Bureau of Experts at the Council of Ministers

Official Translation Department

Law of Medical Devices and Supplies

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Translation of Saudi Laws

NOTE:

The translation of Saudi laws takes the following into consideration:

- Words used in the singular form include the plural and vice versa.
- Words used in the masculine form include the feminine.
- Words used in the present tense include the present as well as the future.
- The word “person” or “persons” and their related pronouns (he, his, him, they, their, them) refer to a natural and legal person.

Law of Medical Devices and Supplies

Article 1

In this Law, the following words and phrases shall have the meanings assigned thereto, unless the context requires otherwise:

Law: Law of Medical Devices and Supplies.

SFDA: Saudi Food and Drug Authority.

Board: SFDA's Board of Directors.

Executive Director: SFDA's Executive Director.

Regulations: Implementing Regulations of the Law.

Medical Device: Any instrument, apparatus, implement, implant, *in vitro* reagent or calibrator, software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; controlling or assisting conception; disinfection of medical devices; providing information for medical or personal purposes by means of *in vitro* examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Medical Supply: A medical material or product used in diagnosis, treatment, replacement, or bracing; or in disability cases or other medical uses for humans, including medical gases.

Accessories of Medical Devices and Supplies: Any material or product intended specifically to be used with a medical device or supply to enable it to achieve its purpose.

Innovative Medical Device or Supply: A medical device or supply which involves innovation in technology, use, or performance and which has not been previously introduced to the local or international market.

Assembled Medical Device or Supply: Articles assembled in one kit to meet user requirements, which may contain non-medical devices or supplies.

Single-use Medical Device or Supply: A disposable article intended for use on a patient in a single medical procedure.

Radioactive Medical Material: A material that emits ionizing radiation either by itself or when used with other medical devices or supplies for the purpose of diagnosis and treatment.

Fraudulent Medical Device or Supply: A device or supply the identity or source of which is deliberately altered with the intent to defraud. A medical device or supply shall be deemed fraudulent if its components have been

altered in a manner that compromises its safety and efficacy, or if it is packed in counterfeit containers.

Reprocessing: Procedures implemented on a used medical device or supply for safe reuse, such as cleansing, disinfection, sterilization, and testing and restoration of its technical functions and safety.

User: A person, whether a professional, non-professional, or patient, who uses a medical device or supply.

Establishment: A legal entity engaged in an activity related to medical devices and supplies.

Manufacturer: Any national or foreign establishment the purposes of which include designing or manufacturing medical devices or supplies for use under its name within the Kingdom or abroad. Manufacturing shall include refurbishing, assembling, packaging, and labelling.

Health Care Provider: Any government or private establishment that provides health care services.

Authorized Representative: A legal person based in the Kingdom who has written authorization from a manufacturer located outside the Kingdom to represent it in the Kingdom with regard to the implementation of this Law and its Regulations.

Circulation of Medical Devices and Supplies: The provision of medical devices and supplies at no cost or for a fee, whether for distribution or use.

License: A document issued by the SFDA to engage in any of the activities subject to this Law.

MDNR: The Medical Devices National Registry established by the SFDA.

Registration: A procedure for registering in the MDNR any medical device or supply and any establishment that engages in any activity governed by this Law.

Marketing Authorization: A document issued by the SFDA permitting the circulation of a medical device or supply in the market.

Certificate of Free Sale: A document issued by the SFDA stating that a manufacturer is registered in the Kingdom and that the medical devices and supplies to be exported have obtained marketing authorization.

Verification of Clinical Studies: An applied research in which a medical device or supply is used on humans to assess its safety and efficacy.

Classification System: A system approved by the SFDA to assess the safety and the level of risk of a medical device or supply.

Quality Management System: A system approved by the SFDA to verify the quality, effectiveness, and safety of a medical device or supply in accordance with the latest version of the Technical Standard (ISO 13485) or its equivalent, as provided in the Regulations.

Quality Assurance: A set of technical tests, measurements, and calibrations approved by the SFDA to verify the safety, accuracy, and quality of medical

imaging devices, in order to ensure the efficacy of diagnosis and treatment.

Technical Regulations: Mandatory documents issued by the SFDA for medical devices and supplies which specify the basic standards of safety, performance, and manufacturing and provide relevant instructions, including terms and symbols as well as packaging and labelling requirements.

Standard Specifications: Non-mandatory documents approved by the SFDA, including rules, guidelines, specifications of medical devices and supplies, or production processes and methods related thereto as well as terms and symbols, and packaging and labelling requirements.

Identifying Information: Any statement, information, or illustration printed on a medical device or supply, including identifying information, technical description, method of use, and manner of storage and transportation.

Technical and Clinical Standards: A set of standards that determine the quality, effectiveness, and safe use of a radioactive material in medical applications.

Safety Alert: A notice issued by the National Center for Medical Devices Reporting indicating the risk associated with a medical device or supply and the corrective action required to avoid such risk.

Field Safety Corrective Action: An action taken by the manufacturer to limit or reduce the risks compromising the safety of a medical device or supply.

Accidents of Medical Devices and Supplies: Any defect or change in the characteristics or performance of a medical device or supply that may directly or indirectly cause or contribute to the death or serious injury of a user.

NCMDR: The National Center for Medical Devices Reporting.

Article 2

The following activities shall be subject to the provisions of this Law:

1. Designing and manufacturing medical devices and supplies.
2. Importing, marketing, distributing, and storing medical devices and supplies.
3. Providing services to verify the conformity of medical devices and supplies with the technical regulations and the Quality Management System, and to verify quality assurance.
4. Verifying clinical studies.
5. Providing technical consultation services in the field of medical devices and supplies.
6. Providing inspection services of medical devices and supplies to ensure their conformity with the technical regulations and standards.
7. Providing maintenance services for medical devices and supplies.
8. Representing a manufacturer located outside the Kingdom.

Article 3

Under this Law, accessories of medical devices and supplies and assembled medical devices and supplies shall be deemed medical devices and supplies.

Article 4

Without prejudice to the powers of the Nuclear and Radiological Regulatory Commission (NRRC) to issue licenses for engaging in activities related to the use of radioactive medical materials, the technical and clinical specifications of such materials must be approved by the SFDA prior to obtaining the NRCC's license.

Article 5

Application of this Law shall not prejudice the powers of the NRRC to issue licenses for protection against ionizing radiation emitted by medical devices.

Article 6

Subject to Article 4 of this Law, an establishment may not engage in any of the activities subject to this Law unless registered and a license is obtained; as for manufacturers, an industrial license must be obtained from the competent agency.

Article 7

An entity licensed to verify clinical studies shall, prior to conducting any verification procedure, obtain the SFDA's approval in accordance with the Regulations.

Article 8

Medical devices or supplies may not be circulated unless registered and a marketing authorization is obtained. The SFDA may exempt certain medical devices and supplies from the marketing authorization requirement upon verifying, in accordance with rules approved by the Board, that they are safe and are not intended to be used for commercial purposes.

Article 9

The SFDA may, in accordance with the Regulations, exempt innovative medical devices or supplies from certain conditions and procedures required to obtain a marketing authorization, provided the exemption does not compromise their safety when used.

Article 10

The Regulations shall specify the conditions and procedures necessary for registration; issuance of the marketing authorization; and for license issuance, renewal, amendment, transfer, and revocation.

Article 11

Imported medical devices and supplies may not be cleared unless approved by the SFDA.

Article 12

The Regulations shall determine the conditions for issuing a certificate of free sale.

Article 13

The SFDA may, pursuant to a medical report, permit the entry of personal-use medical devices and supplies in limited quantities, provided they are not used for commercial purposes.

Article 14

Any person who dispenses or sells fraudulent, unregistered, or unauthorized medical devices or supplies shall, upon knowledge thereof, notify the SFDA of any information relating to the dispensed or sold devices or supplies and their quantity, as well as the name and address of any person to whom the medical devices or supplies are dispensed or sold, and shall refund the buyer.

Article 15

Subject to the provisions of the Commercial Agencies Law, a manufacturer who is located outside the Kingdom and who wishes to circulate his products in the Kingdom shall appoint an authorized representative. The Regulations shall determine the requirements the representative must satisfy as well as the obligations and responsibilities of the two parties.

Article 16

The manufacturer shall provide after-sale services for its medical devices and supplies and shall comply with the provisions of this Law and its Regulations.

Article 17

Establishments shall provide the identifying information to be placed on medical devices and supplies. The Regulations shall determine such information.

Article 18

A health care provider shall not deal with any establishment which engages in any activity governed by this Law, unless it is registered and licensed to engage in such activity.

Article 19

Single-use medical devices or supplies may not be reprocessed.

Article 20

Used medical devices or supplies may not be destroyed, reprocessed, refurbished, resold, loaned, or donated except as specified by the Regulations.

Article 21

The manufacturer shall classify medical devices and supplies in accordance with the Classification System.

Article 22

Establishments seeking to circulate medical devices and supplies in the Kingdom shall adhere to the Quality Management System.

Article 23

Medical devices or supplies categorized as high risk under the Classification System may not be dispensed for use outside the facility of the health care provider without prescription. The SFDA shall issue a list of such medical devices and supplies.

Article 24

Medical devices and supplies may not be advertised nor promoted without the SFDA's approval. Advertisement and promotion shall be in accordance with the conditions determined by the Regulations.

Article 25

Awareness and charitable campaigns, and the like, relating to medical devices and supplies may not be organized without the SFDA's approval. Such campaigns shall be in accordance with the conditions determined by the Regulations.

Article 26

The SFDA shall monitor the compliance of health care providers with technical regulations within health care facilities in order to ensure the safety and efficacy of medical devices and supplies in diagnosis and treatment.

Article 27

An establishment or an authorized representative shall provide the SFDA with the documents or information required thereby in accordance with this Law and its Regulations.

Article 28

The manufacturer, authorized representative, and health care provider shall report to the NCMDR any adverse event relating to their medical devices and supplies.

Article 29

The NCMDR shall issue a safety alert to warn users and health care providers

of any risks arising from the use of medical devices and supplies.

Article 30

The manufacturer and the authorized representative shall, in relation to their medical devices and supplies, report the following to the NCMDR:

1. Safety alerts issued by similar regulatory authorities outside the Kingdom.
2. Risks compromising the safety of the medical device or supply.
3. Completion of the Field Safety Corrective Action.

Article 31

An establishment and a health care provider shall, in the event of a safety alert, suspend the circulation of medical devices and supplies pending a notification by the NCMDR indicating that the Field Safety Corrective Action has been completed.

Article 32

An establishment or an authorized representative shall, if requested by the SFDA, track medical devices and supplies in accordance with the Regulations.

Article 33

The SFDA shall be in charge of inspecting establishments and medical devices and supplies to ensure application of the Law, the Regulations, and the technical regulations. Inspection shall be carried out by inspectors who are appointed pursuant to a decision by the chairman of the Board; they shall be deemed preliminary criminal investigation officers with the power to:

1. detect and report medical devices and supplies in violation of this Law; and
2. take the following actions regarding the items in violation of this Law:
   a) seize said items and related documents, if necessary;
   b) collect samples for analysis; and
   c) recommend the destruction of items proven to be fraudulent or harmful.

Destruction shall, pursuant to a decision by the SFDA and following standard technical procedures, be carried out by a committee, or more, formed for such purpose pursuant to a decision by the chairman of the Board. The violator shall incur destruction costs.

Article 34

Any person subject to this Law shall maintain the confidentiality of information he becomes privy to by virtue of his duties.

Article 35

An inspector shall show his credentials upon performing his inspection duties, and the establishment shall cooperate with him.

Article 36

SFDA inspectors may, pursuant to a decision issued by the Executive Director, be financially rewarded for performing their duties.

Article 37

A reward not exceeding 25% of the fine may, pursuant to a decision issued by the Executive Director, be awarded to any person, other than SFDA inspectors, who aids in detecting any violation of the provisions of this Law and the Regulations.

Article 38

The SFDA shall, in coordination with the Ministry of Finance, set the rules governing the rewards referred to in Articles 36 and 37 of this Law.

Article 39

The SFDA may take the necessary precautionary measures if it suspects any harm, misleading claim, or compromise to the safety and efficacy of medical devices and supplies, as determined by the Regulations.

Article 40

Medical devices and supplies may not be circulated if the SFDA decides to withdraw the same from the market or prohibit circulation thereof.

Article 41

A person shall be deemed in violation of this Law if he:

1. defrauds or attempts to defraud with regard to medical devices or supplies;
2. knowingly sells or dispenses fraudulent medical devices or supplies or possesses the same for the purpose of trading;
3. brings, or attempts to bring, into the Kingdom medical devices or supplies that are unregistered, fraudulent, or unauthorized for marketing;
4. manufactures medical devices or supplies in violation of this Law, the Regulations, and the technical regulations;
5. affixes false information on medical devices and supplies or uses such information for the promotion thereof;
6. transports or stores medical devices or supplies in violation of the SFDA's transportation and storage requirements;
7. brings or attempts to bring into the Kingdom containers or labels of medical

devices or supplies with the intent to defraud;

8. manufactures, prints, possesses, sells, or displays containers or labels of medical devices or supplies with the intent to defraud; or
9. commits any other violation of this Law.

Article 42

1. Without prejudice to any harsher penalty provided for in any other law, any person who commits any violation of this Law or the Regulations shall be subject to one or more of the following penalties:
   a) A fine not exceeding five million riyals.
   b) Temporary closure of the establishment for a period not exceeding 180 days.
   c) Suspension of the marketing authorization of medical devices and supplies subject of the violation for a period not exceeding one year.
   d) Revocation of the marketing authorization of medical devices and supplies subject of the violation.
   e) Preventing the violator from engaging in any activity related to medical devices and supplies for a period not exceeding 180 days.
   f) Revocation of the license.
   g) The penalty imposed pursuant to sub-paragraphs (a), (b), (c), and (e) of this paragraph may be doubled if the violation is repeated. A violation shall be deemed a repeated violation if it is committed within one year from the date the first violation is committed.
2. A person who commits any of the acts stipulated in Article 41(1, 2, 3, 7 and 8) of this Law shall be subject to imprisonment for a period not exceeding ten years, a fine not exceeding ten million riyals, or both. In addition to said penalties, the penalties stipulated in paragraph (1) (b, c, d, e, and f) of this Article may be imposed. The penalty shall be doubled if the violation is repeated.

Article 43

The SFDA shall impose the penalties stipulated in Article 42(1) of this Law, according to the classification of violations and penalties approved by the Board, taking into account the nature of the activity and the gravity of the violation on a case-by-case basis as well as the aggravating and mitigating circumstances of each violation. The imposition of penalties shall be approved pursuant to a decision issued by the Executive Director or his designee. In all cases, the SFDA may take necessary precautionary measures.

Article 44

1. A committee, or more, composed of at least three members, including at least one legal counselor, shall, pursuant to a Board decision, be formed to review appeals filed with the SFDA against penalty decisions issued in

accordance with Article 42(1) of this Law.

2. Committee work procedures and remuneration of its members shall be determined pursuant to a Board decision.
3. Committee decisions may be appealed before the administrative court.

Article 45

If the violation is subject to Article 42(2) of this Law, it shall be referred to the Public Prosecution for investigation and to the competent court in accordance with statutory procedures.

Article 46

A judgment or penalty decision, as the case may be, may include a provision to publish its ruling at the expense of the violator in a local newspaper published in the area of his residence, or, if none is available, in a newspaper published in the nearest area or through any other appropriate medium, depending on the type, gravity, and impact of the violation, provided that the publication is made after the judgment becomes final, the decision becomes unappealable due to the expiration of the period of appeal, or the issuance of a final judgment dismissing the appeal.

Article 47

A person who sustains damage arising from a violation of this Law may file a claim for compensation before the competent court.

Article 48

The Board shall issue the Regulations within 180 days from the date of publication of this Law in the Official Gazette; the Regulations shall enter into force on the date this Law enters into force.

Article 49

This Law shall enter into force 180 days following the date of its publication in the Official Gazette.