Information Document 23	Manufacturer:Shenzhen Aeon Technology Co., Ltd		Product: Pulse Oximeter	ID:
Medical Devices Essential Principles Checklist	**A/NA** *	**Medical Device Standards applied by manufacturer** Only if the manufacturer applied standards published as Medical Device Standard Orders or Conformity Assessment Standard Order by the TGA	**Other standards or procedures applied by manufacturer** EN; ISO; international , local standards 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.

* APplicable or not to the device – if not applicable justification is to be included

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.	A		EN ISO 14971: 2012 IEC 60601-1:2012 IEC60601-1-2:2014 IEC 60601-1-11:2015	A310-CE-03E TRS18030352 2018-04-26 TRE18070082 2018-04-08 TRS18030351 2018-04-26 A310-CE-09E

Information Document 23	Manufacturer:Shenzhen Aeon Technology Co., Ltd			Product: Pulse Oximeter	ID:
Medical Devices Essential Principles Checklist	**A/NA** *	**Medical Device Standards applied by manufacturer** Only if the manufacturer applied standards published as Medical Device Standard Orders or Conformity Assessment Standard Order by the TGA	**Other standards or procedures applied by manufacturer** EN; ISO; international , local standards 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.	

* APplicable or not to the device – if not applicable justification is to be included

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.	A		EN1041 EN ISO 14971:2012 IEC 60601-1:2012 IEC60601-1-2:2014 IEC 60601-1-11:2015	A310-CE-03E TRS18030352 2018-04-26 TRE18070082 2018-04-08 TRS18030351 2018-04-26 A310-CE-09E
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.	A		EN ISO 14971: 2012:2012	A310-CE-03E A310-CE-04E

Information Document 23	Manufacturer:Shenzhen Aeon Technology Co., Ltd			Product: Pulse Oximeter	ID:
Medical Devices Essential Principles Checklist	**A/NA** *	**Medical Device Standards applied by manufacturer** Only if the manufacturer applied standards published as Medical Device Standard Orders or Conformity Assessment Standard Order by the TGA	**Other standards or procedures applied by manufacturer** EN; ISO; international , local standards 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.	

* APplicable or not to the device – if not applicable justification is to be included

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.	A		EN ISO 14971: 2012	A310-CE-03E
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.	A		EN ISO 14971: 2012 IEC 60601-1: 2012 ISO 80601-2-61:2011 IEC 60601-1-11:2015	A310-CE-03EA310-CE-06E A310-USER MANUAL TRS18030352 2018-04-26 TRS18030351 2018-04-26 TRS18030353 2018-04-26
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		EN ISO 14971: 2012	A310-CE-03E A310-USER MANUAL

* APplicable or not to the device – if not applicable justification is to be included

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.	A		EN ISO 14971: 2012 IEC 60601-1: 2012 ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	A310-CE-03E A310-CE-09E TRS18030352 2018-04-26 SDWH-M201802121, SDWH-M201802122
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		There aren't product contaminants and residues in the transport, storage and use of the devices.	
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.	NA		Medical device does not need to be loaded with medicinal products	

* APplicable or not to the device – if not applicable justification is to be included

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: (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.	NA			Medical device does not contain substance referred to 7.4.
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			Medical device is designed and manufactured without substances leaking, especially in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 and does not contain administer and/or remove medicine or other substances of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC
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.	A		IEC 60601-1: 2012 IEC60601-1-2:2014	A310-CE-09E TRS18030352 2018-04-26 TRE18070082 2018-04-08
8.	***Infection and microbial contamination***				

* APplicable or not to the device – if not applicable justification is to be included

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.	A		IEC 60601-1: 2012	TRS18030352 2018-04-26
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.	NA			Does not involve Tissues of animal origin.

* APplicable or not to the device – if not applicable justification is to be included

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.	NA			Medical device is not non-reusable, sterilized device.
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.	NA			Medical device is not non-reusable, sterilized device.
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			Medical device is not non-reusable, sterilized device.
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.	A		IEC 60601-1: 2012	TRS18030352 2018-04-26 A310-USER MANUAL

* APplicable or not to the device – if not applicable justification is to be included

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 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.	A		IEC 60601-1: 2012 IEC60601-1-2:2014 EN ISO 14971: 2012 ISO 80601-2-61:2011	A310-CE-03 A310-USER MANUAL TRS18030352 2018-04-26 TRE18070082 2018-04-08 TRS18030353 2018-04-26
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.	A		EN 1041: 2008	A310-USER MANUAL
11.	***Protection against radiation***				

* APplicable or not to the device – if not applicable justification is to be included

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.	A		IEC 60601-1: 2012 IEC60601-1-2:2014	A310-CE-09E
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.	NA			Medical device doesn't have radiation necessary for a specific medical purpose.
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.	A		EN60601-1-2:2014	TRE18070082 2018-04-08
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.	A		IEC60601-1-2:2014	TRE18070082 2018-04-08

* APplicable or not to the device – if not applicable justification is to be included

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. (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.	NA			Devices do not intend to emit ionizing radiation
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			No electronic programmable systems
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.	NA			Not to maintain patient safety equipment

* APplicable or not to the device – if not applicable justification is to be included

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.	NA			No alarm system, with LED indicator.
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			Devices don't intend to monitor one or more clinical parameters
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.	A		IEC60601-1-2:2014	TRE18070082 2018-04-08
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.	A		EN ISO 14971: 2012 IEC 60601-1: 2012	A310-CE-03E TRS18030352 2018-04-26
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.	A		ISO14971 IEC 60601-1: 2012	A310-CE-03E TRS18030352 2018-04-26
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.	(3) A	(4)	(5) EN ISO 14971: 2012 (6) IEC 60601-1: 2012	(7) A310-CE-03E (8) TRS18030352 2018-04-26

* APplicable or not to the device – if not applicable justification is to be included

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.	A		EN ISO 14971: 2012 IEC 60601-1: 2012	A310-CE-03E TRS18030352 2018-04-26
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.	A		EN ISO 14971: 2012 IEC 60601-1: 2012	A310-CE-03E TRS18030352 2018-04-26
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.	A		IEC 60601-1: 2012 EN ISO14971:2012	A200-CE-03E TRS18030352 2018-04-26

* APplicable or not to the device – if not applicable justification is to be included

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. (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.	A		IEC 60601-1: 2012 ISO 80601-2-61：2011 ISO14971:2012	A200-CE-03E TRS18030352 2018-04-26 TRS18030353 2018-04-26
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.	A		ISO 80601-2-61：2011 ISO14971:2012	A200-CE-03E TRS18030353 2018-04-26

Information Document 23	Manufacturer:Shenzhen Aeon Technology Co., Ltd			Product: Pulse Oximeter	ID:
Medical Devices Essential Principles Checklist	**A/NA** *	**Medical Device Standards applied by manufacturer** Only if the manufacturer applied standards published as Medical Device Standard Orders or Conformity Assessment Standard Order by the TGA	**Other standards or procedures applied by manufacturer** EN; ISO; international , local standards 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.	

* APplicable or not to the device – if not applicable justification is to be included

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 (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.	A		EN 1041: 2008 EN 980: 2008	A310-CE-03E A310-CE-07E A310-USER MANUAL

Information Document 23	Manufacturer:Shenzhen Aeon Technology Co., Ltd		Product: Pulse Oximeter	ID:
Medical Devices Essential Principles Checklist	**A/NA** *	**Medical Device Standards applied by manufacturer** Only if the manufacturer applied standards published as Medical Device Standard Orders or Conformity Assessment Standard Order by the TGA	**Other standards or procedures applied by manufacturer** EN; ISO; international , local standards 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.

* APplicable or not to the device – if not applicable justification is to be included

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 under clause 13.3, the information must be provided on a leaflet supplied with the device. (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.	A		EN 1041: 2008 EN 980: 2008	A310-CE-07E A310-USER MANUAL

* APplicable or not to the device – if not applicable justification is to be included

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.	NA items: (3), (5), (6), (7), (8), (9), (10), (13)		EN 1041: 2008 EN 980: 2008	A310-CE-07E

Information Document 23	Manufacturer:Shenzhen Aeon Technology Co., Ltd		Product: Pulse Oximeter	ID:
Medical Devices Essential Principles Checklist	**A/NA** *	**Medical Device Standards applied by manufacturer** Only if the manufacturer applied standards published as Medical Device Standard Orders or Conformity Assessment Standard Order by the TGA	**Other standards or procedures applied by manufacturer** EN; ISO; international , local standards 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.

* APplicable or not to the device – if not applicable justification is to be included

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 (12) For a device that is intended by the manufacturer to be supplied in a	A		EN 1041: 2008 EN980:2008 EN ISO14971:2012	A310-USER MANUAL

	(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. (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				

* APplicable or not to the device – if not applicable justification is to be included

	(24) Adequate information about any medicinal product that the device is designed to administer, including and limitations on the substances t hat 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; (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				
14.	***Clinical evidence***				

Information Document 23	Manufacturer:Shenzhen Aeon Technology Co., Ltd			Product: Pulse Oximeter	ID:
Medical Devices Essential Principles Checklist	**A/NA** *	**Medical Device Standards applied by manufacturer** Only if the manufacturer applied standards published as Medical Device Standard Orders or Conformity Assessment Standard Order by the TGA	**Other standards or procedures applied by manufacturer** EN; ISO; international , local standards 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.	

* APplicable or not to the device – if not applicable justification is to be included

	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.	A		EN ISO 14971: 2012 IEC 60601-1:2012 IEC60601-1-2:2014 IEC 60601-1-11:2015	A310-CE-05E
15.	***Principles applying to IVD medical devices only***				
	(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.	NA			
	(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.	NA			
	(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.	NA			
	(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.	NA			
	(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.	NA			
	(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.	NA			
	(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.	NA			