chairman of the advisory committee b) CEO (secretary & convenor) of the advisory committee c) Representatives of the following concerned ministries or departments of : i) Science & Technology / National GLP Authority / National Accreditation Board for Laboratories ii) Biotechnology iii) DGHS / Drugs Controller General of India iv) Atomic Energy / Atomic Energy Regulatory Board v) Ministry of Information Technology or an Expert in Electronic Instrumentation and electromagnetic interference regulation; vi) Consumer Affairs vii) Environment d) Two representatives of the medical device industry, of	Advisory Committee

	whom at least one shall be from the small scale sector e) One representative of the Indian Medical Association f) One representative of Indian Council for Medical Research g) Two biomedical technologists h) Two biomaterial scientists i) One representative of Pharmacy council of India j) Director General of Bureau of Indian Standards k) Member(s) of MDRA & Chairpersons of the Technical Panels on invitation of the chairperson, as and when deemed necessary,	
AO	52) The Advisory Committee shall facilitate and ensure close co-operation between the MDRA and the enforcement agencies and other organizations operating in the healthcare sector. 53) The Advisory Committee shall advise the MDRA on matters such as: a) the performance of its duties and in particular in drawing up of a proposal for the MDRA's work programme, b) identification of experts for technical panels and functioning of the technical panels c) selection of standards including that for risk benefit analysis of medical devices d) functioning of notified bodies and testing laboratories e) vigilance and post market surveillance of medical devices f) view points of the medical device industry and healthcare professionals g) matters of interdisciplinary nature h) matters relating to reuse, refurbished devices, donated device, custom made devices, devices for clinical evaluation etc. and also of safe disposal thereof after use i) regulations and strategies in the context of emerging areas of scientific advancement and technological developments j) interactions with other regulatory bodies in the country k) developments in the medical device industry in the	Functions of Advisory Committee

	global context, and l) Such other matters as may be specified by Regulations. 54) The Advisory Committee shall meet regularly and not less than two times a year, at the initiative of the convener or on directive from the chairperson.	

AP	55) The MDRA shall, and as and when deemed necessary, establish Technical Panels, which shall consist of independent scientific experts. 56) The Technical Panel shall invite appropriate representative of the relevant segments of the industry besides representatives of the medical professional representatives for deliberations so as to ensure harmonious coordination in planning and control of the activities. 57) MDRA shall create the following three Technical panels as standing panels for matters pertaining to: a) Classification of medical devices and disputes regarding the same b) Conformity assessment and Technical standards c) Medical device testing and evaluation 58) Without prejudice to the provisions of clause (56) and clause (57), the MDRA may also establish as many Technical panels as it considers necessary on matters such as: a) Good manufacturing practices and quality systems b) Medical device packaging and sterilization c) Medical instrumentation and radiation safety and also d) Sector wise such as i) Anesthesiology and Respiratory Therapy Devices ii) Cardiovascular devices iii) Dental products iv) ENT devices v) Gastroenterology and Urology devices vi) Plastic surgery devices vii) Obstetrics and Gynecology devices viii) Ophthalmic devices ix) Orthopedic and Rehabilitation devices x) Hospital disposables xi) Neurological devices xii) Radiological devices xiii) Biological devices xiv) and combinational products	Technical Panels

	e) Risk Management of medical devices and risk benefit assessment 59) The Technical panels excepting those mentioned in clause (57) above may be constituted for a specified period of time or for a specific task. The MDRA may, from time to time, re-constitute the Technical panels by adding new members or by omitting the existing members or by changing the name of the panel as the case may be. 60) The Technical Panels may have independent chairpersons and the chairpersons of these Technical panels may be invited to the meetings of the MDRA or the Advisory committee as deemed necessary. 61) The MDRA shall, for stated reasons, be at liberty to accept or not, the recommendations or scientific opinions given to it by the Technical panels. 62) The CEO shall be responsible for the general coordination necessary to ensure consistency of the scientific procedure and in particular with regard to the adoption of working procedures and harmonization of working methods of the Technical Panels. 63) The Advisory Committee shall advise the MDRA on the identification of experts to be nominated to the Technical Panels so as to utilize the expertise of such persons while formulating scientific opinions and strategies.	

AQ	64) The procedure for the operation and co-ordination of the advisory committee and the Technical Panels shall be governed by the provisions in the regulations. 65) The regulations to be framed shall prescribe the principles and procedures governing the following among others - a) the number of members in each Technical Panel; b) the procedure for sitting fees and the procedure for reimbursing the expenses of members of the advisory committee and Technical Panel; c) the procedural aspects governing the assignments and discharge of the duties and responsibilities of the Advisory committee and Technical Panel; d) quorum for meetings, the manner of issuing notices to members and invitees for hearings, and such other matters.	Procedure for Advisory Committee and Technical Panels

	CHAPTER 3: ESSENTIAL PRINCIPLES OF MEDICAL DEVICE SAFETY AND PERFORMANCE	
AR	66) The MDRA shall be bound by the following essential principles while regulating safety and performance of medical devices, viz.: - • Use of medical devices should not compromise health and safety • Design and manufacture of medical devices must conform with safety principles • Medical devices should be suitable for the intended purpose • Long-term safety must be assured • Medical devices should not be adversely affected by transport or storage • Benefits of medical devices must outweigh any side effects 67) MDRA shall issue regulations relating to: a) Essential principles of Safety and Performance of medical devices b) Design and Manufacturing requirements bearing in mind the following: i) Chemical, physical and biological properties ii) Infection and microbial contamination iii) Manufacturing and environment properties iv) Devices with a diagnostic or measuring function v) Protection against radiation vi) Requirements for medical devices connected to or equipped with an energy source vii) Protection against mechanical risks viii) Protection against the risks posed to the patient by supplied energy or substances ix) Protection against the risks posed to the patient for devices for self testing or administration x) Information supplied by the manufacturer xi) Performance evaluation including, where appropriate, clinical evaluation 68) MDRA shall bear in mind that conformity to applicable medical device standards is one way of demonstrating compliance with the requirements of the essential principles of safety and	Essential Principles of Medical device safety and performance

	performance. 69) The regulations, when framed, shall be notified by the MDRA in the Gazette of India and placed before the parliament for ex-post facto approval or changes. 70) These essential and other requirements must be interpreted and applied in such a way as to take into account the technology and practice existing at the time of design as also technical and economical considerations compatible with protection of a high level of health and safety. 71) The electromagnetic compatibility and the requirements for the design and manufacture of devices that emit ionizing radiation shall form an integral part of the safety of medical devices and the regulations should contain specific clauses on these subjects taking into account the current national laws relating to electromagnetic compatibility and ionizing radiation.	

	CHAPTER 4: CLASSIFICATION OF MEDICAL DEVICES	
AS	72) While classifying medical devices under the regulation, the MDRA shall bear in mind that: a) There is complexity and wide variety requiring classification of medical devices so that the level of regulation can be proportional to the level of risk associated with them b) The level of risk inherent in the use of a particular device depends substantially on its intended purpose and is defined by the nature or degree of contact with the human body and the duration of such contact. 73) The risk classification system may generally consist of four risk classes namely i) Class A- devices involving lowest risk levels ii) Class B- devices involving low to moderate risks iii) Class C- devices involving moderate to high risks iv) Class D- devices involving highest risks 74) Under the regulations, it shall be open to the MDRA to frame the rules for classification of medical devices and publish the same in the Gazette of India. 75) It shall be open to the MDRA to take decisions with regard to the proper classification or reclassification of the devices or, where appropriate, the adjustment of the classification rules from time to time.	General principles of Risk based classification of Medical Devices

	CHAPTER 5: MEDICAL DEVICE STANDARDS	
AT	77) In the regulations, the MDRA shall specify standards that form the basis for the conformity assessment of the medical devices. These standards shall a) provide reference criteria that a product, process or service must meet. b) provide information that enhances safety, reliability and performance of medical devices. c) assure consumers about reliability or other characteristics of medical devices d) provide technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that medical devices are fit for their purpose. 78) Standards notified by the Bureau of Indian Standards or other international standards making bodies like International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the International Telecommunication Union (ITU), standards in the Indian Pharmacopoeia and other international Pharmacopoeia monographs may be selected by MDRA based on their suitability and on the recommendations of the Advisory Committee or Technical panel. 79) MDRA should provide a mechanism for recognizing international standards to provide manufacturers with a method of demonstrating compliance with the principles of medical device safety and performance. 80) While it may be preferable for harmonization purposes to use international standards, it may also be appropriate for MDRA to accept the use of national / regional standards or industry standards as a means of demonstrating compliance. 81) The selection of standards should preferably reflect current, broadly applicable technology while not discouraging the use of new technologies. Note: Standards may represent the current state of the art in a technological field. However, not all devices, or elements of device safety and/or performance may be addressed by recognized standards, especially for new types of devices and emerging technologies. 82) During the conformity assessment procedure, if it is found that a standard does not exist for a particular medical device or a standard can not be applied to it in full, it will be open to the MDRA to prescribe appropriate requirements for demonstrating compliance with the essential principles.	Selection and application of medical device standards

	CHAPTER 6: CONFORMITY ASSESSMENT AND PLACING ON THE MARKET	
AU	83) It shall be binding on manufacturers of medical devices to conform to the essential principles of safety and performance and to demonstrate conformity before placing the medical devices on the market or export from India as stipulated in this Act.	Placing medical devices on the market
AV	84) It will be open to the MDRA to specify through the regulations, the requirements relating to conformity assessment and the application of quality management systems for medical devices, and other requirements to be followed by the manufacturers. 85) The conformity assessment procedures, or any part of the conformity assessment procedures prescribed by the MDRA, may: a) be limited in their application to one or more medical device classifications; or b) apply differently to different medical device classifications, different kinds of medical devices 86) Without limiting clause(84), the regulations may relate to all or any of the following: a) application of quality management systems for the manufacture of medical devices; b) declaration or certification of compliance with the essential principles, or the quality management systems for the manufacture of medical devices; c) notification of, and assessment of, changes to a manufacturer's product range, product design or quality management systems; d) declarations to be made by manufacturers of medical devices that conformity assessment procedures have been applied to the devices; e) marks to be affixed to medical devices indicating the application of the conformity assessment procedures to the devices; f) monitoring and inspecting the design of medical devices or the manufacturing processes for medical devices; g) monitoring the performance of medical devices; h) corrective action required in relation to the design, manufacture, packaging, labelling and supply of medical	Conformity assessment procedures

devices;

i) Keeping records of the manufacture of medical devices, the design of medical devices or the manufacturing processes for medical devices.

87) MDRA shall take all necessary steps to ensure that medical devices can be placed on the market, exported or put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose and as per specifications.

88) MDRA shall ensure that the conformity assessment is carried out by the notified bodies / or the MDRA itself based on the following criteria:

a) In the case of **Class A** medical devices, save those which have a measuring function or those which are required to be sterile, manufacturer need only make a declaration of conformity as prescribed by the regulations and rules framed by MDRA

b) In the case of **Class A** medical devices which have a measuring function or which are required to be sterile, the Notified Bodies shall be authorized by MDRA to carry out the conformity assessment and issue conformity certificate as set out in the regulations and rules framed by MDRA

c) In the case of **Class B** and **Class C** medical devices, the Notified Bodies shall be authorized by MDRA to carry out the conformity assessment and issue conformity certificate as set out in the regulations and rules framed by MDRA

d) In the case of **Class D** medical devices, MDRA or the authorized Notified body shall be competent to carry out conformity assessment and issue conformity certificate as set out in the regulations and rules framed by MDRA

e) In the case of custom-made devices, the manufacturer shall follow the procedure prescribed in the regulations and draw up the declaration of conformity before placing such device on the market

89) Manufacturers shall make an application to MDRA or a notified body as appropriate for conformity assessment. The technical documentation requirements to be submitted with the application and other requirements shall be specified in the rules.

90) The decisions taken by the notified bodies or MDRA with respect to the conformity assessment shall be valid for a specified period as stipulated in the rules and may be extended on application.

91) The records and correspondence relating to the conformity

assessment shall be in English.

92) The MDRA may, in exceptional cases and for sufficient reasons to be recorded in writing, authorize, temporarily and for a stated period, the placing on the market and putting into service of particular devices for which conformity assessment procedures stated in this chapter have not been complied with, if such a course is necessary to meet an emergency and in the interest of protection of public health.

93) During the conformity assessment, the MDRA and/or the notified body may, in appropriate cases, take account of the data or results of any testing, assessment or verification operations, which, have been carried out at an earlier or intermediate stage of product development of a medical device seeking conformity.

94) The manufacturer shall make the technical documentation pertaining to conformity assessment available to MDRA for inspection purposes for a period ending at least five years after the last product has been manufactured. Where neither the manufacturer nor his authorized representative is established in India, this obligation to keep the technical documentation must fall to the person(s) who places the medical device in the Indian market.

95) The technical documentation must allow assessment of the conformity of the product with the requirements of this Act. It must include in particular:

a) a general description of the device, including any variants planned,

b) the intended use/purpose of the device

c) design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc.,

d) the descriptions and explanations necessary to understand the above mentioned drawings and diagrams and the functions of the product,

e) the results of the risk analysis

f) a list of the applicable standards referred to in chapter 5 of this Act, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Act, if the standards referred to in chapter 5 have not been applied in full,

g) in the case of products placed on the market in a sterile condition, description of the methods used for sterilization,

h) when connected to any device(s) having the characteristics specified by the manufacturer, the results of the design calculations and of the inspections carried out, etc.;

	i) if the device is to be connected to other device(s) in order to operate as intended, proof that it conforms to the essential requirements j) the test reports and, where appropriate, clinical data k) the label and accompanying information such as instructions for use. 96) MDRA shall specify in the regulations, the requirements of conformity assessment for custom medical devices and the procedure relating to medical devices for clinical investigations.	
AW	97) MDRA shall prescribe in the regulations, a method to be adopted for identification of conforming medical devices. The medical devices put into the market on and from the date of commencement of this provision should, as a general rule, bear an identification mark or number or any other inscription or method specified in the regulations, to indicate their conformity with the provisions of this Act. 98) The regulations shall provide for conditions and procedures for permission to affix the conformity identification in medical devices. 99) When a conformity assessment has been carried out and conformity certificate issued by a notified body, the conformity identification shall be accompanied by the identification number of the notified body. 100) It shall be ensured by the manufacturer and / or his representatives that no medical device, label, packaging material or user manual of a medical device should carry any mark, inscription or number misleadingly similar to conformity identification mark.	Identification of conforming products/ marking
AX	101) The MDRA shall with the assistance of its Advisory Committee, lay down the procedure to be adopted for qualification and selection of notified bodies to carry out the task of conformity assessment as envisaged in this Act. The Advisory committee shall consider and adopt the criteria and requirements laid down in national or international standards for accreditation of the conformity assessment bodies. 102) The selection of notified bodies will be for a definite period of time and renewable as envisaged in the rules. It shall be open to MDRA to revoke and withdraw the selection of the notified body at any time, if it finds subsequently that the notified body no longer meets the prescribed criteria for performance. MDRA shall also ensure that all affected parties are promptly informed of this decision. 103) When selecting a notified body, MDRA shall also identify the	Notified Body

	areas in which the notified body is deemed to be competent to carry out conformity assessment. A unique identification number shall also be issued to the notified body by the MDRA. 104) The list of notified bodies and changes there to made subsequently shall be notified in the Gazette of India. 105) MDRA shall treat all notified bodies on a par with each other and will give fair and equal treatment to them. 106) The manufacturers will be at liberty to select any notified body, competent to perform conformity assessment in its area of operation and to the particular device classification. 107) The manufacturers shall have the opportunity to report any grievance or complaint on the functioning of a notified body to the MDRA, which shall be dealt with by MDRA in accordance with the rules framed for the purpose. 108) The notified body and the manufacturer, or his authorized representative established in the country, shall lay down, by common accord, the time limits for completion of the assessment.	
AY	109) The MDRA, with the prior approval of the Central Government shall make rules providing for registration of manufacturers of medical devices with the MDRA. Such rules shall be notified in the Central Gazette. Any manufacturer who, under his own name, places any device or devices on the market shall be bound to register his unit and products in accordance with the provisions of the rules. This shall include any natural or legal person who offers for sale a combination of devices, custom or procedure packs and any natural or legal person carrying out the business of sterilization contract or third party sterilization of medical devices. 110) Manufacturers shall, within two weeks from the date on which the device is placed on the market inform the MDRA, of their address and details of the registered place of business, place of manufacture and the description of the device(s) concerned. 111) Where a manufacturer or trader who places devices referred to in clause (109) on the market under his own name does not have a registered place of business in India, he shall intimate in writing to the MDRA, details of the authorized person(s) in India responsible for marketing them in India. Such authorized representative(s) shall inform the MDRA their registered place of business, full postal address, and the category of devices concerned and also apply for registration under the rules. 112) MDRA may with the prior approval of the Central Government modify or amend from time to time, the rules relating to the registration of medical device framed by it and shall notify them in the Central Gazette.	Liability for Registration

AZ	113) Manufacturers shall be liable to allow the MDRA, its officers, employees or authorized representatives to carry out necessary inspections and also to supply it with all relevant information, and in particular: a) the documentation on the quality system, b) the data stipulated relating to quality assurance, safety testing & evaluation, calibration data, qualification reports of the personnel concerned, results of analyses, calculation tests, etc., c) supply samples if asked for by MDRA or under the orders of the CEO	Power of MDRA to inspect
BA	114) MDRA shall frame rules governing the period for which its records shall be retained. While doing so, modern methods including electronic documentation may also be borne in mind	Records of MDRA

	CHAPTER 7: IMPORT OF MEDICAL DEVICES	
BB	115) MDRA shall ensure that any medical device imported into India meets the requirements of the essential principles of safety and performance as stipulated in this Act. MDRA may, for this purpose, formulate regulations for prescribing the ways and means for ascertaining conformity. 116) Every manufacturer or his representative shall ensure that the medical device imported into India satisfy the requirements of this Act and rules regulations made there under, at all stages of production, processing, import, distribution and sale within the businesses under his control. 117) The manufacturer or his representative who wishes to import a medical device into India shall ensure that information about the manufacturer / representative is provided in such a way as to allow his identification. 118) If the manufacturer / representative of a medical device arranges for a label or mark to be attached or affixed to the device for the purpose of complying with Conformity declaration, labeling requirements or for any other purpose, the label must not in any way adulterate the device or obscure the information provided with the device by the manufacturer.	Import of Medical Devices

	CHAPTER 8: REFURBIHSED / DATE EXPIRED MEDICAL DEVICES	
BC	119) MDRA shall make and publish regulations governing the use of refurbished medical devices whether imported or otherwise, to ensure that the safety of the patient and or user and other persons is not compromised. 120) MDRA shall also make and publish regulations governing the conditions for use of date expired medical devices whether imported or otherwise, and providing for penalties for contravention of the specification given by manufacturer, to ensure that the safety of the patient and other persons is not compromised.	Conditions governing use of Refurbished/ Date expired medical devices

	Chapter 9: VIGILANCE AND REPORTING OF ADVERSE EVENTS/INCIDENTS	
BD	121) MDRA shall, through regulations, prescribe the procedures and methods to obtain information from the manufacturer/ hospitals, healthcare delivery professionals and users on any adverse events/incidents related to the use of medical devices and take appropriate precautionary/preventive measures as it may deem fit to minimise the risks and hazards associated with its use. Such regulations may provide for mandatory reporting by the manufacturers and voluntary reporting by users or other interested persons or organizations of such events and steps to be taken based on such information.	Vigilance by MDRA

	CHAPTER 10: ENFORCEMENT OF THIS ACT	
BE	122) MDRA shall be the agency primarily responsible for the enforcement of this Act. 123) MDRA shall monitor, verify and ensure that medical device manufacturers fulfill the relevant requirements of this Act, at all stages of medical device business. 124) MDRA shall appoint officers for efficient and effective implementation of this Act, who shall have following functions namely to : a) Disseminate information and build awareness amongst the various stakeholders such as medical device manufacturers, medical practitioners and health care professionals, vendors, users etc.; b) Conduct or organize training programme for personnel; c) carry out survey of the manufacturers to find out the compliance with the provisions of this Act; d) carry out surveillance of the notified bodies; e) coordinate and interact with other regulatory bodies and f) ensure a uniform and efficient implementation of the provision of this Act. 125) The officers of the MDRA may take a sample of any medical device which appears to be intended for sale, or to have been sold, which may be required as evidence for proceedings under any of the provisions of this Act or of the rules, regulations or orders made there under and send the same for analysis to a medical device testing laboratory for further examination. 126) Officers of the MDRA shall report to the CEO of any information regarding violations by manufacturers or others or any other matter that requires the intervention of the MDRA for the effective implementation of this Act. 127) When the CEO is convinced, based on the report of the Officers of MDRA or otherwise, regarding violations of the provisions of this Act and the rules and regulations there under, he shall, after affording an effective opportunity to the manufacturer or affected party to be heard, direct him, in writing, to end the infringement or comply with the conditions or directions imposed by MDRA which may include recalling/withdrawing of medical devices from the market. In the case of non-compliance with such directive, the CEO may take all appropriate measures to restrict or prohibit the placing on the market of the medical device in question and for the purpose he may direct any	Enforcement of the Act

	subordinate officer to seek the lawful assistance of the District Magistrate, police or other appropriate authorities including public servants. 128) Any decision taken by MDRA pursuant to this Act: a) to refuse or restrict the placing on the market or the putting into service of a medical device or the carrying out of clinical investigations; or b) to withdraw medical devices from the market, shall state the exact grounds on which it is based. Such decisions shall be communicated in wiring to the party concerned within four weeks. Such communication shall also convey information about the remedies and avenues for challenge available to him under the Act including the time limits concerned. 129) Any decision taken by MDRA pursuant to this Act to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations or to withdraw devices from the market, shall be appealable.	
BF	130) The MDRA shall notify Medical Device Laboratories and research institutions preferably accredited by National Accreditation Board for Testing and Calibration Laboratories, National GLP Authority or any other equivalent accreditation agency for the purposes of evaluation of medical devices under this Act. 131) The MDRA shall, establish or recognize by notification, one or more Referral Medical Device Laboratories to carry out the functions entrusted to the referral medical device laboratory by this Act or any rules and regulations made there under. 132) The MDRA shall frame regulations specifying- a) the functions of medical device laboratory and referral medical device laboratory ; b) the procedure for submission to the said laboratory of samples of medical devices for analysis or tests, and c) such other matters as may be necessary or expedient to enable the said laboratory to carry out its functions effectively.	Medical Device Laboratories

	CHAPTER 11: MEDICAL DEVICE SAFETY APPELLATE TRIBUNAL	
BG	133) The Central Government, by notification, shall establish one or more tribunals to be known as the Medical Device Safety Appellate Tribunal (MDSA) to hear appeals from the decisions of the MDRA. 134) The Presiding Officer of the MDSA Tribunal shall be appointed by the Central Government by notification in the Central Gazette. It shall be a single member Tribunal. No person shall be qualified for appointment as a Tribunal unless he is or has been a Judge of a High Court. 135) The term of office, salary and allowances, resignation and removal of the Tribunal shall be prescribed by the Central Government. 136) The procedure of appeal and powers of the Tribunal shall be such as may be prescribed by the regulations. The Tribunal shall not be bound by the procedure laid down by the Code of Civil Procedure, 1908; but shall be guided by the principles of equity, justice and good conscience. Subject to the other provisions of this Act and the rules made there under, the Tribunal shall have powers to regulate its own procedure including the place at which it shall have its sittings.	Establishment of Medical Device Safety Appellate Tribunal
BH	137) The Tribunal shall have, for the purposes of discharging its functions under this Act, the same powers as are vested in a civil court under the Code of Civil Procedure, 1908, while trying a suit, in respect of the following matters, namely:- a) summoning and enforcing the attendance of any person and examining him under oath; b) requiring the discovery and production of documents or other electronic records; c) receiving evidence on affidavits; d) issuing commissions for the examination of witnesses or documents; e) reviewing its decisions; f) dismissing an application for default or deciding the case ex-parte; g) any other power which may be conferred by the Central Government through appropriate notification. 138) Every proceeding before the Tribunal shall be deemed to be a judicial proceeding within the meaning of sections 193, 228,	Procedure and Powers of Tribunal

	and 196 of the Indian Penal Code and it shall be deemed to be a civil court for the purposes of section 195 and Chapter XXVI of the Code of Criminal Procedure, 1973. 139) In proceedings before the Tribunal, the appellant may either appear in person or authorize any of his/its officers or one or more legal practitioners to represent his/its case before the Tribunal. 140) The provisions of the Limitation Act, 1963, shall, except as otherwise provided in this Act, apply to an appeal made to the Tribunal. 141) Subject to judicial review before the Supreme Court or High Court, the decision of the Tribunal shall be final.	

	CHAPTER 12: OFFENCES AND PENALTIES	
BI	142) Any person who manufactures, makes available for sale, or sells to the purchaser's prejudice any medical device, which is not in compliance with the provisions of this Act or the regulations made there under, shall be punished with fine which may extend to five lakh rupees or with rigorous imprisonment which may extend to one year or both.	Penalty for medical device that does not conform to this Act
BJ	143) Whoever, by himself or through any other person on his behalf, manufactures or makes available for sale or stores or sells or distributes or imports any medical device which is misbranded as per the definitions and provisions of this Act or under regulations framed there under shall be punished with a fine which may extend to three lakh rupees or with rigorous imprisonment which may extend to 6 months or both.	Penalty for a misbranded medical device
BK	144) Any person who willfully tampers with any medical device, package or labelling with malafide or criminal intentions or for commercial or financial motives and places the same on the market jeopardizing the safety of the users, patients or others shall be punishable with rigorous imprisonment for a term which may extend to six months or with fine which may extend to two lakh rupees or both.	Penalty for tampering with a medical device
BL	145) If a medical device manufacturer or his authorized representative, without reasonable ground, fails to comply with the requirements of this Act or the regulations or orders issued there under, as directed by the MDRA or its officers , he shall be punished with a fine which may extend to five lakh rupees or with rigorous imprisonment which may extend to one year or both.	Penalty for failure to comply with the directions of the MDRA etc.
BM	146) Whoever, bound under this Act or the Rules or Regulations framed hereunder to provide information to an authority under this Act, fails to furnish or furnishes / produces information which he knows is false or misleading, shall be punished with imprisonment of either direction for a term which may extend to three months or with fine which may extend to one lakh rupees.	Punishment for false information or failure to provide information

BN	147) Whoever, bound under the Act to register his product with the MDRA, manufactures, imports, sells, stores, or distributes any medical device without such registration shall be punishable with rigorous imprisonment for a term which may extend to six months or with fine which may extend to one lakh rupees.	Punishment for carrying out business without registration
BO	148) Whoever retains, removes or tampers with any medical device, package or labelling or advertising material or other thing that has been seized under this Act, without the permission of MDRA or its officers shall be punishable with rigorous imprisonment for a term which may extend to six months or with fine which may extend to Rupees Fifty thousand.	Punishment for interfering with seized items
BP	149) Whoever, without reasonable excuse, resists, obstructs, or attempts to obstruct, threaten, intimidate or assault an officer of the MDRA in exercising his functions under this Act, shall be punishable with imprisonment for a term which may extend to six months or with fine which may extend to Rupees Fifty thousand.	Punishment for obstructing a MDRA officer
BQ	150) If any person who has been convicted of the commission of, or attempt to commit, or abetment of, or criminal conspiracy to commit, any of the offences punishable under this Act is subsequently convicted of the commission of, or attempt to commit, or abetment of, or criminal conspiracy to commit, an offence punishable under this Act with the same amount of punishment shall be punished for the second and every subsequent offence with rigorous imprisonment for a term which shall not be less than one-half of the maximum term of imprisonment, and also be liable to fine which shall extend to one-half of the maximum amount of fine prescribed for the offence. 151) Where any person is convicted by a competent court of criminal jurisdiction outside India under any corresponding law, such person shall be dealt with for the purposes of clause 150 as if he had been convicted by a court in India. 152) The Court may, in appropriate cases cause the offender's name, place of residence, the offence and the penalty imposed, to be published at his own expense in specified newspapers or in such other manner as the court may direct and the expenses	Punishment for subsequent offenses

	of such publication, in case of non payment, shall be recoverable in the same manner as if it were a fine imposed by Court.	
BR	153) Any person who imports into India any medical device in contravention of the provisions of this Act, or rules or regulations made there under, shall, in addition to any penalty to which he may be liable under the provisions of the Foreign Trade (Development and Regulation) Act 22, 1992 and the Customs Act 52, 1962 be also liable for punishment under this Act. 154) It shall be competent for the convicting Court or any higher court to which the case may be taken to, to direct that any particular medical device involved in the case shall be confiscated and destroyed irrespective of any order for return passed by any other authority under the Foreign Trade (Development and Regulation) Act 22,1992 or the Customs Act 52, 1962, or any other enactment.	Penalty for contravention of provisions of this Act in case of import of medical devices to be in addition to penalties provided under any other Act.
BS	155) It shall be lawful for any police officer not below the rank of a Sub Inspector of police of a police station which has received a valid complaint relating to an offence under this Act: a) To enter, if necessary, by force, whether by day or night and with such assistance as he considers necessary, any premises which he has reason to suspect, are being used for purposes connected with the commission of the offence; b) To search the said premises; c) To take into custody and produce before any Judicial magistrate all such persons against whom the offence is alleged or against whom a complaint has been made or credible information has been received or a reasonable suspicion exists of their having a been concerned with the use of the said premises for purposes connected with the offence; and d) To seize, all things, equipments and relevant records found in the said premises which are intended to be used, or reasonably suspected to have been used, in connection with the offence in question 156) Any officer authorized under this Act or under the Rules framed under this Act may, a) at all reasonable times, enter into and search any premises which he has reason to suspect, are being used for the	Power to enter, search and seize

	purposes connected with the commission of an offence under the Act or the Rules, b) Examine any person having the control of, or employed in connection with, any such offence; c) Order the production of any documents, books or records in the possession of such person and relating to the offence alleged against him, and d) Inspect and seize any register, books of accounts, documents or any other literature found in the said premises. 157) All searches under this section shall be made in accordance with the procedure prescribed under the code of Criminal Procedure, 1973	
BT	158) No prosecution for an offence under this Act shall be instituted except by, or with the written consent of an officer authorized for the purpose under the Rules framed under this Act. Provided that a prosecution for an offence under this Act may be instituted by a purchaser or recognised consumer association referred to in the Consumer Protection Act if he or it produces a copy of the Purchase Bill issued in his favour in respect of the Medical Device concerned along with the information to the Police. 159) Notwithstanding anything contained in the Code of Criminal Procedure, 1973 an offence, punishable under this Act shall be cognizable and non-bailable. Procedure for trial shall be that prescribed for trial of warrant cases initiated on police report. 160) No Court inferior to that of Metropolitan Magistrate or a, Judicial Magistrate of the first class shall be competent to try any offence under this Act 161) No prosecution for an offence under the Act shall be instituted in respect of the same facts on which a penalty has been imposed under this section on compounding the offence.	Cognizance of offences and procedure for trial
BU	162) Where any person has been convicted under this Act for the contravention of any of the provisions of this Act or of any Rule there under, it will be open to the court of conviction or any superior Court to which the case might be taken to, to order that the stock of the defective medical device concerned and the illegal gains made by the offender by contravention of the provision concerned may be forfeited to the Government. Provided that where the Court is satisfied that the device is	Forfeiture of property

	capable of being made to conform to prescribed standards for consumption after reprocessing or modification, and there is reasonable possibility of rectification through such reprocessing/modification, the Court may order the stock of device concerned to be returned to the manufacturer or other person from whom it was seized, as the case may be, on his executing a bond with or without sureties, on undertaking that the stock or any part thereof would not be sold or made available for consumption to the public or any other consumer without the necessary re processing/modification carried out under the supervision of an authorized officer named in the Rules framed under this Act.	
BV	163) Where a person committing a contravention of any of the provisions of this Act or of any rule, direction or order made there under is a company, every person who, at the time the contravention was committed, was in charge of, and was responsible to the company, for the conduct of the business of the company as well as the company, shall be deemed to be guilty of the contravention and shall be liable to be proceeded against and punished accordingly. Provided that nothing containing in this clause shall render any such person liable to punishment if he proves that the contravention took place without his knowledge or that he exercised all due diligence to prevent such contravention. 164) Notwithstanding anything contained in Clause 163, where a contravention of any of the provisions of this Act or of any rule, direction or order made there under has been committed by a company and it is proved that the contravention has taken place with the consent or connivance of, or is attributable to any neglect on the part of any director, manager, secretary or other officer of any company, such director, manager, secretary or other officer shall also be deemed to be guilty of the contravention and shall be liable to be proceeded against and punished accordingly. Explanation.-For the purposes of this section,- (i) "company" means any body corporate and includes a firm or other association of individuals; and (ii) "director", in relation to a firm, includes a partner in the firm.	Offences by companies
BW	165) No suit shall be brought in any civil court to set aside or modify any proceeding taken or order made under this Act and no prosecution, suit or other proceeding shall lie against the Government or MDRA or any of their officers for anything done or intended to be done in good faith under this Act.	Bar of suits in civil courts

BX	166) The CEO of the MDRA may accept from any person against whom a reasonable suspicion exists that he has committed any offence under the Act a sum of money, not exceeding the maximum fine prescribed for the offence concerned, and compound the offence which such person is suspected to have committed, and When any property has been seized as liable to confiscation, release the same to the person from whom the seizure was effected on payment of the penalty aforementioned. The decisions of the CEO in such compounding shall be promptly informed to the MDRA for ratification. 167) On payment of such penalty, the suspected person, if in custody, shall be discharged and the property, if any, seized shall be released, and no further proceedings shall be taken against such person or property; provided that such composition can be done, if charge is already laid by the Police before Court on completion of investigation, or an appeal is pending before the MDSA only with the permission of the Court/MDSA as the case may be.	Power to compound offences

	CHAPTER 13: FINANCE, ACCOUNTS AND REPORTS OF MDRA	
BY	168) The MDRA shall prepare, in such form and at such time in each financial year as may be prescribed by the Central Government, its budget for the next financial year, showing the estimated receipts and expenditure of the MDRA and forward the same to the Central Government. 169) The MDRA with the prior approval of the Central Government shall adopt financial regulation, specifying, in particular, the procedure for drawing up and implementing the Authority's budget.	Budget of MDRA
BZ	170) The Central Government may, after due appropriation processes, make over to the MDRA grants of such sums of money as the Central Government may think fit. 171) The MDRA on the recommendation of the Advisory Committee shall specify a fee structure for conformity assessment and other services of MDRA.	Finances of MDRA
CA	172) Notwithstanding anything contained in the Wealth-tax Act, 1957, the Income Tax Act, 1961, or any other enactment for the time being in force relating to tax on wealth, income, profits or gains, the Authority shall not be liable to pay wealth-tax, income tax or any other tax in respect of their wealth, income, profits or gains derived.	Exemption from tax on wealth and income.
CB	173) The MDRA shall maintain proper accounts and relevant records as may be prescribed by rules and prepare an annual statement of accounts in such form as may be prescribed by the Central Government in consultation with the Comptroller and Auditor General of India 174) The Comptroller and Auditor-General and any person appointed by him in connection with the audit of the accounts of the MDRA under this Act shall have the same rights and privileges and authority in connection with such audit as the Comptroller and Auditor General generally has in connection with the audit of Government accounts and, in particular, shall have the right to demand the production of books, accounts, connected vouchers and other documents and papers and to inspect any of the offices of the MDRA for these purposes. 175) The accounts of the MDRA, as certified by the Comptroller and Auditor General or any other person appointed by him in this behalf, together with the audit report thereon shall be forwarded annually to the Central Government by the MDRA and the Central Government shall cause the audit report to be	Accounts and Audits of MDRA

	laid, as soon as may be after it is received, before each House of Parliament.	
CC	176) The MDRA shall prepare once every year, in such form and at such time as may be prescribed by the central Government, an annual report giving a summary of its activities during the previous year and copies of the report shall be forwarded to the Central Government. 177) A copy of the annual report received under the above provision shall be laid, as soon as may be after it is received, before each House of Parliament.	Annual Report of MDRA

	CHAPTER 14: MISCELLANEOUS	
CD	178) Without prejudice to the foregoing provisions of this Act, it shall be open to the Central Government to issue directions to the MDRA with regard to the exercise of its powers and in performance of its functions under this Act, and the MDRA shall be bound by such directions on questions of policy, other than those relating to technical and scientific matters, provided that the MDRA shall, as far as practicable, be given an opportunity to express its views before any such direction is given. 179) 1f any dispute arises between the Central Government and the MDRA as to whether a question is or is not a question of policy, the decision of the Central Government thereon shall be final. 180) The MDRA shall furnish to the Central Government such returns or other information with respect to its activities as the Central Government may, from time to time, require.	Power of Central Governme nt to issue directions to MDRA and obtain reports
CE	181) The Members and officers of the MDRA and MDSA shall be deemed, when acting or purporting to act in pursuance of any of the provisions of this Act, to be public servants within the meaning of section 21 of the Indian Penal Code.	Legal status of MDRA members and employees
CF	182) The MDRA may, with the prior approval of the Central Government, make and publish, through notification in the Gazette of India, regulations consistent with this Act, to regulate its function and activities contemplated in the Act 183) In particular, and without prejudice to the generality of the foregoing power, and in addition to those mentioned in clause 182, such regulations may provide for all or any of the following matters, namely a) salaries and other conditions of service of officers and other employees of the MDRA; b) rules of procedure for transaction of business and holding of meetings of MDRA; c) functions and procedures to be followed by the Advisory Committee and Technical committees d) prescribing and collecting fees for conformity assessment, registration and other services of MDRA e) procedure to be followed to suit emergency situations in	Power of MDRA to make regulations

	the interest of public safety and health; f) the procedure and manner of marking and labeling of medical devices; g) conditions and guidelines relating to medical device withdrawal or recall; h) regulations relating to functioning of Officers empowered to carry out surveillance and vigilance i) notifying procedure for the registration of medical device manufacturers j) any other matter which is required to be, or may be, specified by the Act or the rules in respect of which provision is to be made by regulations. 184) Every rule and every regulation made under this Act shall as soon as maybe, after it is made, be placed before each House of Parliament, and if both Houses agree in making any modification in the rule or regulation, or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation.	
CG	185) The Authority may, by general or special order in writing, delegate to any member, officer of the Authority or any other person subject to such conditions, if any, as may be specified in the order, such of its powers and functions under this Act (except the power to compound offences, settle disputes and to make regulations) as it may deem necessary.	Delegation
CH	186) If any difficulty arises in giving effect to the provisions of this Act, the Central government may, by order, published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as may appear to be necessary for removing the difficulty; 187) Every order made under this clause shall be laid, as soon as may be after it is made, before each House of Parliament.	Power to remove difficulties
CI	188) Subject to the Provisions of Section 190, provisions derogatory to those contained herein as might be available in the Drugs and cosmetics Act 1940 as it stands now after amendments or in any other enactment, Central or State shall hereby stand repealed and it is made clear that provisions of this Act shall supervene contradictory provisions, if any, contained in any other enactment with regard to matters provided for herein. 189) Notwithstanding such repeal, anything done or any action	Repeal and saving.

	taken under the said enactments shall be deemed to have been done or taken under the corresponding provisions of this Act.	
CJ	190) MDRA shall notify and specify the time deadlines and such arrangements as necessary to enable the manufacturers of medical devices already in the market to smoothly switch over to compliance with the provisions and requirements of this Act but not later than the date prescribed in clause (4). NOTE: This is to ensure that during the initial implementation of this Act, availability of medical devices in the market to meet the requirements of all consumers will not in anyway be affected or reduced.	Transitional arrangements