Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Complying with the Essential Principles on the safety and performance of medical devices

Guidance on how medical devices must comply with the Essential Principles, which set out fundamental safety and performance requirements.

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Purpose

The Essential Principles (the Principles) are legislative requirements relating to the safety and performance characteristics of medical devices. The Principles are in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Manufacturers of medical devices must hold scientific and other evidence that demonstrates that their devices meet the Principles before their devices can be supplied in Australia. Sponsors must either also hold, or be able to get, this evidence from their manufacturer(s) on request and within a reasonable time frame.

Importing, supplying, or exporting a medical device that does not meet the Principles is an offence under the *Therapeutic Goods Act 1989* (Part 4-11).

Legislation

Therapeutic Goods (Medical Devices) Regulations 2002

Principle 1: Use of medical devices not to compromise health and safety

The legislated requirements

Devices must be designed and produced so they won't compromise the safety and health of patients or other people. Every device comes with potential benefits as well as risks. Principle 1 states that the benefits to the patient must outweigh the risks, while still ensuring that health and safety can be protected to a high level.

All manufacturers must comply with this Principle.

The legislation says:

Principle 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 or any other person, when the device is used on a patient under the

conditions and for the purposes for which the device was intended and, if applicable, by a user with appropriate technical knowledge, experience, education or training; and

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.

Guidance for manufacturers

You must consider the Principles when designing, developing, manufacturing, and supplying your device. You must consider risks from normal use and known and foreseeable hazards and unwanted effects that could arise throughout the expected lifetime of the device. Undesirable hazards and risks must be removed and minimised as far as possible. All hazards and risks must be acceptable when weighed against the benefits of the intended performance (see Principle 6).

Some aspects for you to consider include:

- design, materials and construction of
- intended purpose of
- who will use
- how will people use
- the intended treatment setting of the device.

You should apply and maintain a risk-management process. This includes ongoing risk analyses that consider potential and known hazards that could occur during:

- design

- production,
- use, and
- decommissioning

throughout the expected lifetime of the device. You should examine and test risk-mitigation strategies to show that any measures used to reduce identified risks are effective.

You should apply a risk-management process before product development begins, as this will generate safety requirements for the design, manufacturing, and operation specifications. The design specification should include design transfer (to production) and production requirements (for example, specifications, tolerances, testing).

You must record well-reasoned evidence-based analyses of:

- known and foreseeable hazards from using the device, and
- benefits from using the device for the patient and user of the medical device.

These analyses must compare the risks and benefits from using the device and recognize the importance of safety for patients, users and other persons.

You must generate evidence that you meet Principle 1. At minimum, you should:

- identify and record the intended user. Explain in the Instructions for Use (IFU) what technical knowledge, experience, education and training is needed to use the device safely and as intended (if applicable). See also Principle 9, Principle 12.1 and Principle 13.
- identify and record the intended environment for use, including any required risk controls (for example, electrical or radiation safety)

- record evidence of design (including, where possible, designing out risks)
- record evidence of verification and validation (including testing)
- apply a rigorous, well-reasoned and documented risk management process
- review relevant published literature
- review your, and your customers', experience with the device
  assess and record compliance of the device and its packaging with specifications and relevant technical standards (for example, IEC 60601)
  review and document the labelling, IFU and patient information provided with the device. Include guidance to help the intended user decide whether the device is working correctly or not. Include calibration, maintenance, and servicing information where applicable
- perform studies to design and test for human factors (including useability) with a representative sample of intended users, where applicable
- validate information provided with the device (for example, labels and IFU) with a representative sample of intended users
- review and record final release procedures
- generate and critically evaluate the clinical evidence (see Principle 14). This could include a robust search of international and national studies.
- review the latest research on effective methods for protecting health and safety to a high level.

Principle 2: Design and construction of medical devices to conform with safety principles

The legislated requirements

Principle 2 focuses on manufacturers identifying and minimising risks from their medical devices during the design and construction stages. Manufacturers must consider current advances in technology and safety approaches to identify, eliminate, reduce, and manage risks.

All manufacturers must comply with this Principle.

The legislation says:

Principal 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 adopte

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.

Meeting Principle 2: Guidance for manufacturers

To meet Principle 2, you must design and construct your device to reduce risks from use. You should:

- identify hazards and risks
- remove or reduce these risks as much as possible
- develop adequate protection measures where risks cannot be removed
- inform users of risks.

You should document an analysis of safety and design to show compliance with Principle 2.

You should regularly review and update records and designs to account for advances in technology (this is also referred to in the legislation as the generally acknowledged state-of-the-art). You should also consider new information gained from adverse-event reporting and consumer complaints.

When developing the device design and construction processes, you need to consider all possible risks from the device. This includes risks from using the device as intended and from foreseeable misuse.

Your device design and construction process should include the removal of risks where possible. Where risks cannot be removed, efforts must be made to reduce risks to the lowest possible level. For remaining risks, you must put in place appropriate measures, including alarms, to protect your users and other people. You must alert and inform users residual risks arising from any shortcomings from your protection measures and provide guidance on how they can reduce or manage them further.

Work undertaken by you could involve, but is not restricted to:

- outlining your approach to safety management. This includes the methodology applied, responsible personnel, and plans for review
- performing and recording safety analyses, taking care to avoid confirmation bias
- reviewing your experience with the device
- recording compliance with, and/or consideration of, relevant standards and best-practice guides, science, and engineering methods.

Note

Compliance with relevant Australian and international technical standards is often used by manufacturers to show compliance with Principle 2. However, standards are not mandatory, and you can use other relevant methods of design, construction, and testing in order to comply with Principle 2.

If your device does not comply with relevant standards, you should record why you made this decision. You should also explain how your methods of design, construction, and testing for safety and performance are equivalent to, or better than, using the relevant standard(s).

Principle 3: Medical devices to be suitable for intended purpose

The legislated requirements

Manufacturers must ensure their devices perform in the way intended. The design of the device, the manufacturing process used, and the packaging in which the device is sold and transported must also be suitable for the intended purpose of the device.

All manufacturers must comply with this Principle.

The legislation says:

Principal 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.

Meeting Principle 3: Guidance for manufacturers

You must ensure your device performs in the way you intend it to. You must also ensure your device is designed, produced, and packaged in a way that it is suitable for its intended purpose.

Work you could do includes:

- developing and following appropriate test protocols and methods to demonstrate that the design, production, and packaging of your device enables it to perform as intended.
- preparing appropriate test reports and data supporting your claims.
- implementing and (where appropriate) obtaining certification of a quality management system.
- generating clinical evidence to demonstrate that your device performs as intended (see Principle 14 and Principle 15).
- determining and validating requirements for maintenance and calibration.
- monitoring the performance of your device in the field.
- monitoring customer feedback and adverse-event reports.
- ensuring software downloads, updates, or data transfers are accurate and deployed using appropriate controls. See also Principle 5 and Principle 12.1.

Principle 4: Long-term safety

The legislated requirements

Devices must remain safe to use for their expected lifetime when used according to instructions.

All manufacturers must comply with this Principle.

The legislation says:

Principle 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.

Meeting Principle 4: Guidance for manufacturers

You must generate and document evidence that your device is designed and produced in a way that ensures it will continue to meet Principle 1, Principle 2 and Principle 3:

- throughout the expected lifetime of your device
- under the stresses expected to be experienced by your device during normal conditions of use
- considering the maintenance and calibration requirements you specify for the intended users (see Principle 13 and Principle 12.1).

You should evaluate any adverse effects that could occur from stresses you expect to be experienced by your device during normal use and include them in a documented risk assessment.

'Expected lifetime' includes that experienced during manufacture, transport, and storage. Device lifetimes can be affected by the duration of use, or number of acceptable uses, that you indicate in the information you provide to users.

You must consider expected patient lifetimes when determining expected device lifetime for implanted devices that are not meant to be removed, or that are intended to be removed after a defined duration.

You must demonstrate safety of your device throughout its expected lifetime. Your assessment could involve:

- bench testing
- shelf-life testing (accelerated or real-time) and characterisation data (for example, from post-market signals)
- estimating ageing characteristics
- generating appropriate clinical evidence
- clinical evaluation
- well-reasoned and documented risk management activities
- review of post-market data, including for similar devices where this is supported by appropriate explanation and expert opinion that demonstrates how this relates to the subject device
- documented reviews of complaint history
- software updates for software-based devices.

Principle 5: Medical devices not to be adversely affected by transport or storage

The legislated requirements

A medical device must not be adversely affected during transport and storage providing that the manufacturer's instructions are followed.

The legislation says:

Principle 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.

Meeting Principle 5: Guidance for manufacturers

For every device, you must design, produce, package, label, and provide the necessary instructions for use so that its characteristics and performance are not adversely affected by transport or storage.

Things you could do include:

- label the device with recommended storage and transport conditions and shelf-life, where this is important for its performance

- identify the likely environmental and other conditions your device could be subject to during transport and storage
- test the design, production, and packaging of your device to ensure it is not adversely affected by transport and storage
- test simulated conditions of transport and storage, including those that may reasonably be expected during transport of your device. Simulated testing conditions should reflect your labelled storage conditions and claims under worst-case conditions
- identify and comply with relevant technical standards and guidance
- validate instructions and any other information for users of the device about its storage, handling, transport, and distribution
- deploy software downloads, updates, and data transfers with appropriate controls to ensure accuracy. See also Principle 12.1
- document ongoing reviews of complaint history.

Principle 6: Benefits of medical devices to outweigh any undesirable effects

The legislated requirements

The benefits of using a medical device must outweigh any unwanted effects from its use for both patients and users (for example, healthcare professionals and caregivers).

Manufacturers need to find ways to maximise benefits and reduce identified risks.

All manufacturers must comply with this Principle.

The legislation says:

Principle 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.

Meeting Principle 6: Guidance for manufacturers

You must hold evidence that the benefits of using your device outweigh the undesirable effects.

Work you do could involve:

- producing evidence that your device is designed to be safe and performs well
- recording well-reasoned risk-management for your device
- monitoring, review, and analysis of post-market performance data for your device
- literature reviews of your device and similar devices
- review of clinical, safety, and technical experience with previously supplied devices
- critical appraisal of your clinical evidence (see Principle 14), including but not limited to:
    - assessing the significance of the medical conditions being treated
    - comparison with alternative treatments
    - clinical literature reviews

    - clinical trials
    - post-market data
    - risk–benefit analysis.

You must identify and record any undesirable effects from using your device including those related to potential misuse. You must record a comparison of any undesirable effects with the known or expected benefits of using your device.

When considering the benefit versus undesirable effects, you should also consider current advances in technology and the generally acknowledged state-of-the-art (see Principle 2) to determine:

- minimum acceptable benefits
- maximum acceptable undesirable effects and risks

and to compare these to alternative treatments.

After reviewing the evidence, you may find that the benefit outweighs the risk for a smaller set of scenarios or patient cohorts than initially expected. Should this occur, you should either:

- amend your intended purpose to align with available evidence
- amend your design or production of the device to increase the benefits or minimise the risks (see Principle 2).

Principle 7: Chemical, physical and biological properties

The legislated requirements

Materials used in the manufacture of a medical device must be compatible with biological tissues, cells, body fluids, and specimens.

The legislation says:

Principle 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.

Meeting Principle 7.1: Guidance for manufacturers

You must be able to demonstrate that the materials used in your medical device are appropriate for its intended purpose. For example, you should consider quality, toxicity, flammability, and biocompatibility risks, and whether design, processing, labelling or instructions controls could remove or reduce the risks.

Historical data on materials used in any similar devices should be reviewed and included in the documented analysis.

You should perform a biological evaluation in accordance with relevant technical standards and state-of-the-art methods.

> Manufacturers should consider the *ISO 10993—Biological evaluation of medical devices* standard which is the generally acknowledged state-of-the-art for biocompatibility. Manufacturers must either meet or exceed the requirements of this standard, noting that the standard is not mandatory and there may be better ways to demonstrate safety and performance.

It may be possible to limit the degree of testing by considering the results of previous relevant tests on the same materials used in the same or similar applications.

The work you do could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- documented analysis and review of historical data on materials used in similar devices
- a biological evaluation based on relevant standards and state-of-the-art methods.

The legislated requirements

Any risks from contaminants and residues from a medical device must be minimised.

The legislation says:

Principal 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.

Meeting Principle 7.2: Guidance for manufacturers

> Manufacturers should consider the *ISO 10993—Biological evaluation of medical devices* standard which is the generally acknowledged state-of-the-art for biocompatibility. Manufacturers must either meet or exceed the requirements of this standard, noting that the standard is not mandatory and there may be better ways to demonstrate safety and performance.

The work you do could involve, but is not restricted to:

- identifying and quantifying contaminants and residues
- eliminating contaminants and residues wherever possible
- minimising contaminants and residues as much as possible where it is not possible to eliminate them
- In some cases it may be appropriate to supply labelling and instructions for use with your device to inform users how to reduce risks from contaminants and residues that cannot be eliminated
- a well-reasoned and documented risk analysis that indicates how you have addressed risks relating to contaminants and residues.

1. Principle 7.2 relates closely to Principle 2.

Contaminants and residues could include:

- solvents, processing aids, and additives used during manufacturing
- manufacturing intermediates
- mould-release agents
- particulate contamination
- fluid spillage
- sterilisation residues
- endotoxins.

Medical Device Standards Order (Endotoxin Requirements for Medical Devices) 2018 sets out a standard for minimising the risks associated with endotoxin contaminants and residues in or on certain types of medical devices. For those types of devices, compliance with the order demonstrates compliance with Principle 7.2. You must either meet or exceed the requirements in the order. More information on standards orders is available at: Standards orders and medical devices.

The legislated requirements

The legislation says:

Principal 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.

Meeting principle 7.3: Guidance for manufacturers

> Manufacturers should consider the *ISO 10993—Biological evaluation of medical devices* standard which is the generally acknowledged state-of-the-art for biocompatibility. Manufacturers must either meet or exceed the requirements of this standard, noting that the standard is not mandatory and there may be better ways to demonstrate safety and performance.

The work you do could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- biological evaluation and testing (see *ISO 10993—Biological evaluation of medical devices*)
- preclinical studies evaluating the biological safety of your device
- labelling or instructions to inform users how to reduce any risks that cannot be eliminated from materials that may contact your device
- labelling and instructions to warn users about materials that are incompatible with your device

- documenting an analysis of any materials required to clean, disinfect, or sterilise your medical device, and the effects of these materials during these procedures
- if your device administers a medicine, demonstrating that the design, production, and packaging of your device account for any provisions or restrictions for the medicine and ensure that the medicine can perform as intended. Contraindications to the medicine may be indicated in the instructions supplied with your device.

The legislated requirements

A medicinal substance in a medical device must meet the requirements for medicines.

The legislation says:

Principal 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.

The TGA is preparing guidance for manufacturers about Principle 7.4 for publication.

The legislated requirements

Any risks from substances that may leach from a medical device must be minimised.

The legislation says:

Principal 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.

Meeting Principle 7.5: Guidance for manufacturers

> Manufacturers should consider the ISO *10993—Biological evaluation of medical devices* standard which is the generally acknowledged state-of-the-art for biocompatibility. Manufacturers must either meet or exceed the requirements of this standard, noting that the standard is not mandatory and there may be better ways to demonstrate safety and performance.

The work you could do includes, but is not restricted to:

- detailing the materials used in your device, including those that could leach from the device such as:
    - additives
    - sterilant residues

    - process residues
    - degradation products
    - solvents
    - plasticisers
    - lubricants
    - colouring agents
    - fillers
    - monomers.
- designing your device to prevent unintended and undesirable leaching.
- a well-reasoned and documented risk analysis addressing issues including:
    - Could any substances leach from your device?
    - Are any substances that could leach from your device hazardous to humans?
    - Is the concentration and exposure (level, time, frequency, etc.) of any leached hazardous substances likely to approach the acceptable limit for toxic effects?
    - Could substances that may leach from your device effect its ongoing operation (for example, through contamination of circuit boards, mechanical mechanisms, or loss of lubrication of components)?
- biological evaluation and testing (see *ISO 10993—Biological evaluation of medical devices*)
- in vivo toxicokinetic studies where relevant (see *ISO 10993—Biological evaluation of medical devices* Parts 16 and 17)
- in vitro testing of your medical device (for example, to assess any substances leached from your medical device by physiologic media that normally contacts your device, such as blood)

- design and testing documentation about unintentional leaching of substances, including for electronic or mechanical components.

The legislated requirements

Risks caused by any substance unintentionally entering or leaving a device must be minimised.

The legislation says:

Principal 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.

Meeting principle 7.6: Guidance for manufacturers

Unintentional ingress means substances that are not intended to enter your device, and *unintentional egress* means substances that are not intended to leave your device.

> Manufacturers should consider the *ISO 10993—Biological evaluation of medical devices* standard which is the generally acknowledged state-of-the-art for biocompatibility. Manufacturers must either meet or exceed the requirements of this standard, noting that the standard is not mandatory and there may be better ways to demonstrate safety and performance.

The work you do could include, but is not restricted to:

- a well-reasoned and documented risk analysis
- preclinical studies evaluating the biological safety of your device
- biological evaluation and testing (see *ISO 10993—Biological evaluation of medical devices*)
- in vitro testing of your medical device (for example, to assess any substances egressed out of the medical device by physiologic media that normally contacts your device, such as blood)
- design and testing documentation about unintentional ingress or egress of substances, including for electronic or mechanical components.

Principle 8: Infection and microbial contamination

The legislated requirements

Medical devices must be designed and produced in a way that removes or reduces infection risks. Medical devices can pose infection risks to patients, users, or others.

The legislation says:

Principle 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:

3. allows it to be easily handled; and
4. if appropriate, minimises contamination of the device or specimen by the patient, user or other person; and
5. if appropriate, minimises contamination of the patient, user or other person by the device or specimen.

Meeting Principle 8.1: Guidance for manufacturers

Guidance for manufacturers in complying with Principle 8.1 is under active review and will be added to this web page once complete.

The legislated requirements

Medical devices containing tissues, tissue derivatives, cells, or substances of animal, microbial or recombinant origin must meet the highest standards of safety.

The legislation says:

Principle 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 of animal origin that have been rendered non-viable; and
    b. tissues, tissue derivatives, cells or substances of microbial or recombinant origin.
2. If the tissues, tissue derivatives, cells or substances originated from animals, the animals must have been subjected to appropriate veterinary controls and supervision, having regard to the

intended use of the tissues, 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.

Meeting Principle 8.2: Guidance for manufacturers

Below are some examples of materials of non-viable animal, microbial, or recombinant origin, and examples of medical devices that contain or are exposed to such materials during manufacture (for example, manufacturing reagents such as enzymes or cell culture media).

> Therapeutic goods that comprise or contain live animal cells, tissues or organs are not medical devices and are regulated as biologicals.

Kinds of materials and some examples

Animal origin

An invertebrate or vertebrate member of the animal kingdom

- Bovine, porcine, lapine
- Crustacean
- Coral

Microbial origin

Microorganisms

- Bacteria
- Yeast

Recombinant origin

Genetically modified (GMO) biological organisms

- Microbial cells
- Animals
- Plants

Examples of medical devices containing these materials

Biological heart valves

Porcine valve, valves made of bovine or equine pericardium

Wound dressings

Gelatin or collagen from porcine skins; recombinant plant expressing human collagen genes

Collagen corneal shields

Collagen from porcine skins

Vascular grafts

Vascular graft coated with porcine collagen or gelatin

Catgut sutures

Bovine or ovine animal intestines

Intra-ocular fluids

Hyaluronic acid extracted from rooster combs or harvested from a microbial cell line

Meniscus joint fluid replacement

Hyaluronic acid extracted from rooster combs or harvested from a microbial cell line

Anti-adhesion barriers

Hyaluronic acid extracted from rooster combs or harvested from a microbial cell line

Tissue augmentation

Hyaluronic acid extracted from rooster combs or harvested from a microbial cell line

Catheters with 'lubricious' coating

Hyaluronic acid extracted from rooster combs or harvested from a microbial cell line

Blood cell separation devices

Monoclonal antibody derived from microbial cell line expressing human gene

Special risks with these types of medical devices

Medical devices incorporating these materials pose a special risk for both patients and healthcare providers due to the potential for pathogen transmission to humans.

A particular risk relates to possible transmission of Transmissible Spongiform Encephalopathies (TSEs) associated with materials originating from human and some other animal species.

Principle 8.2 describes requirements to ensure the safety of medical devices containing materials non-viable animal, microbial or recombinant origin. The subsections below further elaborate on the specific requirements for each of these materials, and detail evidence that is suitable in demonstrating compliance with this Principle.

Considerations for microbial or recombinant origin substances include:

- the composition of fermentation or growth media
- the identification of components

- the origin of the components (animal, microbial or plant)
- the management of suppliers, purchasing information
- verification testing.

Microbial species should be identified, fully characterised, and tested for the absence of viruses.

Specific requirements for animal-origin components

The work you undertake could involve, but is not restricted to:

- effective risk management activities that justify the use of animal material including the choice of animal species and tissues. Refer to Transmissible Spongiform Encephalopathies: TGA approach to minimising the risk of exposure for further information on TSE risk minimisation and assessment against the European Pharmacopoeia monograph.
- implementing a quality management system that ensures:
    - quality control processes and procedures are in place to prevent contamination with potential infectious or transmissible agents including TSEs and disinfection or decontamination procedures in the event of contamination
    - evidence of adequate segregation between animal species in abattoirs or tissue supplier facilities
    - there is a documented system for animal and tissue traceability
    - there are procedures for the selection, review, and auditing of tissue suppliers
    - that the device manufacturer keeps records of audits of animal tissue suppliers

- that the name and address for suppliers of any animal materials are recorded and maintained.

Recognised standards

Principle 2 requires you to adopt manufacturing solutions (design and construction) that have regard to the generally acknowledged state of the art. The state-of-the-art requirements for manufacturers using material of animal origin are defined in ISO 22442 — Medical devices utilizing animal tissues and their derivatives.

ISO 22442 specifies relevant quality assurance techniques for the analysis and management of risk in the manufacture of medical devices, such as:

- sourcing
- collecting
- handling of animal materials and their derivatives, and
- viral and transmissible agent elimination or inactivation.

The requirements extend to raw materials of animal origin that are used in the manufacture of a device (for example, in fermentation or growth media).

ISO 22442 requirements should be considered throughout the product life cycle. The standard has three parts:

- ISO 22442-1 — Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management
- ISO 22442-2 — Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling

- ISO 22442-3 — Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents

We consider the European Pharmacopoeia to be the state-of-the-art for TSE risk minimisation. We will also accept compliance to ISO 22442 parts 1, 2, and 3.

Compliance with ISO 22442 or the European Pharmacopoeia is not mandatory. However, if you choose to follow a different approach, its relevance and adequacy in achieving an equivalent or higher level of safety must be demonstrated.

Documented compliance with these standards can form the evidence to demonstrate compliance with elements of Principle 8.2.

Management of changes

Changes to suppliers, sourcing, collection, or handling of animal material require you to perform a risk analysis to determine whether your changes have reduced the safety or performance of the device. This includes considering whether the change affects the validation of the inactivation or elimination of viruses or TSE agents.

Specific requirements for microbial-origin components

In addition to the general requirement above, you are required to hold the following information for medical devices containing components of microbial origin:

- the name of the microorganism to species level
- identification
- cell bank qualification to demonstrate that it has been fully characterised and tested for the absence of viruses

- composition of fermentation or growth media:
    - identification of all components
    - origin of components: animal, microbial, or plant
    - suppliers, specifications, and certificates of analysis of the components.
- information on whether any non-viable animal–origin materials were used in the manufacturing process. If so, the specific requirements for animal-origin components must be met for reagents containing animal-origin material used in the manufacturing process.

Specific requirements for recombinant-origin components

In addition to the general requirement above, you are required to hold the following information for medical devices containing components of recombinant origin:

- identification and source of nucleotide sequence coding
- source of expression construct or host animals
- composition of fermentation or growth media, including:
    - identification of all components
    - origin of components: animal, microbial, or plant
    - suppliers, specifications, and certificates of analysis of the components.

You must hold information on whether any non-viable animal-origin materials were used in the manufacturing process. The specific requirements for animal-origin components must be met if the manufacturing process reagents contain animal-origin material.

There may be additional requirements as specified by the Office of Gene Technology Regulator (OGTR).

Poisons Standard Considerations

Some medical devices incorporate substances of animal or microbial origin where that substance is scheduled in the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP, or Poisons Standard).

Entries in the Poisons Standard refer to all salts and derivatives of the named substance unless specifically exempted. Some special clinical uses of collagen, hyaluronic acid and lactic acid render that medical device subject to scheduling requirements—see Schedule 4 of the Poisons Standard.

Medical devices containing substances that are scheduled in the Poisons Standard must comply with any corresponding labelling requirements in the Poisons Standard.

Import Permits

Medical devices containing animal-origin materials require an import permit from the Department of Agriculture, Fisheries and Forestry. Information relevant to requirements on import permits and conditions of import can be obtained from Biosecurity Import Conditions system.

The legislated requirements

Medical devices intended to be supplied in a sterile state must be supplied sterile.

The legislation says:

Principle 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.

Meeting Principle 8.3: Guidance for manufacturers

Guidance for manufacturers in complying with Principle 8.3 is under active review and will be added to this web page once complete.

The legislated requirements

Medical devices you supply in a non-sterile state must be packed and supplied to maintain the level of cleanliness you specify. If the device is intended to be sterilised before use, you must pack the device in a way that is suitable for the recommended method of sterilisation.

The legislation says:

Principle 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.

Meeting Principle 8.4: Guidance for manufacturers

Guidance for manufacturers in complying with Principle 8.4 is under active review and will be added to this web page once complete.

The legislated requirements

If you supply a medical device both as a sterile and non-sterile device, you must clearly indicate whether the device is sterile or not.

The legislation says:

Principle 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.

Meeting Principle 8.5: Guidance for manufacturers

Guidance for manufacturers in complying with Principle 8.5 is under active review and will be added to this web page once complete.

Principle 9: Construction and environmental properties

The legislated requirements

Principle 9.1 requires manufacturers of devices intended to be used in combination with other devices or equipment to ensure that both their device and the other devices or equipment operate safely and not have their intended performance be impaired.

The legislation says:

Principal 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.

Meeting Principle 9.1: Guidance for manufacturers

To demonstrate that your medical device meets the requirements of Principle 9.1, you will need to consider:

- if your device is intended to be used in combination with any other device or piece of equipment

- risks associated with the use of your medical device and any other device or piece of equipment it is intended to be used with
- how using your device together in combination with other equipment or devices could affect safety and intended performance of all connected devices and equipment.

The work undertaken by you could involve, but is not restricted to:

- a well-reasoned and documented risk analysis considering all the other devices meant to be used for the intended purpose of your device
- documenting how your device is designed for use with other medical devices and evidence of appropriate testing procedures demonstrating that the combination of medical devices and equipment results in all devices and equipment operating safely and without any impairment to intended performance
- addressing the use of your device in combination with another medical device / equipment as part of your clinical evidence
- providing all the information for the use of your device in combination with another medical device / equipment as a part of your Instructions for Use (Principle 13)
- for medical electrical devices and systems, compliance to IEC 60601-1 or equivalent or superior method of demonstrating safety of medical electrical equipment and systems. Further information is available in Active medical devices.

The legislated requirements

Principle 9.2 requires manufacturers to design and produce their devices so as to minimise risks associated with their use.

The legislation says:

Principal 9.2: Minimisation of risks associated with use of medical devices

A medical device must be designed and produced in a way that ensures that, as far as practicable, the following risks are removed or minimised:

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

Meeting Principle 9.2: Guidance for manufacturers

To demonstrate that your medical device meets the requirements of Principle 9.2, you will need to consider risks associated with:

- injury from the physical features of your device

- reasonably foreseeable environmental conditions
- reciprocal interference involving other devices that are normally used in conjunction with your device
- potential lack of maintenance or calibration of your device
- the ageing of materials used in your device
- loss of accuracy of any measuring or control mechanism of your device
- a fire or explosion occurring during normal use or storage of your device
- disposal of any waste substances.

The work undertaken by you could involve, but is not restricted to:

- a well-reasoned and documented risk analysis
- documented compliance or consideration of relevant product safety and performance standards.

Principle 10: Medical devices with a measuring function

The meaning of ‘measuring function’ is defined in regulation and applies in specific cases.

Medical devices with a measuring function must provide:

- accurate,
- precise, and

- stable

measurements using Australian legal units of measurements.

The measurements must be within the limits indicated by the manufacturer and appropriate for the intended purpose of the device.

This Principle only applies to medical devices with a measuring function. Principle 10 therefore does not apply to in vitro diagnostic (IVD) medical devices.

The legislation says:

Regulation 1.4: Medical devices with a measuring function

1. For these Regulations, a medical device has a measuring function if the device is intended by the manufacturer to measure:
    a. quantitatively a physiological or anatomical parameter; or
    b. a quantity, or a qualifiable characteristic, of energy or substances delivered to or removed from the human body.
2. This regulation does not apply to an IVD medical device.

Principal 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 be compared to at least one point of reference indicated 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 in writing by the Secretary for the particular device.

Meeting Principle 10: Guidance for manufacturers

Guidance for manufacturers in complying with this Principle is under active review and will be added to the web page once complete.

Principle 11: Protection against radiation

The legislated requirements

The legislation says:

Principle 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.

Principle 11.2: Medical devices intended to emit radiation

1. This clause applies in relation to a medical device that is intended by the manufacturer to emit hazardous levels of visible or invisible radiation because the emission is necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission.
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.

Principal 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.

Principal 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.

Principal 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:
4. the device achieves an appropriate image or output quality for that purpose; and
5. the exposure of the patient, or the user, to radiation is minimised.
6. 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.

Meeting Principles 11.1 - 11.5: Guidance for manufacturers

Guidance for manufacturers in complying with this Principle is under active review and will be added to the web page once complete.

Principle 12: Medical devices connected to or equipped with an energy source

The legislated requirements

Principle 12.1

Principle 12.1 provides general requirements for programmed or programmable medical devices or software that is a medical device. It covers safety, performance, cybersecurity, management of data, privacy, state of the art and best practice.

The legislation says:

Principle 12.1: Medical devices incorporating electronic programmable systems

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
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.
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.

Principle 12.2

Principle 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.

Principle 12.3

Principle 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.

Principle 12.4

Principle 12.4 specifies requirements for medical devices that monitor patient health by measuring clinical parameters over time and detecting changes or the absence of changes. Examples include: heart rate, blood pressure, oxygen levels and blood glucose.

The legislation says:

Principle 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.

Principle 12.5

Principle 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.

Principle 12.6

Principle 12.6 addresses the risk of accidental electric shock from the medical device.

Principle 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.

Principle 12.7

Principle 12.7 addresses mechanical risks posed by the device such as moving parts, resistance, and instability.

Principle 12.7: Protection against mechanical risks

A medical device must be designed and produced in a way that ensures that a patient, the user, and any other person, is protected against any mechanical risks associated with the use of the device.

Principle 12.8

Principal 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.

Principle 12.9

Principle 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.

Principle 12.10

Principle 12.10 addresses risks when the user needs to connect the device to an electricity, gas hydraulic, pneumatic, or other energy supply.

Principle 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.

Principle 12.11

Principle 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.

Principle 12.12

Principle 12.12 addresses risks with medical devices that administer energy or a substance to a patient. For example, a medical device that delivers radiation to treat a cancer patient, or a medical device to deliver painkillers to a patient through intravenous fluids.

Principle 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.

Principle 12.13

Principle 12.13 requires active implantable medical devices to be identifiable without the need for surgery. Examples include heart pacemakers and implantable glucose monitors.

Principle 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.

Meeting Principles 12.1-12.13: Guidance for manufacturers

Guidance for Principles 12.1 - 12.13 is under active review and will be added to the web page once complete.

Principle 14: Clinical evidence

The legislated requirements

Principle 14 requires that use of every medical device is supported with clinical evidence. The clinical evidence must show that the device meets the relevant essential principles.

All manufacturers must comply with this Principle.

The legislation says:

Principle 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.

Meeting Principle 14: Guidance for manufacturers

Note: See regulation 3.11 and the clinical evaluation procedures.

You must hold sufficient clinical evidence showing that:

- your device achieves its intended purpose(s). This includes one or more of the purposes mentioned in the definition of *medical device* in the Act (s41BD), during normal conditions of clinical use. See also Principle 3.
- the risks of known and foreseeable clinical hazards and any adverse effects have been minimised (see the risk minimisation priority order specified by Principle 2(2)).
- the risks of using your device are acceptable when weighed against the performance benefits inherent in its intended purpose - see also Principle 1 and Principle 6
- your claims about your device's safety and performance (for example, on the label, proposed advertising material, and the instructions for use) are supported by suitable evidence.
- all of the above hold true for the entire intended duration of use for the device (see also Principle 4).

The quality and quantity of clinical evidence for your device must be appropriate for its use and class.

Principle 15: Principles applying to IVD medical devices only

The legislated requirements

Principle 15 covers elements that apply to IVD medical devices.

The legislation says:

Principle 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.
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.
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.
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.
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.

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.
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.

Meeting Principle 15: Guidance for manufacturers

You should hold evidence of performance evaluation studies that include:

- evaluation of the IVD analytical and clinical characteristics, and
- useability studies where applicable (for example, self-tests).

Technical file requirements and performance evaluation guidance for IVDs is at: Application audit (technical file review) of IVD medical device applications.

Related links

Quality, safety, and performance requirements for medical devices

Demonstrating compliance with the Essential Principles

Topics: Safety In Vitro Diagnostic medical devices (IVDs)

Page history

28 March 2024
Information on Principles 8.10 and 11 published.

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Information on Principles 6 and 14 published.

23 January 2024
Information on Principle 7 published.

19 December 2023

Information on Principles 3 and 4 published.

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25 August 2022
Information on Principles 1, 2 and 9 published.

Related guidance

Meeting rules for active medical devices that use energy to operate

1 August 2023

Guidance on the requirements that specifically apply to active medical devices.