Medical Devices Bill

Chapter 1 Preliminary		
Introduction and citation	1	(a) The purpose of this act is to establish regulations and policies to maintain safety and quality of medical devices in the Maldives, establish quality of such devices, determine parties responsible for procedures and establish implementing processes.
		(b) This Act shall be cited as 'Medical Devices Act'
Objectives	2	(a) Establish main policies, rules and regulations required to maintain quality and safety of medical devices
		(b) Establish policies and regulations on manufacture, import, export, packing, labeling, advertising, storage, buying, sales, storage for sale, use and disposal of medical devices, issuing licenses for such parties and inspection of medical devices.
		(c) Establish policies, standards and regulations for medical device quality and safety to ensure safety to service receivers and providers
		(d) Ensure accountability of health service providers and other parties using medical devices including the public, to maintain quality and safety of medical devices
		(e) Develop policies under this Act for restricting the rights of companies or other parties in the case of adverse effects caused by a medical device.
		(f) Identify offences and penalties to maintain the safety and quality of medical devices
		(g) Establish and run 'Medical Device Safety Board'
Responsibility of quality and safety of medical devices	3	(a) The Minister of Health bears all responsibilities of ensuring quality and safety of medical devices and increasing awareness on this
		(b) The Minister of Health shall exercise such powers and discharge such functions as are laid down in this Act.
Decentralization	4	(a) The Minister can decide which city councils, atoll councils and island councils shall implement this Act and to which extent.
		(b) City councils, atoll councils, island councils and other service providers must be assigned responsibilities according to their implementation capacity and availability of resources.

		(c) Responsibilities assigned under (a) and (b) of this section should be given in writing and notified publicly.
Medical Devices Regulatory Authority	5	(a) An authority must be established under this Act, to regulate and maintain safety and quality of medical devices. The government can declare an existing authority as the above mentioned Authority.
		(b) The head of the Authority under (a) of this section will be Director General. This is a civil service position and the person for this position will be selected by the civil service commission.
		(c) The Director General will work under the general supervision of the Minister of Health.
		(d) The budget required for functioning of the Authority and all work for maintaining the quality and safety of medical devices should be included in the annual budget and disbursed accordingly.
		(e) For Implementation of this Act the government must arrange the inclusion of appropriate technical and administrative staff in the civil service.
Responsibilities of the Authority	6	The following are the roles and responsibilities of the Authority.
		(a) Develop, organize, implement and monitor a mechanism to ensure quality and safety of medical devices.
		(b) It shall be the objective of the authority to issue license, maintain quality and monitor the import, export, manufacture, sale, advertise, machine calibration and certifying parties, usage and disposal of medical devices and parties involved in other related fields of work.
		(c) Under the Ministers counsel, develop national policies, standards, rules and regulations related to medical devices.
		(d) Set goals and standards to be reached on implementation of this Act and decide on programs to conduct under this Act to ensure quality and safety of medical devices.
		(e) Categorize medical devices based on levels of risk it poses and establish standards for methods and extent of control and implement these standards
		(f) All health service providers and other users shall report to the Authority of any adverse events/incidents related to the use of medical devices
		(g) Inspect and monitor to maintain the safety and quality of medical

		devices.
		(h) Determine which medical devices can and cannot be imported and used in the Maldives, prohibit import and use of medical devices in the country and classify banned medical devices.
		(i) If a medical device used in Maldives is found to be unsafe or low quality, the authority shall inform the public and prohibit the use of such devices. The Authority shall remove such devices without compensation and order the disposal of such devices.
		(j) Study problems related to medical device use faced by health service providers and other users and disseminate information accordingly.
		(k) Publish publicly a list of medical devices that can be imported or used in Maldives and prohibit the import or use of any other medical devices.
		(l) Increase public awareness and disseminate information on safety of medical devices.
		(m) To ensure safety and quality of medical devices and to effectively implement this Act, establish agreements with other countries and international NGOs and conduct programs in association with them.
		(n) Establish a laboratory with appropriate equipments, technical and administrative staff to test the quality of medical devices. Determine the services which would be provided by the laboratory and ensure continuous service.
		(o) Develop standards and regulations for the use of medical devices, appropriate environment and energy for efficient operation of devices and other areas.
		(p) Develop procedures for maintaining the quality of medical devices imported and exported in Maldives and develop ways to implement these procedures.
		(q) Establish standards and regulation on medical devices which are received as aid to Maldives.
CHAPTER 2 National Medical Device Board		
Establishment of National Medical Device Board	7	To maintain the quality and safety of medical devices the Government of Maldives shall establish the Medical Device Board within 6 months of implementation of this act and gazette it.

Composition of the National Medical Device Board	8	(a) The Board shall consist of a chairperson and the following positions
		1. Director General Authority – ex officio Chair person
		2. Head of Division of the medical device regulatory authority
		3. An eminent medical device expert to be nominated by the government
		4. A biomedical engineer or electric/electronic engineer or an experienced person in similar fields approved by the government
		5. Specialist with experience on medical devices such as anesthetics or surgeons (Can be nominated by medical council or government)
		6. Expert in nursing (Can be nominated by nursing council or government)
		7. An allied health professional with experience on medical devices
		8. A high level expert in business field
		9. A high level staff from Maldives National Chamber of Commerce
		10. A senior technical staff from Ministry of Health involved in the quality control of health centers.
		11. One member from the public or one member from an NGO working in the health field.
		(b) The term of office of all members except the three members stated in 1, 2, 3 of (a) of this section is three years. The position will be considered vacant before end of term of office in the event of death, resignation or removal from the Board for any other reasons. Members shall be eligible for reappointment for a further period of two years.
		(c) Presence of 1/3 (quarter) members of the Board shall be deemed a quorum.
		(d) A meeting of the Board shall be held at least 4 (four) times during a year.
		(e) All decisions shall be by majority of Board members present at the meeting
		(f) The meetings may be convened at the initiative of the Chairman or on request of 1/3 (quarter) members of the Board
		(g) The Authority shall submit a request to the regulation committee of the majilis for any changes to the composition of this Board.
		(h) Board regulation shall be made and published within three months of establishment of the Board.
Responsibilities of the Board		(a) Establish a system to monitor the safety and quality of medical devices and guide/advice on implementation of this system.
		(b) Determine devices that can be imported, exported and used in Maldives
		(c) Supervise and advise the scientific committee and temporary panel working under the Board.

		(d) Coordinate and assist organizations and other parties involved in regulating medical devices.
		(e) Advise the Authority in enforcing this Act.
		(f) Advice to make regulations under this Act.
		(g) Represent different components of the Board in enforcing this Act.
		(h) Assist the Authority in handling and solving different issues arising from enforcing this Act.
Establishment of Scientific Committee/ Task force	10	To ensure the safety and quality of medical devices a technical or administrative committee, panel or task force may be established to advice on specific issues under this Act. These committees shall be governed by regulations issued under this Act.
CHAPTER 3 System to control medical devices		
Import license	11	(a) All medical devices listed for licensing shall not be imported to Maldives without a license.
		(b) A regulation shall be issued for the procedures for licensing, other issues of license and conditions for licensee.
		(c) Import license holders shall only import approved devices and devices with market approval
		(d) It is prohibited to import the following devices in to Maldives
		1. Counterfeit medical devices
		2. Low quality or substandard medical devices
		3. Damaged or expired medical devices
		4. Medical devices unsafe for providing health services
		(e) Refurbished medical devices imported to Maldives shall not be more than 3 (three) years from the date of manufacture.
		(f) The Authority has the discretion to determine specific category of devices that cannot be imported as refurbished medical devices.
		(g) Policies and procedures shall be made under this Act, on importation of medical devices, refurbished medical devices and used medical devices received as aid to Maldives
		(h) Policies and standards shall be made and published under this Act, on

		importation of medical devices, refurbished medical devices and used medical devices for personnel use or as samples.
Export of medical devices	12	(a) It is prohibited to import medical devices except with a license from the Authority.
		(b) For the purpose of this Act export means, devices manufactured, devices repacked or relabeled after importing or devices shipped name of Maldives.
Market approval of medical devices	13	(a) Only market approved medical devices can be imported, sold, made available for sale and used in Maldives
		(b) Policies and standards for issuing of market approval shall be made and published under this Act
		(c) In the event of questions about the quality and safety of a market approved medical device the Authority shall hold the market approval temporarily or cancel the approval if the claim is proved.
License to distribute and sell medical devices	14	(a) Medical devices can only be distributed and sold by license holders
		(b) For parties meeting the requirements sales and distribution license shall be issued together with import license. Importation is prohibited for only sales and distribution license holders.
		(c) Policies, conditions and standards for medical device distribution and sale shall be made and published under this Act.
		(d) Medical device distribution and sales license holders can only sell devices approved for sale in Maldives.
		(e) It is prohibited to sell or make available for sale any medical device imported for personal use or as a sample.
Cancellation of license and approval	15	(a) License or approval will be cancelled automatically if the company on whose application a license in issued is dissolved or for any reasons stops the work for which license was issued.
		(b) License issued based of false information shall be revoked. It is prohibited to use this license for any purpose.
		(c) Any changes in licensee or information of the licensee shall be informed to the Authority and license shall be changed accordingly.
Chapter 4 Responsibilities of medical device sale and use		

Main responsibilities for parties involved in/sale of medical devices	16	(a) Parties involved in distribution and sale of medical devices stated as to be reported to the Authority, shall submit accurate reports of distribution and reports on adverse effects/incidents based on information obtained from the device users according to the procedures stated by the Authority.
		(b) In the event of change of licensee, change in any information or change of office of licensee the Authority shall be informed within 30 days. The licensee shall bear all responsibilities of any transactions done before these changes are reported.
		(c) Written approval shall be obtained from the Authority prior to changing location of medical device display and storage.
		(d) Provide services for medical devices stated as critical and requiring servicing and maintenance. A list of such critical medical devices shall be published under this Act and the Authority has the power to add or remove devices from this list with the advice of the Board.
		(e) Such devices shall be given market approval with the submission of guarantee of post sale servicing by the manufacturer or a party approved by the manufacturer.
		(f) Any transactions or sale of medical devices shall be in a location and to the extent approved by the Authority.
Warranty by manufacturer, importer or distributer	17	According to the regulations under this Act, a written document shall be provided by the manufacturer, importer or seller to the buyer stating that the quality of medical device suits all conditions and standards stated under this Act
Main responsibilities of health centers and health service providers using medical devices	18	(a) A written document stating the origin and quality of medical device, warranty of the device and document stating that the device is operating as required shall be displayed at health centers and where the device is being used during the use of device and not less than 3 (three) years after stopping use of device. If any issue arises during this period these documents shall be safely kept until the issue is resolved.
		(b) Operating manuals/service manuals shall be displayed and easily accessible to the users of devices at health centers using medical devices. All users shall be capable and trained to use the specific device.
		(c) For the medical device stated as to be reported to the Authority, according to the procedures stated by the Authority, service providers shall report any adverse events/incidents from using medical devices
Chapter 5		

Labeling and advertising medical devices		
Label and other information	19	(a) The following information shall be available for medical devices imported, sold and stored for sale in Maldives
		1. Name, category, type
		2. Name and complete address of manufacturer, supplier name and complete address. (If information about manufacturer is included in the label, written information of supplier shall be available with the device)
		3. Content of the machine
		4. Lot number and batch number
		5. License number
		6. Instructions of use, safe keeping and storage
		7. Single use items shall be labeled 'SINGLE USE ONLY' with bold letters more prominent than the rest of the label
		8. Information on safety precautions and warnings.
		9. Expiry date
		10. Any other information stated by regulations under this Act.
		(b) Medical device label, service manual and other documents shall be in English or Divehi
		(c) Labels and all documents related to medical devices imported, used and sold in Maldives shall be clearly written and easily visible in Divehi or English. If the label is in another language that label shall not be larger or more visible than the Divehi or English label.
		(d) For the purpose of this Act, preparation for reuse of single use or disposable medical devices shall be considered as manufacturing.
Advertising	20	(a) It is prohibited to use false, misleading or inaccurate information when advertising medical devices.
		(b) Medical devices shall only be advertised with approval from the Authority.
		(c) Medical devices that can and cannot be advertised, policies and standards of advertisement shall be made and published.

Chapter 6 Power to control medical devices		
Authorities powers to control medical devices	21	(a) Determine list of medical devices which require license for import, manufacture, sale and use in Maldives
		(b) Determine name, category and type of medical devices which can be imported, manufactured, sold and used in Maldives and determine standards and quality of these devices.
		(c) Establish policies and procedures for import, export, storage, made available for sale, sale, use and disposal of medical devices.
		(d) Determine approvals and licenses that need to be obtained for different stages of medical devices. Determine policies, procedures and standards for using these licenses, issuing of licenses and cancellation or revoking of licenses.
		(e) Determine devices prohibited to import, sell, manufacture and use in Maldives. Based on science of predicted adverse effects of using such devices in the country, prohibit use of or ban specific medical devices.
		(f) Determine a list of specific medical devices that can only be used when calibrated and a document is issued stating that the equipments is in proper working conditions by a capable trained person.
		(g) Determine that instructions, safety precautions and warning shall be included with the medical device in writing, symbols or as pictures.
		(h) Establish the quality and standard of medical device container and other components of packing and determine specific packing or containers that cannot be used.
		(i) Policies, conditions and standards for transport, safe keeping, storage, disposal of medical devices shall be made and published as a regulation under this Act.
		(j) Determine which medical devices require after sales service after manufacture, import and distribution and establish policies, standards and regulations for this service.
		(k) Determine which medical devices cannot be advertised and establish and publish policies, standards and regulations for advertisement of devices that can be advertised.
		(l) Prohibit the advertisement of a medical device and order a party to stop advertising.

		(m) The Authority shall, in its discretion call upon any party for any issues arising from implementation of this Act.
Recalling of medical devices from the market	22	(a) Seller and users of medical devices shall arrange for the recall or stop use of any medical devices not conforming to the regulations and devices considered as unsafe.
		(b) Action shall be taken against the party, if the situation in (a) of this section arises from non compliance with this Act or the Regulations framed hereunder
Powers of the Director General in ensuring quality and safety of medical devices	23	(a) Compulsory licensing for import, export, storage warehouses, and health centers using medical devices. Inspect such places and temporarily hold or revoke license and take required actions.
		(b) Compulsory registration and approval for import, export, manufacture, use and advertisement of medical devices in Maldives. Prohibit import, export, manufacture, use and advertisement of medical devices, cancel license and take required actions.
		(c) Surveillance of medical devices, testing for safety and quality of devices, collecting and testing samples of devices which can be sampled, restricting devices. Prohibition of import, sale and use of low quality or unsafe devices and ordering for disposal of such devices.
		(d) Compulsory to provide adequate facilities for medical devices which require special working environments and conditions.
		(e) Compulsory for health service providers and health centers to ensure that medical devices are operated/used by specially trained, skilled and capable personnel
		(f) Take actions against any individuals, parties or companies who do not comply with this Act or the Regulations framed hereunder.
		(g) Medical devices which can be used personally for personal use is not covered by this Act. This does not apply if this medical device is used in health centers or by health service providers.
		(h) Make policies and regulations for medical devices that can be imported to Maldives for personal use.
Chapter 7 Offenses and Penalties		
Penalties by companies and	24	(a) If an offense is committed by a company involved in business of medical devices, all parties responsible for, working in and involved in the

establishments involved in business of medical device.		company when the offense was committed will be held liable and tried and punished by a court of law.
		(b) Whoever, by himself or through any other person on his behalf, manufactures, makes available for sale, stores, sells or imports any medical device without compliance with this Act or the Regulations framed hereunder shall be punished with a fine ranging from MVR 10000 to MVR 100,000. If such offenses are repeated medical device import and sale licenses shall be seized.
Penalties for specific offenses	25	(a) Whoever, manufactures, makes available for sale, sells, imports, advertise or use inadequately any devices as stated below shall be punished with a fine ranging from MVR 10000 to MVR 50,000 or with imprisonment for a period of 3 to 12 months. 1. Misbranded medical devices 2. Sub standard medical devices 3. Used devices or devices illegal to be imported and marketed in Maldives 4. Reuse of single use only medical devices or disposable devices except under a regulation framed under this Act.
		(b) Whoever fails to report written documents on any incidents/events concerned with import, keeping for sale, sale and use of medical devices and obstruction of investigation of such events/incidents shall be punished with a fine ranging from MVR 50000 to MVR 100000.
		(c) Whoever, bound under this Act or the Regulations framed hereunder provide false information or shows any misdemeanor shall be punished with a fine ranging from MVR 10000 to MVR 200000 or with imprisonment for a period not more than 12 months.
		(d) Whoever manufactures or assembles a medical device without a license or a device not approved for manufacture in the country shall be punished with a fine ranging from MVR 10000 to MVR 100000
		(e) Whoever manufactures, sells, imports, buys, markets or use in a health service center, a medical device not approved for import or without market approval shall be punished with a fine ranging from MVR 10000 to MVR 100000 together with prohibition of use and disposal of such device.
		(f) Whoever imports medical devices or fails to report change in licensee information according to section 16 (a) of this Act shall be punished with a fine ranging from MVR 100000 to MVR 200000.
		(g) Whoever changes medical device seller, distributer and location of

		storage without prior approval from the Authority according to section 16(c) of this Act shall be punished with a fine ranging from MVR 2000 to MVR 10000.
		(h) Whoever operates or uses a medical device improperly or without required training shall be punished with a fine ranging from MVR 200 to MVR 100000.
		(i) Whoever imports a medical device without conforming to Section 19 of this Act and without labels or documents in English or Divehi as required by this Act or regulations framed hereunder, shall be punished with a fine ranging from MVR 1000 to MVR 50000 together with prohibition of import of such devices.
		(j) Whoever imports, makes available for sale, markets, advertises, sells or gives away any counterfeit medical devices, shall be punished with a fine ranging from MVR 10000 to MVR 100000.
		(k) Whoever imports or sells low quality, unsafe, hazardous or dysfunctional medical devices shall be punished with a fine ranging from MVR 10000 to MVR 100000.
		(l) Whoever advertises a medical device without prior approval shall be punished with a fine ranging from MVR 2000 to MVR 50000.
		(m) Owners of newspaper, radio or TV station that carries such an advertisement shall be punished with a fine ranging from MVR 5000 to MVR 50000.
		(n) Whoever uses a license after it has been revoked/cancelled by the Authority shall be punished with a fine ranging from MVR 50000 to MVR 100000.
		(o) Whoever faces any adverse incidents/events from import, sale, advertisement and use of medical devices without compliance with this Act or regulations framed herewith is not restricted from appealing to a court of law and compensations by law in addition to any penalty which the offender may be liable to under provisions of this Act.
		(p) Whoever, repeats any offenses in this Act shall be punished with a fine of not more than MVR 500000 in addition to the penalty stated in the Act for each repeated offense
		(q) Whoever uses any device stated for disposal by this Act shall be punished with a fine ranging from MVR 50000 to MVR 100000
		(r) Whoever commits any offense for which penalties are not specified in

		this Act or does not comply with regulations framed under this Act shall be punished with a fine ranging from MVR 1000 to MVR 500000.
Chapter 8 General		
Definitions	26	(a) 'Medical device' means any instrument, apparatus or machinery used by doctors, nurses and other health professionals for diagnosis, monitoring and treatment of diseases, and support of the anatomy or of a physiological process of human body.
		(b) 'Market approval' means approval issued for selling, keeping for sale, advertisement and use of medical devices for providing health services.
		(c) 'Counterfeit medical devices' means any devices deliberately mislabeled to pass of as an approved device or a device copied from the original.
		(d) 'Substandard medical device' means devices of quality lower than the set standards or devices which cannot be properly used for the purpose it was designed for.
		(e) 'Unsafe medical devices' means used medical devices and devices which do not conform to the hygienic standards or contaminated devices.
		(f) 'Refurbished medical devices' 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
		(g) 'Calibrate' means setting the controls for efficient performance of the machine.
Commencement	27	This Act comes into operation within six months of ratification and gazetting.
Making and implementing regulations	28	All regulations framed under this Act shall be implemented by Medical Device Regulatory Authority. All regulations shall be completed within one year of commencement of this Act.

Reasons for submission of this Bill:

Health services are widely provided in Maldives by the Government and Private Sector. The purposes of this Act are; ensuring the quality and safety of medical devices/equipments used in Maldives, inspection and monitoring of equipments to ensure safety for protection of the people receiving services, reduction of adverse events/incidents of using medical devices, establishing a system for monitoring the quality of devices and ensuring continuity of the said services.