Medical Devices **Essential Principles Checklist**	**Legal Manufacturer:**		**Product Name:**
South African Licensed Medical Device Establishment Name: …… **License Number**: …….	**A/NA** *	**Method of Conformity** **Medical Device Standards or procedures applied by manufacturer** e.g. South African National Standards (SANS); EN; ISO or company procedures identified by number / title.	**Evidence of compliance or reason for non- applicability** This column to contain direct reference to documents such as: study results, test reports, design outputs identified by number / title within the Quality System.

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1.	**GENERAL PRINCIPLES**			
1	**Use of medical devices not to compromise health and safety** A medical device is to be designed and produced in a way that ensures that: 1) the device will not compromise the clinical condition or safety of a patient, or the safety and health of the user or any other person, when the device is used on a patient under the conditions and for the purposes for which the device was intended and, if applicable, by a user with appropriate technical knowledge, experience, education or training; and 2) any risks associated with the use of the device are: (a) acceptable risks when weighed against the intended benefit to the patient; and (b) compatible with a high level of protection of health and safety.	A		

2.	**Design and construction of medical devices to conform with safety principles** (1) The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles, having regard to the generally acknowledged state of the art. (2) Without limiting subsection (1), in selecting appropriate solutions for the design and construction of a medical device so as to minimise any risks associated with the use of the device, the manufacturer must: a) first, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; and b) second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and c) third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and d) fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted. In paragraph 2 (d): ***residual risk***, for a medical device, means the risk remaining after the measures described in paragraphs (2) (a), (b) and (c) have been applied.	A		
3.	**Medical devices to be suitable for intended purpose** A medical device must: a) perform in the way intended by the manufacturer; and b) be designed, produced and packaged in a way that ensures that it is suitable for one or more of the purposes mentioned in the definition of medical device in the Medicines and Related Substances Act, 1965 (Act 101 of 1965).	A		

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4.	**Long-term safety** A medical device must be designed and produced in a way that ensures that if: a) the device is used within the period, indicated by the manufacturer, in which the device can be safely used; and b) the device is not subjected to stresses that are outside the stresses that can occur during normal conditions of use; and c) the device is regularly maintained and calibrated in accordance with the manufacturer's instructions; d) the characteristics and performances mentioned in clauses 1, 2 and 3 are not adversely affected.	A		
5.	**Medical devices not to be adversely affected by transport or storage** A medical device must be designed, produced and packed in a way that ensures that the characteristics and performance of the device when it is being used for its intended purpose will not be adversely affected during transport and storage that is carried out taking account of the instructions and information provided by the manufacturer	NA		
6.	**Benefits of medical devices to outweigh any undesirable effects** The benefits to be gained from the use of a medical device for the performance intended by the manufacturer must outweigh any undesirable effects arising from its use.	A		

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2.	PRINCIPLES ABOUT DESIGN AND CONSTRUCTION			
7.	***Chemical, physical and biological properties***			
7.1	**Choice of materials** In ensuring that the requirements of the General Principles are met in relation to a medical device, particular attention must be given to: a) the chemical and physical properties of the materials used in the device; and b) the compatibility between the materials used and biological tissues, cells, body fluids and specimens; c) having regard to the intended purpose of the device.	NA		
7.2	**Minimisation of risks associated with contaminants and residues** 1) A medical device must be designed, produced and packed in a way that ensures that any risks associated with contaminants and residues that may affect a person who is involved in transporting, storing or using the device, or a patient, are minimised, having regard to the intended purpose of the device. 2) In minimising risks, particular consideration must be given to the likely duration and frequency of any tissue exposure associated with the transportation, storage or use of the device.	NA		

7.3	**Ability to be used safely with materials, etc** A medical device must be designed and produced in a way that ensures that the device can be used safely with any material, substance or gas with which the device may come into contact during normal use or use in routine procedures. If the device is intended to be used to administer medicine, it must be designed and produced in a way that ensures that the device: a) is compatible with the provisions and restrictions applying to the medicine to be administered; and b) allows the medicine to perform as intended.	NA		
7.4	**Verification of incorporated substance** If a medical device incorporates, or is intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device: a) the safety and quality of the substance must be verified in accordance with the requirements for medicines; and b) the ancillary action of the substance must be verified having regard to the intended purpose of the device.	NA		
7.5	**Minimisation of risks associated with leaching substances** A medical device must be designed and produced in a way that ensures that any risks associated with substances that may leach from the device are minimised.	NA		

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7.6	**Minimisation of risks associated with ingress or egress of substances** A medical device must be designed and produced in a way that ensures that any risks associated with unintentional ingress of substances into, or unintentional egress or leaking of substances out of, the device are minimised, having regard to the nature of the environment in which the device is intended to be used.	NA		
8.	***Infection and microbial contamination***			
8.1	**Minimisation of risk of infection and contamination** A medical device must be designed and produced in a way that ensures that the risk of infection to a patient, a user, or any other person, is eliminated or minimised. The device must be designed in a way that: a) allows it to be easily handled; and b) if appropriate, minimises contamination of the device or specimen by the patient, user or other person by the device or specimen and. c) if appropriate, minimises contamination of the patient, user or other person by the device or specimen.	NA		

8.2	**Control of animal, microbial or recombinant tissues, tissue derivatives, cells and other substances** 1) This section applies to a medical device that contains: a) Tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable; and b) tissues, tissue derivatives, cells or substances of microbial or recombinant origin. 2) If the tissues, tissue derivatives, cells or substances originated from animals, the animals must have been subjected to appropriate veterinary controls and supervision, having regard to the intended use of the tissues, cells or substances. 3) If the medical device contains tissues, tissue derivatives, cells or substances of animal origin, a record must be kept of the country of origin of each animal from which the tissues, tissue derivatives, cells or substances originated. 4) The processing, preservation, testing and handling of tissues, tissue derivatives, cells or substances of animal, microbial or recombinant origin must be carried out in a way that ensures the highest standards of safety for a patient, the user of the device, and any other person. 5) In particular, the production process must implement validated methods of elimination, or inactivation, in relation to viruses and other transmissible agents.	NA		

8.3	**Medical devices to be supplied in a sterile state** Medical devices that are intended by the manufacturer to be supplied in a sterile state must be designed, produced and packed in a way that ensures that the device is sterile when it is supplied, and will remain sterile, if stored and transported in accordance with the directions of the manufacturer, until the protective packaging is opened or damaged. a) The device must be produced and sterilised using an appropriate validated method. b) The device must be produced in appropriately controlled conditions.	NA		
8.4	**Medical devices to be supplied in a non-sterile state** A medical device that is intended by the manufacturer to be supplied in a non-sterile state must be packed in a way that ensures that the device maintains the level of cleanliness stipulated by the manufacturer. If the device is intended to be sterilised before it is used, the device must be packed in a way that: a) ensures that the risk of microbial contamination is minimised; and b) is suitable, having regard to the method of sterilisation that the manufacturer indicates is to be used for the device. c) The device must be produced in appropriately controlled conditions.	NA		
8.5	**Distinction between medical devices supplied in sterile and non-sterile state** If a medical device is supplied in both a sterile state and a non-sterile state, the information provided with the device must clearly indicate whether the device is in a sterile state or a non-sterile state.	NA		

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9.	***Construction and environmental properties***			
9.1	**Medical devices intended to be used in combination with other devices or equipment** A medical device that is intended by the manufacturer to be used in combination with another medical device or other equipment (including a connection system) must be designed and produced in a way that ensures that: a) the medical device, and any other device or equipment with which it is used, operate in a safe way; and b) the intended performance of the device, and any other device or equipment with which it is used, is not impaired. Any restrictions on use must be indicated on the label or in the instructions for use.	A		

9.2	**Minimisation of risks associated with use of medical devices** A medical device must be designed and produced in a way that ensures that, as far as practicable, the following risks are removed or minimised: a) the risk of injury arising from the physical features of the device; b) any risks associated with reasonably foreseeable environmental conditions; c) the risk of reciprocal interference involving other devices that are normally used in an investigation or treatment of the kind for which the device is intended to be used; d) any risks arising if maintenance or calibration of the device is not possible; e) any risks associated with the ageing of materials used in the device; f) any risks associated with loss of accuracy of any measuring or control mechanism of the device; g) the risk of fire or explosion occurring during normal use of the device, and in the event of a single fault condition, especially if the device is intended to be exposed to flammable substances or substances that can cause combustion; h) the risks associated with disposal of any waste substances.	A		

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10.	***Medical devices with a measuring function***			
	A medical device that has a measuring function must be designed and produced in a way that ensures that the device provides accurate, precise and stable measurements within the limits indicated by the manufacturer and having regard to the intended purpose of the device. The measurement, monitoring and display scale of the device must be designed and produced in accordance with ergonomic principles, having regard to the intended purpose of the device. The measurements made by the device must be expressed: a) in South African legal units of measurement; or b) if the device measures a physical quantity for which no South African legal unit of measurement has been prescribed under the requirements of the Trade Metrology Act and Regulations, 1973 (Act 77 of 1973), and the Measuring Units and National Measuring Standards Act, 1973 (Act 76 0f 1973).	NA		
11.	***Protection against radiation***			
11.1	**Minimisation of exposure to radiation** This Essential Principle is intended to cover all forms of radiation. A medical device must be designed and produced in a way that ensures that the exposure of a patient, the user, or any other person, to radiation is minimised, having regard to the levels of radiation required to enable the device to perform its therapeutic and diagnostic functions and the intended purpose of the device.	NA		

11.2	**Medical devices intended to emit radiation** This applies to a medical device that is intended by the manufacturer to emit hazardous levels of visible or invisible radiation because the emission is necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission. a) The device must be designed and produced in a way that ensures that the user can control the level of the emission. b) The device must be designed and produced in a way that ensures the reproducibility and tolerance of relevant variable parameters. c) If practicable, the device must be fitted with a visual indicator or an audible warning, or both, that operates if potentially hazardous levels of radiation are emitted.	NA		
11.3	**Minimisation of exposure to unintended radiation** A medical device must be designed and produced in a way that ensures that the exposure of a patient, the user, or any other person, to the emission of unintended, stray or scattered radiation is minimised.	NA		
11.4	**Operating instructions** The operating instructions for a medical device that emits radiation must include detailed information about the following matters: a) the nature of the radiation emitted; b) the means by which patients and users can be protected from the radiation; c) ways to avoid misusing the device; d) ways to eliminate any risks inherent in the installation of the device.	NA		

11.5	**Medical devices intended to emit ionising radiation – additional requirements** In addition to clauses 11.1 to 11.4, the device must be designed and produced in a way that ensures that, if practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be controlled and varied, having regard to the intended purpose of the device. 1) If the device is intended to be used for diagnostic radiology, the device must be designed and produced in a way that ensures that, when used in relation to a patient for a purpose intended by the manufacturer: a) the device achieves an appropriate image or output quality for that purpose; and b) the exposure of the patient, or the user, to radiation is minimised 2) If the device is intended to be used for therapeutic radiology, the device must be designed and produced in a way that ensures that the delivered dose of radiation, the type and energy of the radiation beam and, if appropriate, the energy distribution of the radiation beam can be reliably controlled and monitored.	NA		
12.	***Medical devices connected to or equipped with an energy source***			
12.1	**Medical devices incorporating electronic programmable systems** A medical device that incorporates an electronic programmable system must be designed and produced in a way that ensures that: a) the performance, reliability, and repeatability of the system are appropriate for the intended purpose of the device; and b) any consequent risks associated with a single fault condition in the system are minimised.	NA		

12.2	**Safety dependent on internal power supply** This section applies to a medical device if the safety of a patient on whom the device is to be used will depend on an internal power supply for the device. a) The device must be fitted with a means of determining the state of the power supply.	NA		
12.3	**Safety dependent on external power supply** This section applies to a medical device if the safety of a patient on whom the device is to be used will depend on an external power supply for the device. It applies if the safety of the patient will depend on the external power supply for the device. a) The device must be fitted with an alarm system that indicates whether a power failure has occurred.	NA		
12.4	**Medical devices intended to monitor clinical parameters** A medical device that is intended by the manufacturer to be used to monitor one or more clinical parameters of a patient must be fitted with an appropriate alarm system to warn the user if a situation has developed that could lead to the death of the patient or a severe deterioration in the state of the patient's health.	NA		
12.5	**Minimisation of risk of electromagnetic fields** A medical device must be designed and produced in a way that ensures that the risk of an electromagnetic field being created that could impair the operation of other devices or equipment being used in the vicinity of the medical device is minimised	NA		
12.6	**Protection against electrical risks** A medical device must be designed and produced in a way that ensures that, as far as possible, when the device is installed correctly, and the device is being used for an intended purpose under normal conditions of use and in the event of a single fault condition, patients, users, and any other persons, are protected against the risk of accidental electric shock.	NA		

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12.7	**Protection against mechanical risks** A medical device must be designed and produced in a way that ensures that a patient, the user, and any other person, is protected against any mechanical risks associated with the use of the device.	NA		
12.8	**Protection against risks associated with vibration** A medical device must be designed and produced in a way that ensures that any risks associated with vibrations generated by the device are minimised. If vibrations are not part of the intended performance of the device, particular attention must be given to relevant technical progress, and the available means, for limiting vibrations, particularly at source.	NA		
12.9	**Protection against risks associated with noise** A medical device must be designed and produced in a way that ensures that any risks associated with noise emitted by the device are minimised. If noise is not part of the intended performance of the device, particular attention must be given to relevant technical progress, and the available means, for reducing the emission of noise, particularly at source.	NA		
12.10	**Protection against risks associated with terminals and connectors** A medical device that is intended by the manufacturer to be connected to an electric, gas, hydraulic, pneumatic or other energy supply must be designed and produced in a way that ensures that any risks to the user associated with the handling of a terminal or connector on the device, in relation to the energy supply, are minimised.	NA		

12.11	**Protection against risks associated with heat** A medical device must be designed and produced in a way that ensures that, during normal use, any accessible part of the device (other than any part intended by the manufacturer to supply heat or reach a given temperature), and any area surrounding an accessible part of the device, does not reach a potentially dangerous temperature.	NA		
12.12	**Protection against risks associated with administration of energy or substances** This section applies in relation to a medical device that is intended by the manufacturer to be used to administer energy or a substance to a patient. 1) The device must be designed and produced in a way that ensures that: a) the delivered rate and amount of energy, or of the substance, can be set and maintained accurately to ensure the safety of the patient and the user; and b) as far as possible, the accidental release of dangerous levels of energy or of the substance is prevented. 2) The device must be fitted with a means of indicating or, if appropriate, preventing inadequacies in the rate and amount of energy, or of the substance, administered that might cause danger to the patient, the user or any other person. 3) The functions of each control and indicator on the device must be clearly specified on the device. 4) If the instructions for the operation of the device, or the operating or adjustment parameters for the device, are displayed by means of a visual system incorporated into the device, the instructions or parameters must be able to be understood by the user and, if appropriate, the patient.	NA		

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12.13	**Active implantable medical devices** 1) An active implantable medical device must display a code that can be used to identify: a) the type of device; and b) the manufacturer of the device; and c) the year of manufacture of the device. 2) The code must be able to be read without the need for surgery to the person in whom the device is implanted.	NA		

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13.	***Information supplied by the manufacturer***			
13.1	**Information to be provided with medical devices – general** Refer to the requirements of the Medicines and Related Substances Act 101, as amended and Medical Device Regulations 1) The following information must be provided with a medical device: (a) information identifying the device; (b) information identifying the manufacturer of the device; (c) information explaining how to use the device safely; having regard to the training and knowledge of potential users of the device. In particular: (d) the information required by section 13.3 must be provided with a medical device; and (e) if *instructions for use* of the device are required under subsection 13.4, the information mentioned in subsection 13.4.1must be provided in those instructions. 2) The information must be provided in English, and may also be provided in any other South African language. 3) The format, content and location of the information must be appropriate for the device and its intended purpose. 4) Any number, letter, symbol, or letter or number in a symbol, used in the information must be legible and at least 1 millimetre high. 5) If a symbol or identification colour that is not included in a medical device standard is used in the information provided with the device, or in the *instructions for Use* of the device, the meaning of the symbol or identification colour must be explained in the information provided with the device or the *instructions for use* of the device.	NA		

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13.2	**Information to be provided with medical devices – location** Refer to the requirements of the Medicines and Related Substances Act 101, as amended and Medical Device Labelling Regulations 1) Unless it is impracticable or inappropriate to do so, the information required to be provided with a medical device must be provided on the device itself. If this is not practicable, the information must be provided: a) on the package used for the device; or b) in the case of devices that are packaged together because individual packaging of the devices for supply is not practicable – on the outer packaging used for the devices. If it is not practicable to comply with either of the above, the information must be provided on a leaflet supplied with the device, or in a printed document or using other appropriate media.	NA		

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13.3	**Information to be provided with medical devices – particular requirements** Refer to the requirements of the Medicines and Related Substances Act 101, as amended and Medical Device Regulations Information to be provided with medical devices as a label where possible on the medical device or IVD, or on the packaging of each unit or on the packaging of multiple devices or IVDs The following information must be provided with a medical device. The name or trade name of the medical device; a) product description and intended use; b) the — (i) registration number of the medical device allocated in terms of Section 15(5) of the Act; or (ii) application number allocated by the Authority followed by the expression “Act 101/1965”; c) a product catalogue code, where applicable; d) the name and business address of the licensee as per regulation 13(1)(*a*)(i) or 13(1)(*a*)(ii); e) the name and business address of the holder of the certificate of registration; f) where appropriate, an indication that the medical device contains or incorporates a scheduled or biological substance; g) the batch or lot number, where applicable; h) the serial number, where applicable; i) for accessories, the serial number may be substituted with a control number and for software it may be substituted with a version number; k) the expiry date, where applicable; l) where there is no indication of the expiry date, the manufacturing date;			

13.3 cont.	**Information to be provided with medical devices – particular requirements *continued.*** m) an indication of the special storage or handling conditions applicable; n) if the medical device is supplied sterile, an indication of its sterile state and, where appropriate, the sterilisation method; o) where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package; (p) warnings or precautions, where applicable; and (q) where appropriate an indication that the medical device is intended for— (i) single use; (ii) clinical clinical trial or premarket clinical performance study; (iii) non-clinical research, teaching or testing purposes; (iv) exhibition or appraisal purposes (v) *in vitro* diagnostic (IVD) use or Laboratory Developed Tests; and (vi) where relevant, "for professional use only" or “near patient testing” or “point of care” or “self-testing”.	NA		

13.4	**Instructions for use** Refer to the requirements of the Medicines and Related Substances Act 101, as amended and Medical Device Regulations 1) Information to be provided as *Instructions for Use* with the medical device or IVD, or on the packaging of each unit or on the packaging of multiple devices or IVDs. 2) Instructions for the use of a medical device must be provided with the device. However, instructions for the use of a medical device need not be provided with the device, or may be abbreviated, if: a) the device is a Class A medical device and b) the device can be used safely for its intended purpose without instructions. 3) *Instructions for the use* of a medical device must contain the information, that is applicable to the type of medical device (IVD or NON- IVD) as per the Medical Device Regulation. ***Instructions for the use* of a NON IVD medical device** must contain: (a) The name or trade name of the medical device; (b) the— (i) registration number of the medical device allocated in terms of section 15(5) of the Act; or (ii) application number allocated by the Authority followed by the expression "Act 101/1965"; (c) the name and business address of the licensee as per regulation 13(1)(*a*)(i) or 13(1) (*a*)(ii); (d) the name and business address of the holder of the certificate of registration; (e) where practical, the approved intended purpose or use of the medical device and where appropriate, the intended user;	NA		

13.4 cont.	**Instructions for use *continued.*** (f) residual risks, contraindications and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard; (g) specifications that the user requires in order to use the medical device appropriately, including but not limited to the degree of accuracy claimed in the case of a device with a measuring function; (h) if the medical device contains, or incorporates, a scheduled substance or a biological substance, identification of that substance, as appropriate; (i) details of any preparatory treatment or handling of the medical device required before it is ready for use including but not limited to sterilisation, final assembly or calibration; (j) any requirements for— (i) special facilities; or (ii) special training or qualifications of the intended user or third parties; (k) the information needed to verify whether the medical device is properly installed and is ready to perform as intended by the manufacturer, together with, where relevant— (i) details of the nature, and frequency of preventive and regular maintenance, and of any preparatory cleaning or disinfection; (ii) identification of any consumable components and how to replace them; (iii) information on any necessary calibration to ensure that the medical device operates properly and safely during its intended life span; and (iv) methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing medical devices; (l) an indication of any special transport, storage or handling requirements; (m) if the medical device is supplied sterile, instructions in the event of the sterile packaging being damaged before use;	NA		

13.4 cont.	**Instructions for use *continued.*** (n) if the medical device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation; (o) if the medical device is reusable, information – (i) on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilisation; and (ii) to identify when the medical device should no longer be reused including signs of material degradation or the maximum number of allowable reuses; (p) for medical devices intended for use together with other medical devices or general purpose equipment— (i) information to identify such medical devices or equipment, in order to obtain a safe combination; and (ii) information on any known restrictions to combinations of medical devices and equipment; (q) if the medical device emits hazardous, or potentially hazardous levels of radiation for medical purposes— (i) detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation; and (ii) the means of protecting the patient, user, or third party from unintended radiation during use of the medical device; (r) information that allows the user and patient to be informed of warnings, precautions, measures to be taken and limitations of use regarding the medical device which information must cover, where appropriate— (i) warnings, precautions and measures to be taken in the event of malfunction of the medical device or changes in its performance that may affect safety; (ii) warnings, precautions and measures to be taken in regard 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;	NA		

13.4 cont.	**Instructions for use *continued.*** (iii) warnings, precautions and measures to be taken in regard to the risks of interference posed by the reasonably foreseeable presence of the medical device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the medical device affecting other equipment); (iv) if the medical device administers a scheduled substance or a biological substance, any limitations or incompatibility in the choice of substance to be delivered; (v) warnings, precautions and limitations related to any scheduled substance or biological substance that is incorporated into the medical device as an integral part of the medical device; and (vi) precautions related to materials incorporated into the medical device that are potentially carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction of the patient or user; (s) warnings and precautions to be taken related to the disposal of the medical device, its accessories and the consumables used with it, if any: Provided that this information includes, where appropriate – (i) infection or microbial hazards which may include explants, needles or surgical equipment contaminated with potentially infectious substances; (ii) environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation; and (iii) physical hazards; (t) for medical devices intended for use by a layperson, the circumstances when the user must consult with a health care provider; (u) the date of issue or latest revision of the instructions for use; and (v) appropriate service and maintenance instructions for the medical device and associated technical equipment, where applicable.	NA		

Medical Devices **Essential Principles Checklist**	**Legal Manufacturer:**		**Product Name:**
South African Licensed Medical Device Establishment Name: …… **License Number**: …….	**A/NA** *	**Method of Conformity** **Medical Device standards or procedures applied by manufacturer** e.g. South African National Standards (SANS); EN; ISO or company procedures identified by number / title.	**Evidence of compliance or reason for non-applicability** This column to contain direct reference to documents such as: study results, test reports, design outputs identified by number / title within the technical dossier & quality system.

* APPLICABLE OR NOT TO THE DEVICE – IF NOT APPLICABLE JUSTIFICATION IS TO BE INCLUDED

14.	***Clinical evidence***			
	Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the Essential Principles. SAHRPA expects manufacturers to hold evidence that demonstrates that: a) the medical device achieves its intended purpose(s) during normal conditions of clinical use b) the known and foreseeable clinical risks and any adverse effects have been minimised c) the risk of using the medical device is acceptable when weighed against the benefits inherent in the intended purpose(s) d) any clinical claims about the device's performance and safety (for example on the label and the Instructions for Use) are supported by clinical data. A properly developed risk analysis is crucial in determining what type of clinical data is required for a particular device. An outcome of the analysis is the identification of any residual risks. The clinical data are expected to quantify and address those risks.	NA		
15.	***Principles applying to IVD medical devices only***			
15.1	1) An IVD medical device must be designed and manufactured in a way in which the analytical and clinical characteristics support the intended use, based on appropriate scientific and technical methods.	A		
	2) An IVD medical device must be designed in a way that addresses accuracy, precision, sensitivity, specificity, stability, control of known relevant interference and measurement of uncertainty, as appropriate.	A		

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	3) If performance of an IVD medical device depends in whole or part on the use of calibrators or control materials, the traceability of values assigned to the calibrators or control material must be assured through a quality management system.	A		
	4) An IVD medical device must, to the extent reasonably practicable, include provision for the user to verify, at the time of use, that the device will perform as intended by the manufacturer.	A		
	5) An IVD medical device for self-testing must be designed and manufactured so that it performs appropriately for its intended purpose, taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in the user's technique and environment.	A		
	6) The information and instructions provided by the manufacturer of an IVD medical device for self-testing must be easy for the user to understand and apply.	A		
	7) An IVD medical device for self-testing must be designed and manufactured in a way that reduces, to the extent practicable, the risk of error in the use of the device, the handling of the sample and the interpretation of results	A		

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15.2	***Instructions for the use* of an IVD medical device** must contain: a) The name or trade name; b) the— (i) registration number of the medical device allocated in terms of section 15(5) of the Act; or (ii) application number allocated by the Authority followed by the expression "Act 101/1965"; c) the name and business address of the holder of the certificate of registration; d) the name and business address of the licensee as per regulation 13(1)(*a*)(i) or 13(1) (*a*)(ii); e) the intended purpose and use, including but not limited to— (i) what is detected; (ii) its function; (iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate; (iv) whether it is automated or not; (v) whether it is qualitative or quantitative; (vi) the type of specimens required (e.g. serum, plasma, whole blood, tissue biopsy, urine); and (vii) testing population; f) an indication that it is for *in vitro* diagnostic use and, where relevant, for "professional use only", for "near patient testing", for "point of care", for "self-testing" or for "research use only"; g) the intended user, as appropriate; h) the test principle;	A		

15.2 cont.	**Instructions for the use of an IVD medical device *continued.***	A		

i) whether provided as an individual reagent or in an IVD kit with other appropriate articles, a description of—

a) the reagent and appropriate articles, which must include calibrators and controls;

b) any limitation upon the use of the reagent or the IVD kit, such as suitability for a dedicated instrument;

c) the composition of the reagent by nature and concentration of the active ingredients; and

d) a statement, where appropriate, that the medical device contains other ingredients which might influence the measurement;

j) a list of materials provided and a list of special materials required but not provided;

k) if intended for use together with other IVDs, medical devices, or general purpose equipment—

a) information to identify such IVDs, medical devices or equipment, in order to obtain a safe combination; and

b) information on any known restrictions to combinations of IVDs, medical devices and equipment;

l) an indication of any special transport, storage and handling requirements;

m) in use stability which may include the storage conditions, and shelf life following the first opening of the immediate container or primary packaging, together with the storage conditions and stability of working solutions, where relevant;

n) if the IVD is supplied sterile, instructions in the event of the sterile packaging being damaged before use;

15.2 cont.	**Instructions for the use of an IVD medical device *continued*.** o) information that allows the user to be informed of warnings, precautions, measures to be taken and limitations of use regarding the IVD, which information must cover, where appropriate— (i) warnings, precautions and measures to be taken in the event of malfunction of the IVD or its degradation as suggested by changes in its appearance that may affect performance; (ii) warnings, precautions and measures to be taken with regard 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; (iii) warnings, precautions and measures to be taken with regard to the risks of interference posed by the reasonably foreseeable presence of the medical device during specific diagnostic investigations, evaluations, therapeutic treatment including electromagnetic interference emitted by the medical device affecting other equipment, where applicable; and (iv) precautions related to materials incorporated into the IVD that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction; p) warnings and precautions related to potentially infectious material that is included in the IVD; q) where relevant, requirements for special facilities including clean room environment, radiation safety or particular qualifications of the medical device user;	A		

15.2 cont.	**Instructions for the use of an IVD medical device *continued.*** r) conditions for collection, handling, and preparation of the specimen; s) details of any preparatory treatment or handling of the IVD before it is ready for use including reconstitution and calibration where applicable; t) the information needed to verify whether the IVD is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant— (i) details of the nature, and frequency, of preventative and regular maintenance including cleaning and disinfection; (ii) identification of any consumable components and how to replace them; (iii) information on any necessary calibration to ensure that the IVD operates properly and safely during its intended life span; and (iv) methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing an IVD; u) where relevant, recommendations for quality control procedures; v) the metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and reference measurement procedures of higher order; w) assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing must be considered; x) analytical performance characteristics, such as sensitivity, specificity, and accuracy; y) where relevant, clinical performance characteristics, such as diagnostic sensitivity and diagnostic specificity; z) where relevant, reference intervals;	A		

Medical Devices **Essential Principles Checklist**	**Legal Manufacturer:**		**Product Name:**
South African Licensed Medical Device Establishment Name: …… **License Number**: …….	**A/NA** *	**Method of Conformity** **Medical Device standards or procedures applied by manufacturer** e.g. South African National Standards (SANS); EN; ISO or company procedures identified by number / title.	**Evidence of compliance or reason for non-applicability** This column to contain direct reference to documents such as: study results, test reports, design outputs identified by number / title within the technical dossier & quality system.

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15.2 cont.	**Instructions for the use of an IVD medical device *continued.*** aa) information on interfering substances or limitations such as visual evidence of hyperlipidaemia or haemolysis, age of specimen that may affect the performance of the assay; bb) warnings or precautions to be taken related to the disposal of the medical device, its accessories, and the consumables used with it, if any, which information must cover, where appropriate— (i) infection or microbial hazards; (ii) environmental hazards; and (iii) physical hazards; cc) for an IVD intended for use by a lay person, the circumstances when the user must consult with a health care provider; dd) where relevant, a bibliography; ee) the date of issue or latest revision of the instructions for use and, where appropriate, an identification number; and ff) appropriate maintenance instructions for technical IVD machines, where applicable.	A		