Guideline for Medical Device Registration

This guideline covers all medical devices to be registered and placed in the Sudanese market and is applicable to any person who is required to register medical device.
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Objective:
This Guideline has been developed to assist in registration of a medical device.

Introduction:
According to National Medicines Law (2009) all medical devices have to be registered before they can be imported and/or placed in the market. An application for the registration of a medical device needs to be submitted using the prescribed form (Appendix - I) (http://nmpb.gov.sd/forms/4298), if the medical device classified as class A; the application process can be done by submitting the Declaration of Conformity.

Definition of Terms:

Medical Device:
‘Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical 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 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, in or on the human body, but which may be assisted in its intended function by such means.

Accessory to a medical device:
Means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use.

**Active medical device:**

Any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patients, without any significant change, are not considered to be active medical devices. Standalone software is considered to be an active medical device.

**Active therapeutic device:**

Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness or injury.

**Active device intended for diagnosis:**

Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

**Central circulatory system:**

The major internal blood vessels including the following:

- Pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, carotid arteries (common, internal and external), cerebral arteries, brachiocephalic artery, aorta (includes all segments of the aorta), inferior and superior vena cava and common iliac arteries.

**Central nervous system:**

The brain, meninges, and spinal cord.

**Cleaning:**

Removal of contamination from an item to the extent necessary for its further processing and its intended subsequent use.

**Disinfection:**

Reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use.

**Duration of use:**
**Transient:** Normally intended for continuous use for less than 60 minutes.

**Short term:** Normally intended for continuous use for between 60 minutes and 30 days.

**Long term:** Normally intended for continuous use for more than 30 days.

**Harm:**
Physical injury or damage to the health of people or damage to property or the environment.

**Hazard:**
Potential source of harm.

**Intended use / Intended purpose:**
The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

**Invasive devices**

**Invasive device:** A device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

**Body orifice:** Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

**Surgically invasive device:**
(a) An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.
(b) A medical device which produces penetration other than through a body orifice.

**Implantable device:** Any device, including those that are partially or wholly absorbed, which is intended:
- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye, by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

**Lay person:**
Individual that does not have formal training in a relevant field or discipline.
Life supporting or life sustaining:
A device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Reusable medical device:
Means a device intended for repeated use either on the same or different patients, with appropriate decontamination and other reprocessing between uses.

Reusable surgical instrument:
Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar surgical procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning and/or sterilization have been carried out.

Risk:
Combination of the probability of occurrence of harm and the severity of that harm.

Sterilization:
Validated process used to render product free from viable microorganisms.

Vital physiological process:
Means a process that is necessary to sustain life, the indicators of which may include any one or more of the following:
- respiration;
- heart rate;
- cerebral function;
- blood gases;
- blood pressure;
- body temperature.

Clinical data:
Safety and/or performance information that are generated from the clinical use of a medical device.

Clinical evaluation:
The assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.
Label:

Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

Instructions for use:

Information provided by the manufacturer to inform the device user of the medical device’s intended purpose and proper use and of any precautions to be taken.

Labeling:

The label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

Conformity Assessment:

The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance for Medical Devices.

Recognised Standards:

Standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Technical documentation:

The documented evidence, normally an output of the quality management system that demonstrates conformity of a device to the Essential Principles of Safety and Performance of Medical Devices.

Summary Technical Documentation (STED):

A summary of technical documentation held or submitted for conformity assessment purposes.

Application for Registration of medical device:

Application for registering medical device should be submitted by:

– the manufacturer of the medical device, or
– the authorized representative of the foreign manufacturer, based in Sudan, or
– the agent or distributor of the foreign manufacturer, based in Sudan

using the application for registration form in (Appendix – 1).

**Classification:**

Medical devices classified into four classes A, B, C, D based on degree of risk with class A being the lowest risk and Class D devices having the highest risk, and the actual classification of each device depends on the claims made by the manufacturer for its intended use and the technology/ies it utilizes.

**Classification rules:**

**1. Non-Invasive Devices**

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<thead>
<tr>
<th>RULE</th>
<th>ILLUSTRATIVE EXAMPLES</th>
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<tbody>
<tr>
<td>Rule 1. All non-invasive devices which come into contact with injured skin: - are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent:</td>
<td>Devices covered by this rule are extremely claiming sensitive. Examples: bandages; cotton wool.</td>
</tr>
<tr>
<td>are in Class B if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound. unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class C.</td>
<td>Examples: non-medicated impregnated gauze dressings.</td>
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<td>Devices used to treat wounds where the subcutaneous tissue is as least partially exposed and the edges of the wound are not sufficiently close to be pulled together. To close the wound, new tissue must be formed within the wound prior to external closure. The device manufacturer claims that they promote healing through physical methods other than ‘primary intent’. Examples: dressings for chronic ulcerated wounds; dressings for severe</td>
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<td>Rule 2(i). All non-invasive devices intended for channeling or storing</td>
<td>burns.</td>
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|  - liquids, or  
  - gases  
for the purpose of eventual infusion, administration or introduction into the body are in Class A, | Such devices are ‘indirectly invasive’ in that they channel or store liquids that will eventually be delivered into the body. 
**Examples:** administration sets for gravity infusion; syringes without needles. |
| **unless** they may be connected to an active medical device in Class B or a higher class, in which case they are Class B; | **Examples:** syringes and administration sets for infusion pumps; anesthesia breathing circuits. 
**NOTE:** “Connection” to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and *vice versa.* |
| Rule 2(ii). All non-invasive devices intended to be used for:  
  - channeling blood, or  
  - storing or channeling other body liquids, or  
  - storing organs, parts of organs or body tissues,  
for the purpose of eventual infusion, administration or introduction into the body are Class B. | Examples: tubes used for blood transfusion, organ storage containers. |
| **unless** they are blood bags, in which case they are Class C. | Example: Blood bags that do not incorporate an anti-coagulant. |
| **Rule 3.** All non-invasive devices intended for modifying the biological or chemical composition of:  
  - blood,  
  - other body liquids, or  
  - other liquids,  
intended for infusion into the body are in Class C, | Such devices are ‘indirectly invasive’ in that they treat or modify substances that will eventually be delivered into the body. They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. 
**Examples:** haemodializers; devices to remove white blood cells from whole blood. 
**NOTE:** For the purpose of this part of the rule, ‘modification’ does not include... |
unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.

Examples: devices to remove carbon dioxide; particulate filters in an extracorporeal circulation system.

**Rule 4.** All other non-invasive devices are in Class A.

These devices either do not touch the patient or contact intact skin only. 

Examples: urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.

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### 2. Invasive Devices

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<th>RULE</th>
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| **Rule 5.** All invasive devices with respect to body orifices (other than those which are surgically invasive) and which:  
  - are not intended for connection to an active medical device, or  
  - are intended for connection to a Class A medical device only.  
  - are in Class A if they are intended for transient use;  
  - are in Class B if they are intended for short-term use;  
  - are in Class C if they are intended for long-term use;  
  unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the eardrum or in a nasal cavity, in which case they are in Class A,  
  unless they are intended for long-term use in the oral cavity as far as the pharynx, in an ear canal up to the eardrum or in a nasal cavity and are not | Examples: examination gloves; enema devices.  
Examples: urinary catheters, tracheal tubes.  
Examples: dressings for nose bleeds.  
Examples: urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning is considered as part of the continuous use).  
Examples: orthodontic materials, removable dental prosthesis. |
liable to be absorbed by the mucous membrane, in which case they are in Class B.

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<tr>
<th>All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class, are in Class B.</th>
<th>Examples: tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips. <strong>NOTE:</strong> Independent of the time for which they are invasive.</th>
</tr>
</thead>
</table>
| **Rule 6.** All surgically invasive devices intended for **transient use** are in Class B, unless they are reusable surgical instruments, in which case they are in Class A; or unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is | A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types of catheter/sucker etc. Examples: manually operated surgical drill bits and saws. **NOTE:** A surgical instrument connected to an active device is in a higher class than A. Examples: catheter containing sealed radioisotopes. **NOTES:** (a) The ‘biological effect’ referred to is an intended one rather than unintentional. The term ‘absorption’ refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. (b) This part of the rule does not apply to those substances that are excreted without modification from the body. Examples: Insufflations gases for the abdominal cavity. Examples: insulin pen for self administration. **NOTE:** The term ‘administration of
potentially hazardous taking account of the mode of application, in which they are in Class C; or

medicines’ implies storage and/or influencing the rate/volume of medicine delivered not just channeling. The term ‘potentially hazardous manner’ refers to the characteristics of the device and not the competence of the user.

**unless** they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D; or

**unless** intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.

**Example:** spinal needle.

**Rule 7.** All surgically invasive devices intended for **short-term use** are in Class B,

Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. **Examples:** infusion cannula; temporary filling materials; non-absorbable skin closure devices; tissue stabilizers used in cardiac surgery. **NOTE:** Includes devices that are used during cardiac surgery but do not monitor or correct a defect.

**unless** they are intended to administer medicinal products, in which case they are in Class C; or

**unless** they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class C; or

**unless** they are intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or

**unless** they are intended to have a biological effect or to be wholly or partly resorbed in the body, in which case they are in Class C; or

**Examples:** surgical adhesive.

**Examples:** brachytherapy device.

**Example:** absorbable suture; biological adhesive.
mainly absorbed, in which case they are in Class D; or

**NOTE:** The ‘biological effect’ referred to is an intended one rather than unintentional. The term ‘absorption’ refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.

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<tr>
<th>Rule 8. All implantable devices, and long-term surgically invasive devices, are in Class C,</th>
<th>Example: maxilla-facial implants; bone plates and screws; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating).</th>
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<td><strong>unless</strong> they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D;</td>
<td>Example: neurological catheter.</td>
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<td><strong>unless</strong> they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.</td>
<td>Example: cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.</td>
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<tr>
<td><strong>Rule 8.</strong> All implantable devices, and long-term surgically invasive devices, are in Class C,</td>
<td>Most of the devices covered by this rule are implants used in the orthopedic, dental, ophthalmic, and cardiovascular fields.</td>
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<tr>
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<td>Example: maxilla-facial implants; bone plates and screws; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating).</td>
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<td><strong>unless</strong> they are intended to be placed into the teeth or on prepared tooth structure, in which case they are in Class B; or</td>
<td>Example: materials for inlays, crowns, and bridges; dental filling materials.</td>
</tr>
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<td><strong>unless</strong> they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D; or</td>
<td>Example: prosthetic heart valves; cardiovascular stents; pacemaker leads and electrodes; deep brain stimulation electrodes; cerebrospinal catheter.</td>
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<td><strong>unless</strong> they are intended to be life supporting or life sustaining, in which case they are in Class D; or</td>
<td>Example: pacemakers; implantable</td>
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</table>
implantable medical devices, in which case they are Class D; or

unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or

Example: implants claimed to be bioactive.

**NOTE**: Hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.

unless they are intended to administer medicinal products, in which case they are in Class D; or

Example: subcutaneous infusion ports for long-term use.

unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class D; or

Example: surgical adhesives intended for long term use.

unless they are breast implants, in which case they are in Class D.

### 3. Active Devices

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<th>RULE</th>
<th>ILLUSTRATIVE EXAMPLES</th>
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<tr>
<td><strong>Rule 9(i)</strong>. All active therapeutic devices intended to administer or exchange energy are in Class B,</td>
<td>Such devices are mostly electrically powered equipment used in surgery; devices for specialized treatment and some stimulators. Examples: muscle stimulators; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy.</td>
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<tr>
<td>unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.</td>
<td>Examples: lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotripters; therapeutic X-ray and other sources of ionizing radiation. <strong>NOTE</strong>: The term ‘potentially hazardous’ refers to the type of</td>
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</table>
Rule 9(ii). All active devices intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices, are in Class C.

Rule 10(i). Active devices intended for diagnosis are in Class B:

- if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class A), or

- if they are intended to image *in vivo* distribution of radiopharmaceuticals, or

- if they are intended to allow direct diagnosis or monitoring of vital physiological processes,

**unless** they are specifically intended for:

a) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac

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Examples: external feedback systems for active therapeutic devices.

Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals.

Examples: magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators.

Example: gamma/nuclear cameras.

Example: electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.

Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors.
performance, respiration, activity of central nervous system, or b) diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.

**Rule 10(ii).** Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class C.

**Example:** ultrasound equipment for use in interventional cardiac procedures.

**Rule 11.** All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B,

**Example:** devices for the control, monitoring or influencing of the emission of ionizing radiation.

Such devices are mostly drug delivery systems or anesthesia equipment. **Examples:** suction equipment; feeding pumps; jet injectors for vaccination; nebulizer to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous.

**unless** this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, in which case they are in Class C.

**Examples:** infusion pumps; anesthesia equipment; dialysis equipment; hyperbaric chambers; nebulizer where the failure to deliver the appropriate dosage characteristics could be hazardous.

**Rule 12.** All other active devices are in Class A.

**Examples:** examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.
### 4. Additional Rules

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<th><strong>RULE</strong></th>
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<tr>
<td><strong>Rule 13.</strong> All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D.</td>
<td>Examples: antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound; blood bags incorporating an anti-coagulant.</td>
</tr>
<tr>
<td><strong>Rule 14.</strong> All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are in Class D, unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only in which case they are in Class A.</td>
<td>Example: porcine heart valves. Examples: leather components of orthopaedic appliances.</td>
</tr>
<tr>
<td><strong>Rule 15.</strong> All devices intended specifically to be used for sterilizing or disinfecting medical devices are in Class B, unless they are disinfectant solutions or washer-disinfectors intended specifically for invasive medical devices, as the end point of processing, in which case they are in Class C; or unless they are intended to clean medical devices by means of physical action only, in which case they are in Class A.</td>
<td>Example: desk-top sterilisers for use with dental instruments. Examples: solutions intended to be used for the disinfection of medical devices without further processing (for example in a steriliser) including those where the infective agent is a prion; washer-disinfector equipment specifically for disinfecting an endoscope or another invasive device.</td>
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</table>
**Rule 16.** All devices that are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class C.

**Rule 17.** All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C, unless they are implantable or long-term invasive devices, in which case they are in Class D.

**Examples:** condoms; contraceptive diaphragms.

**Essential Principles of Safety and Performance Applicable to medical device**

**Safety and Performance of Medical Devices – General Principles:**

1) Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

2) The solutions adopted by the manufacturer for the design and manufacture of the medical devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:
   a) Identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse.
   b) Eliminate risks as far as reasonably practicable through inherently safe design and manufacture.
c) Reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and
d) Inform users of any residual risks.

3) Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.

4) The characteristics and performances referred to in Clauses 1), 2) and 3) should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer’s instructions.

5) Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

6) All known and foreseeable risks, and any undesirable effects, should be minimized and be acceptable when weighed against the benefits of the intended performance of medical devices during normal conditions of use.

**Chemical, physical and biological properties:**

1) The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section 6. Particular attention should be paid to:

   a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,
   
   b) the compatibility between the materials used and biological tissues, cells, and body fluids taking account of the intended purpose of the device,
   
   c) the choice of materials used, reflecting, where appropriate, matters such as hardness, wear and fatigue strength

2) The devices should be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking
account of the intended purpose of the device. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.

3) The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

4) The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

5) Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.

Infection and microbial contamination:

1) The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should:
   a. allow easy handling;
   And, where necessary:
   b. reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use,
   c. prevent microbial contamination of the device or specimen, where applicable, by the patient, user or other person

2) Devices labeled as having a special microbiological state should be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

3) According to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions
indicated by the manufacturer, until the protective packaging is damaged or opened.

4) Devices labeled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.

5) Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.

6) Packaging systems for non sterile devices should maintain the integrity and cleanliness of the product and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.

7) The labeling of the device should distinguish between identical or similar products placed on the market in both sterile and non sterile condition.

Medical devices incorporating a substance considered to be a medicinal product/drug:
1) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and performance of the device as a whole should be verified, as well as the safety, quality and efficacy of the substance in the specific application.

Medical devices incorporating materials of biological origin:
1) Such tissues, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.
2) The selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

3) Processing, preservation, testing and handling of cells and substances should be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

**Environmental properties:**

1) If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer or mechanical coupling, should be designed and constructed in such a way as to minimize all possible risks from incorrect connection.

2) Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate:
   a. the risk of injury to the patient, user or other persons in connection with their physical and ergonomic features;
   b. the risk of use error due to the ergonomic features, human factors and the environment in which the device is intended to be used;
   c. risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature or variations in pressure and acceleration;
d. the risks associated with the use of the device when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use;

e. the risk associated with the possible negative interaction between software and the environment within which it operates and interacts;

f. the risks of accidental penetration of substances into the device;

g. the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;

h. Risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

3) Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.

4) Devices should be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.

5) Devices should be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.

**Devices with a diagnostic or measuring function:**

1) Diagnostic devices and devices with a measuring function, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device, based on appropriate scientific and technical methods. The limits of accuracy should be indicated by the manufacturer.

2) Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.

3) Wherever possible values expressed numerically should be in commonly accepted, standardized units, and understood by the users of the device.
Protection against radiation:

1) Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as reasonably practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

2) Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.

3) Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where reasonably practicable, with visual displays and/or audible warnings of such emissions.

4) Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as reasonably practicable and appropriate.

5) Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where reasonably practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.

6) Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.

7) Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.

Medical devices that incorporate software and standalone medical device software:

1) Devices incorporating electronic programmable systems, including software, or standalone software that are devices in themselves, should be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means should be adopted to
eliminate or reduce as far as reasonably practicable and appropriate consequent risks.

2) For devices which incorporate software or for standalone software that are devices in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation.

**Active medical devices and devices connected to them:**

1) For active medical devices, in the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequent risks.

2) Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.

3) Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.

4) Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

5) Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.

6) Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

7) Devices should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

**Protection against mechanical risks:**

1) Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

2) Devices should be designed and manufactured in such a way as to reduce to the
lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

3) Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

4) Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.

5) Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level, the risk of error when certain parts within the device are intended to be connected or reconnected before or during use.

6) Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal conditions of use.

Protection against the risks posed to the patient or user by supplied energy or substances:

1) Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

2) Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

3) The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.
Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons:

1) Devices for use by lay persons should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the lay person’s technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.

2) Devices for use by lay persons should be designed and manufactured in such a way as to reduce as far as reasonably practicable the risk of error during use by the lay person in the handling of the device and also in the interpretation of results.

3) Devices for use by lay persons should, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.

Label and Instructions for Use:

1) Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.

Conformity assessment:

Conformity Assessment Elements:

The conformity assessments elements include in a conformity assessment system are:

1. a quality management system
2. a system for post-market surveillance
3. summary technical documentation
4. a declaration of conformity
5. the registration of Establishments and their medical device

The conformity assessment elements that appear in this section describe the tasks of the manufacturer and, all five elements are applicable to the medical device according to its classification.
Quality management system (QMS)

The manufacturer should implement, document and maintain a QMS that ensures the medical devices it designs, manufactures and supplies to the market are safe, perform as intended and comply with the international standard. The scope and complexity of the QMS are influenced by the range of different medical devices that are under QMS control, the processes employed the size and structure of the organization.

Conformity assessment of the manufacturer’s QMS is influenced by the class of the medical device, as follows:

- Manufacturers of **Class A** devices should implement and maintain the basic elements of a QMS but have the option of excluding design and development controls from it.
- Manufacturers of **Class B** devices should implement and maintain an effective QMS but may have the option of excluding design and development controls from it.
- Manufacturers of **Class C and D** devices should implement and maintain an effective QMS that includes design and development controls.

System for post market surveillance

Prior to placing the product on the market, the manufacturer will put in place as part of its QMS, a process to assess the continued conformity of the device to the Essential Principles of Safety and Performance throughout the medical device lifecycle. This process will include, at a minimum, complaint handling, vigilance reporting, and corrective and preventive action.

Technical documentation

Manufacturers of all classes (except class A) of device are expected to demonstrate conformity of the device to the *Essential Principles of Safety and Performance of Medical Devices* through the preparation and holding of summary of technical documentation (STED) that shows how each medical device was developed, designed and manufactured together with the descriptions and explanations necessary to understand the manufacturer’s determination with
respect to such conformity. This technical documentation is updated as necessary to reflect the current status, specification and configuration of the device.

A description of that subset will be provided in the *(Appendix – STED 1)*. The extent of evidence on the STED; is likely to increase with the class of the medical device and its complexity.

**Declaration of conformity**

The manufacturer is requires attest that medical device complies fully with the Regulation, Risk Classification and all applicable Essential Principles for Safety and Performance as documented, in the format of Declaration of Conformity *(Appendix – 2)*.

**The registration of Establishments and their medical device**

Prior to placing a medical device on the market, all medical device establishments must be registered according to the Guideline *(http://nmpb.gov.sd/forms/4299)*, and all medical device must be registered according to this guideline.

**Labeling:**

**General Principles**

The primary purpose of labelling is to identify the medical device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on packaging or as instructions for use. The following principles are recommended:

1) The medium, format, content, legibility, and location of the label and instructions for use should be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some devices may include separate information for the professional user and the lay person.
2) The information required on the label, should be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.

3) Where the manufacturer supplies multiple devices to a single user and/or location, it may be sufficient to provide only a single copy of the instructions for use. In these circumstances, the manufacturer should provide further copies upon request.

4) Instructions for use may not be needed or may be abbreviated for devices if they can be used safely and as intended by the manufacturer without any such instructions for use.

5) Labels should be provided in a human-readable format but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.

6) Instructions for use may be provided to the user either in paper or non-paper format (e.g. electronic). They may be supplied by various means either with the medical device or separate from it. Examples of other means are information displayed on a screen incorporated into the device, information downloaded from the manufacturer’s web site using the internet, and machine-readable sources. The means chosen should be appropriate for, and accessible to, the anticipated user population.

7) Where instructions for use are provided on a medium other than paper, the manufacturer should ensure the user has information on how to:

   a) view the instructions for use;
   b) access the correct version of the instructions for use; and
   c) Obtain a paper version of the instructions for use.

8) Residual risks which are required to be communicated to the user and/or other person should be included as limitations, contraindications, precautions or warnings in the labelling.
9) The use of internationally recognised symbols should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the user. Where the meaning of the symbol is not obvious to the device user, e.g. for a newly introduced symbol, an explanation should be provided within the instructions for use.

10) Country-specific requirements for the content of the labelling should be kept to the minimum and, where they currently exist, eliminated as the opportunity arises.

11) Provided that safe and correct use of the device is ensured, the labelling must to be in Arabic and/or English language(s).

**Content of the Label**

The label should contain the following particulars which may appear on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

a) The name of the medical device.

b) The details strictly necessary for a user to identify the device and its use, e.g. ‘cardiac ablation catheter 10 French / 20 cms’ or ‘pediatric thermometer’ or ‘tongue depressor’, and a product catalogue code.

c) The name and address of the manufacturer in a format that is recognisable and allows the location of the manufacturer to be established.

d) For imported medical devices, the name and postal address of either the authorised representative, or importer or distributor established within the importing country/jurisdiction (if applicable). This information may be added by the authorised representative, importer or distributor, rather than be provided by the manufacturer, in which case, the additional label should not obscure any of the manufacturer's labels.

e) Where appropriate, an indication that the device contains or incorporates a medicinal or biological substance, e.g. heparin coated catheter.

f) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol.
g) An unambiguous indication of the date until when the medical device may be used safely, expressed at least as the year and month (e.g. on reagents or consumables), where this is relevant.

h) An indication of any special storage and/or handling condition that applies.

i) If the medical device is supplied as sterile, an indication of its sterile state and, where appropriate, the sterilization method.

j) Warnings or precautions to be taken that need to be brought to the immediate attention of the professional user, the lay person or other person (e.g. ‘CAUTION – LASER’ or ‘CONTAINS POTENTIALLY INFECTIOUS MATERIAL’). This information may be kept to a minimum in which case more detailed information will appear in the instructions for use.

k) If the medical device is intended for single use an indication of that fact.

l) If the device is for use by a single individual and has been manufactured according to a written prescription or pattern (i.e. it is custom made), an indication of that fact.

m) If the device is intended for premarket clinical investigation only, an indication of that fact.

    Note: In this situation, some of the label content listed above may not apply.

n) If the device is intended for non-clinical research, teaching or testing purposes only, an indication of that fact.

    Note: In this situation, some of the label content listed above may not apply.

o) If the device is intended for presentation or demonstration purposes only, an indication of that fact.

    Note: In this situation, some of the label content listed above may not apply.

Content of the Instructions for Use

The instructions for use should contain the following particulars:

a) The name of the medical device.

b) The name and address of the manufacturer in a format that is recognizable and allows the location of the manufacturer to be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance.

c) The medical device’s intended use/purpose including the intended user.
d) The performance of the device intended by the manufacturer.

e) Where the manufacturer has included clinical investigations as part of premarket conformity assessment to demonstrate conformity to Essential Principles, a summary of the investigation, outcome data and clinical safety information, or a reference as to where such information may be accessed.

f) Any residual risks, contraindications and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard.

g) Specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it.

h) If the device contains, or incorporates, a medicinal substance and/or material of biological origin, identification of that substance or material, as appropriate.

i) Details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilization, final assembly, calibration, etc.).

j) Any requirements for special facilities, or special training, or particular qualifications of the device user and/or third parties.

k) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:
   a. details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection;
   b. identification of any consumable components and how to replace them;
   c. information on any necessary calibration to ensure that the device operates properly and safely during its intended life span;
   d. Methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing medical devices.

l) An indication of any special storage and/or handling condition that applies.

m) If the device is supplied sterile, instructions in the event of the sterile packaging being damaged before use.

n) If the device is supplied non-sterile with the intention that it is sterilized before use, the appropriate instructions for sterilization.

o) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization. Information should be provided to identify
when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.

p) For devices intended for use together with other medical devices and/or general purpose equipment:
   a. information to identify such devices or equipment, in order to obtain a safe combination, and/or
   b. Information on any known restrictions to combinations of medical devices and equipment.

q) If the device emits hazardous, or potentially hazardous levels of radiation for medical purposes:
   a. detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation;
   b. the means of protecting the patient, user, or third party from unintended radiation during use of the device;
   c. Information that allows the user and/or patient to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. This information should cover, where appropriate:
      d. warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety;
      e. warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;
      f. warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the device affecting other equipment);
      g. if the device administers medicinal or biological products, any limitations or incompatibility in the choice of substances to be delivered;
h. warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device;
i. Precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or could result in sensitization or allergic reaction of the patient or user.
r) Warnings or precautions to be taken related to the disposal of the device, its accessories and the consumables used with it, if any. This information should cover, where appropriate:
a. infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);
b. environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation);
c. Physical hazards (e.g. from sharps).
s) For devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.
t) Date of issue or latest revision of the instructions for use and, where appropriate, an identification number.