Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Medical devices Essential Principles checklist

Manufacturer name	
Product name	
ID	

Notes on what to include in each column

Applicable/Not applicable – respond with 'A' or 'NA' for the device. If not applicable (NA) include justification.

Medical Device Standards applied by manufacturer - only include standards published by the TGA as Medical Device Standard Orders or Conformity Assessment Standard Order.

Other standards or procedures applied by manufacturer – include; EN, ISO, international or local standards or company procedures identified by number or title.

Evidence of compliance or reason for non-applicability – include direct reference to documents such as: study results, test reports, design outputs identified by number or title within the Quality System.

Note: *Therapeutic Goods Act 1989* (the Act) and *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).

Schedule 1:	Essential Principle from the Regulations	Applicable/ Not applicable	Medical Device Standards applied by manufacturer	Other standards or procedures applied by manufacturer	Evidence of compliance or reason for non-applicability
Part 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: (a) the device will not compromise the clinical condition or safety of a patient, or the safety and health of the user of 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 (b) any risks associated with the use of the device are: (i) acceptable risks when weighed against the intended benefit to the patient; and (ii) compatible with a high level of protection of health and safety.				
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 subclause (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. (3) 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.				

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Part 1.	**General principles**				
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 subsection 41BD(1) of the Act.				
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; the characteristics and performances mentioned in clauses 1, 2 and 3 are not adversely affected.				
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.				
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.				

These clause numbers are in Schedule 1, *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations)

Schedule 1:	Requirement from the Regulations	Applicable/ Not applicable	Medical Device Standards applied by manufacturer	Other standards or procedures applied by manufacturer	Evidence of compliance or reason for non-applicability
Part 2.	**Principles about design and construction**				
7.	**Chemical, physical and biological properties**				
7.1	**Choice of materials** In ensuring that the requirements of Part 1 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; having regard to the intended purpose of the device.				
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.				
7.3	**Ability to be used safely with materials etc** (1) 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. (2) 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.				
7.4	**Verification of incorporated substance** (1) 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:				

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7.4	(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. (2) For the purposes of this clause, any stable derivative of human blood or human plasma is considered to be a medicine.				
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.				
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 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.				
7.7	**Minimisation of risks associated with nanomaterials** (1) A medical device must be designed and produced in a way that ensures that any risks associated with the size and the properties of particles which are, or can be, released into a patient's or user's body are minimised. (2) In minimising risks, particular attention must be given to the use of nanomaterials. (3) Subclause (1) does not apply to particles that come into contact with intact skin only.				
8.	**Infection and microbial contamination**				
8.1	**Minimisation of risk of infection and contamination** (1) 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. (2) 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; and (c) if appropriate, minimises contamination of the patient, user or other person by the device or specimen.				

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Part 2.	**Principles about design and construction**				
8.2	**Control of animal, microbial or recombinant tissues, tissue derivatives, cells and other substances** (1) This clause applies in relation to a medical device that contains: (a) tissues, tissue derivatives, cells or substances or 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, tissue derivatives, 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. **Note:** This may not apply to certain IVD medical devices if the characteristics mentioned in subclause 8.2(5) are integral to the intended purpose of the IVD medical device.				
8.3	**Medical devices to be supplied in a sterile state** (1) This clause applies in relation to a medical device that is intended by the manufacturer to be supplied in a sterile state. (2) The device 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. (3) The device must be produced and sterilised using an appropriate validated method. (4) The device must be produced in appropriately controlled conditions.				

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8.4	**Medical devices to be supplied in a non-sterile state** (1) 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. (2) 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. (3) The device must be produced in appropriately controlled conditions				
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.				
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.				
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;				

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	(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 the 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.				
10.	**Medical devices with a measuring function**				
	(1) 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. (2) 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. (3) The measurements made by the device must be expressed: (a) in Australian legal units of measurement; or (b) if the device measures a physical quantity for which no Australian legal unit of measurement has been prescribed under the National Measurement Act 1960, in units approved by the Secretary for the particular device.				
11.	**Protection against radiation**				
11.1	**Minimisation of exposure to 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.				

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11.2	**Medical devices intended to emit radiation** (1) This clause applies in relation to a medical device that is intended by a 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. (2) The device must be designed and produced in a way that ensures that the user can control the level of the emission. (3) The device must be designed and produced in a way that ensures the reproducibility and tolerance of relevant variable parameters. (4) 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.				
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.				
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.				
11.5	**Medical devices intended to emit ionising radiation – additional requirements** (1) This clause applies, in addition to clauses 11.1 to 11.4, in relation to a medical device that is intended by the manufacturer to emit ionising radiation. (2) 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.				

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	(3) 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. (4) 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.				
12.	**Medical devices connected to or equipped with an energy source**				
12.1	**Programmed or programmable medical device or software that is a medical device** (1) A programmed or programmable medical device, or software that is a medical device, that is intended to make use of either or both of data and information must be designed and produced in a way that ensures that: (a) the safety, performance, reliability, accuracy, precision, useability, security and repeatability of the device are appropriate for the intended purpose of the device; and (b) any consequent risks, or impairment of performance, associated with one or more fault conditions is eliminated or appropriately reduced; and (c) the device is resilient with respect to interactions that could occur during the use of the device and that could result in unsafe performance of the device; and (d) if relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides suitable warnings in a timely manner: (i) following the disruption to services upon which the device is dependent for the device's operation; and (ii) following the performance of the device being adversely affected; and (e) if relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides a means by which the user can verify correct operation of the device; and				

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	(f) if relevant to the safety of a patient, or the safety and health of the user or any other person, the integrity and quality of the data or information is maintained; and (g) if relevant, the privacy of the data or information is maintained. (2) A programmed or programmable medical device, or software that is a medical device, must be developed, produced and maintained having regard to the generally acknowledged state of the art (including for design, development life cycle, development environment, version control, quality and risk management, security, verification and validation, change and configuration management and problem resolution). (3) A programmed or programmable medical device, or software that is a medical device, that is intended to be used in combination with computing platforms must be designed and developed taking into account the capability, resources and configuration of the platforms and the external factors (including information technology environments) related to the use of the platforms. (4) The manufacturer of a programmed or programmable medical device, or software that is a medical device, must provide instructions or information with the device that sets out requirements (including requirements about hardware, software, information technology environments and security measures) necessary to operate the device as intended. (5) A programmed or programmable medical device, or software that is a medical device, must be designed, produced and maintained with regard to best practice in relation to software, security and engineering to provide cybersecurity of the device, including where appropriate the following: (a) protection against unauthorised access, unauthorised influence or unauthorised manipulation; (b) minimisation of risks associated with known cybersecurity vulnerabilities (including either or both of remediation of known vulnerabilities and application of compensating controls); (c) facilitation of the application of updates, patches, compensating controls and other improvements; (d) disclosure of known vulnerabilities in the device or its components and associated mitigations; (e) making available sufficient information for a user to make decisions with respect to the safety of applying, or not applying, updates, patches, compensating controls and other improvements				

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Part 2.	**Principles about design and construction**				
	6) The manufacturer of a programmed or programmable medical device, or software that is a medical device, having regard to the intended purpose of the device, the generally acknowledged state of the art and best practice, must ensure that the data that influences the performance of the device is: (a) representative; and (b) of sufficient quality; and (c) maintained to ensure integrity; and (d) managed to reduce bias.				
12.2	**Safety dependent on internal power supply** (1) This clause applies in relation 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. (2) The device must be fitted with a means of determining the state of the power supply.				
12.3	**Safety dependent on external power supply** (1) This clause applies in relation 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. (2) The device must be fitted with an alarm system that indicates whether a power failure has occurred.				
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				
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.				
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.				

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Part 2.	**Principles about design and construction**				
12.7	**Protection against mechanical risks** A medical device must be designed and produced in a way that ensures that a patient, the users and any other person, is protected against any mechanical risks associated with the use of the device.				
12.8	**Protection against risks associated with vibration** (1) 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. (2) 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.				
12.9	**Protection against risks associated with noise** (1) 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. (2) 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.				
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.				
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.				
12.12	**Protection against risks associated with administration of energy or substances** (1) This clause 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.				

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Part 2.	**Principles about design and construction**				
	(2) 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. (3) 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. (4) The functions of each control and indicator on the device must be clearly specified on the device. (5) 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.				
12.13	**Active implantable medical devices** (1) An active implantable medical device must incorporate, display, emit or exhibit a code or unique characteristic 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 or unique characteristic must be able to be read without the need for surgery to the person in whom the device is implanted.				
13.	**Information supplied by the manufacturer**				
13.1	**Information to be provided with medical devices – general** (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. (2) In particular: (a) the information required by clause 13.3 must be provided with a medical device; and				

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	(b) if instructions for use of the device are required under subclause 13.4, the information mentioned in subclause 13.4(3) must be provided in those instructions. (3) The information: (a) must be provided in English; and (b) may also be provided in any other language. (4) The format, content and location of the information must be appropriate for the device and its intended purpose. (5) Any number, letter, symbol, or letter or number in a symbol, used in the information must be legible and at least 1 millimetre high. (6) 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				
13.2	**Information to be provided with medical devices – location** (1) Unless it is impracticable and inappropriate to do so, the information required to be provided with a medical device must be provided on the device itself. (2) If it is not practicable to comply with subclause (1) in relation to the provision of the information, the information must be provided: (a) on the packaging used for the device; or (b) in the case of devices that are packaged together because individual packaging of the devices is not practicable – on the outer packaging used for the devices. (3) If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information required under subregulation 10.2(1) or clause 13.3: (a) for a medical device that is not software—the information must be provided on a leaflet supplied with the device; or (b) for a medical device that is software—the information must be provided on a leaflet supplied with the device or the information must be provided electronically. (4) If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information under clause 13.4, the information must be provided in printed documents or other appropriate media.				

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Part 2.	**Principles about design and construction**				
13.3	**Information to be provided with medical devices – particular requirements** The information mentioned below must be provided with a medical device. (1) The manufacturer's name, or trade name, and address (2) The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used where these are not obvious (3) Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging (4) Any particular handling or storage requirements applying to the device (5) Any warnings, restrictions on use, or precautions that should be taken, in relation to the use of the device (6) Any special operating instructions for the use of the device (7) If applicable, an indication that the device is intended for a single use only (8) If applicable, an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional (9) If applicable, an indication that: (a) if the device is a medical device other than an IVD medical device – the device is intended for pre-market clinical investigation; or (b) if the device is an IVD medical device – the device is intended for performance evaluation only (10) For a sterile device, the word "STERILE" and information about the method that was used to sterilise the device (11) The batch code, lot number or serial number of the device. (12) If applicable, a statement of the date (expressed in a way that clearly identifies the month and year) up to when the device can be safely used (13) If the information provided with the device does not include the information mentioned in item 12 – a statement of the date of manufacture of the device (this may be included in the batch code, lot number or serial number of the device provided the date is clearly identifiable) (14) If applicable, the words "for export only" **Note:** In addition to the information mentioned above, regulation 10.2 requires certain information to be provided with a medical device				

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Part 2.	**Principles about design and construction**				
13.4	**Instructions for use** (1) Instructions for the use of a medical device must be provided with the device. (2) However, instructions for use of a medical device need not be provided with the device, or may be abbreviated, if: (a) the device is a Class I medical device, a Class IIa medical device or a Class 1 IVD 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 include information mentioned below that is applicable to the device. (1) The manufacturer's name, or trade name, and address (2) The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used (3) Information about any risk arising because of other equipment likely to be present when the device is being used for its intended purpose (for example, electrical interference from electro-surgical devices or magnetic field interference from magnetic resonance images) (4) Information about the intended performance of the device and any undesirable side effects caused by use of the device (5) Any contraindications, warnings, restrictions on use, or precautions that may apply in relation to use of the device (6) Sufficient information to enable a user to identify the device, or if relevant, the contents of the packaging (7) Any particular handling or storage requirements applying to the device (8) If applicable, an indication that the device is intended for a single use only (9) If applicable, an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional (10) If applicable, an indication that: (a) if the device is a medical device other than an IVD medical device – the device is intended for pre-market clinical investigation; or (b) if the device is an IVD medical device – the device is intended for performance evaluation only (11) For a sterile device, the word "STERILE" and information about the method that was used to sterilise the device				

Schedule 1:	Requirement from the Regulations	Applicable/ Not applicable	Medical Device Standards applied by manufacturer	Other standards or procedures applied by manufacturer	Evidence of compliance or reason for non-applicability
Part 2.	**Principles about design and construction**				
	(12) For a device that is intended by the manufacturer to be supplied in a sterile state: (a) an indication that the device is sterile; and (b) information about what to do if sterile packaging is damaged and; (c) if appropriate, instructions for resterilisation of the device. (13) For a medical device that is intended by the manufacturer to be sterilised before use – instructions for cleaning and sterilising the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles (14) Any special operating instructions for the use of the device (15) Information to enable the use to verify whether the device is properly installed and whether it can be operated safely and correctly, including details of calibration (if any) needed to ensure that the device operates properly and safely during its intended life (16) Information about the nature and frequency of regular and preventative maintenance of the device, including information about the replacement of consumable components of the device during its intended life (17) Information about any treatment or handling needed before the device can be used (18) For a device that is intended by the manufacturer to be installed with, or connected to, another medical device or other equipment so that the device can operate as required for its intended purpose – sufficient information about the device to enable the user to identify the appropriate other medical device or equipment that will ensure a safe combination. (19) For an implantable device – information about any risks associated with its implantation (20) For a reusable device: (a) information about the appropriate processes to allow reuse of the device (including information about cleaning, disinfection, packaging, and, if appropriate, resterilisation of the device); and (b) an indication of the number of times the device may be safely reused				

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Part 2.	**Principles about design and construction**				
	(21) For a medical device that is intended by the manufacturer to emit radiation for medical purposes – details of the nature, type, intensity and distribution of the radiation emitted (22) Information about precautions that should be taken by a patient and the user if the performance of the device changes (23) Information about precautions that should be taken by a patient and the user if it is reasonably foreseeable that use of the device will result in the patient or user being exposed to adverse environmental conditions (24) Adequate information about any medicinal product that the device is designed to administer, including and limitations on the substances that may be administered using the device (25) Information about any medicine (including any stable derivative of human blood or blood plasma) that is incorporated, or intended to be incorporated, into the device as an integral part of the device. (25A) For a medical device, other than an IVD medical device, information about any tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin that are included in the device (26) Information about precautions that should be taken by a patient and the user if there are special or unusual risks associated with the disposal of the device (27) Information about the degree of accuracy claimed if the device has a measuring function (28) Information about any particular facilities required for use of the device or any particular training or qualifications required by the user of the device. (29) For an IVD medical device, information (including, to the extent practicable, drawings and diagrams) about the following: (a) the scientific principle (the 'test principle') on which the performance of the IVD medical device relies; (b) specimen type, collection, handling and preparation; (c) reagent description and any limitations (for example, use with a dedicated instrument only); (d) assay procedure including calculations and interpretation of results;				

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Part 2.	**Principles about design and construction**				
	(e) interfering substances and their effect on the performance of the assay; (f) analytical performance characteristics, such as sensitivity, specificity, accuracy and precision; (g) clinical performance characteristics, such as sensitivity and specificity; (h) reference intervals, if appropriate; (i) any precautions to be taken in relation to substances or materials that present a risk of infection (30) For an adaptable medical device, instructions for assembling or adapting the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles (31) For a medical device production system, instructions for the process to be followed in producing the medical device the system is intended to produce which, if followed, will ensure that the device so produced will comply with the applicable provisions of the essential principles				
13A	**Patient implant cards and patient information leaflets**				
13A.1	**Scope of clauses 13A.2 to 13A.4** Clauses 13A.2 to 13A.4 apply to a medical device that is: (a) an implantable medical device or an active implantable medical device; and (b) not a suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip or connector	n/a	n/a	n/a	n/a
13A.2	**Patient implant cards for implantable devices** (1) A card (a patient implant card) that meets the requirements of subclause (2) and clause 13A.4 must be provided with the medical device. (2) The card must include the information mentioned in the following table (in the Regulations). (1)(a) the name of the device; and (1)(b) the model of the device; and (1)(c) the batch code, lot number or serial number of the device; and (1)(d) the unique device identifier of the device (if any) (2) The manufacturer's name, address and website				

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Part 2.	**Principles about design and construction**				
13A.3	**Patient information leaflets for implantable devices** (1) A leaflet (a patient information leaflet) that meets the requirements of subclauses (2) to (4) and clause 13A.4 must be provided with the medical device. (2) The leaflet must include the following information: (a) information identifying the device, or the kind of device; (b) the intended purpose of the device; (c) information explaining how to use the device safely; (d) other information about the device that the manufacturer considers would be useful for patients. (3) In particular, the leaflet must include the information mentioned in the following table (in the Regulations). (1)(a) the name of the device; and (1)(b) the model of the device (2(a) the intended purpose of the device; and (2)(b) the kind of patient on whom the device is intended to be used (3)Any special operating instructions for the use of the device (4)(a) the intended performance of the device; and (4)(b) any undesirable side effects that could be caused by use of the device (5) Any residual risks that could arise due to any shortcomings of the protection measures adopted as mentioned in subclause 2(2) (6)(a) warnings about risks that could arise from the interaction of the device with other equipment; and (6)(b) precautions and other measures that, because of those risks, should be taken by the patient or a health professional **Example 1:** The risk of electrical interference from electro-surgical devices. **Example 2:** The risk of magnetic field interference from magnetic resonance imaging devices. (7)(a) the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and (7)(b) symptoms that could indicate that the device is malfunctioning; and (7)(c) precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and (7)(d) the expected device lifetime; and				

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	(7)(e) anything that could shorten or lengthen the device lifetime; and (7)(f) precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and (7)(g) other circumstances in which the patient should contact a health professional in relation to the operation of the device (8)(a) the materials and substances included in the device; and (8)(b) any manufacturing residuals that could pose a risk to the patient (9) (a) a notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration; and (9)(b) the address of the Therapeutic Goods Administration's website (4) The information in the leaflet must be written in a way that is readily understood by patients.				
13A.4	**Form of patient implant cards and patient information leaflets** (1) The information required by clause 13A.2 or 13A.3 to be included in a patient implant card or patient information leaflet: (a) must be included in English; and (b) may also be included in any other language. **Note:** The information may also include diagrams or drawings. (2) Any number, letter, symbol, or letter or number in a symbol, used in a patient implant card or patient information leaflet must be: (a) legible; and (b) at least 1 millimetre high.				
13B.	**Software – version numbers and build numbers**				
	(1) For a medical device that is software, or that incorporates software, the current version number and current build number of the software must be accessible by, and identifiable to, users of the device. (2) The current version number and current build number of the software: (a) must be in English; and (b) may also be in any other language.				

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Part 2.	**Principles about design and construction**				
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. **Note:** See regulation 3.11 and the clinical evaluation procedures.				
15.	**Principles applying to IVD medical devices only**				
15.1	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.				
15.2	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.				
15.3	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.				
15.4	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.				
15.5	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.				
15.6	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.				
15.7	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.				

These clause numbers are in Schedule 1, *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations)