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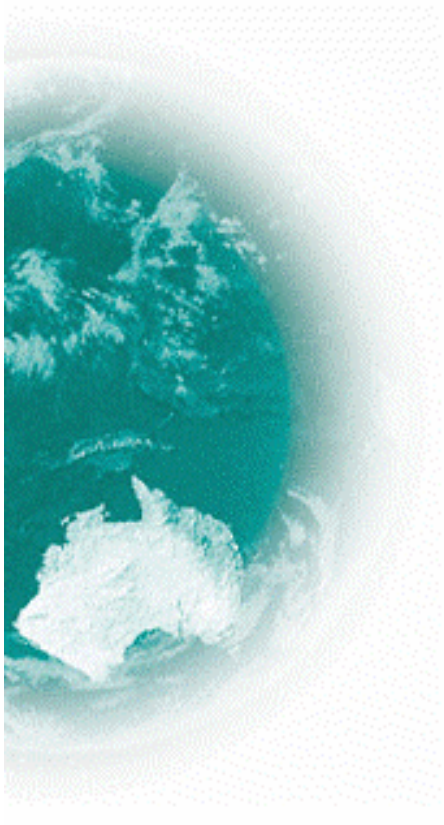
Australian Medical Devices Guidance Document Number XX

Custom Made Medical Devices



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Disclaimer

This document is provided for guidance only.

Please refer to the *Therapeutic Goods Act, 1989* as amended by *the Therapeutic Goods Amendment (Medical Devices) Bill, 2002* and the *Therapeutic Goods (Medical Devices) Regulations, 2002* for legislative requirements.

Further Information

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Amendment Schedule

Version Number	Date of Amendment	Summary of Amendments
1.0	August 2008	First draft for stakeholder comment
1.1	October 2008	Post internal comments – Release Version

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Introduction

This guidance document is one of a series produced to assist a wide-ranging audience to understand the regulatory system for medical devices in Australia that commenced on 4 October 2002. The system has been established by the *Therapeutic Goods Act, 1989* and the *Therapeutic Goods (Medical Devices) Regulations, 2002*.

Although each guidance document has been developed to provide information about particular aspect of the medical devices regulatory system in Australia, it is expected that a certain amount of cross-referencing to other documents in the series will be inevitable.

Purpose

The regulatory framework for medical devices contains provisions for the regulation of manufacturers and sponsors of custom made medical devices, and components of customized medical devices intended by the manufacturer to be assembled into a finished medical device for a specific user.

These provisions impose requirements on this group of manufacturers relating to –

Demonstrating compliance with the essential principles of safety and performance
Documentation of manufacturing processes
Labeling of the finished medical device
Record keeping
Post market reporting
Notification of manufacturing activities to the TGA

The last of these provisions was not implemented at the time of introduction of the new regulations in October 2002, but is now being introduced as the final step in establishment of the regulations.

This document is intended to provide guidance on regulatory obligations and responsibilities for manufacturers of custom made and customised medical devices.

Custom Made Medical Devices

Introduction

Medical devices are regulated in Australia using a framework that aligns with the guidance provided by the Global Harmonisation Task Force (GHTF) – an international organization with representatives from both major regulatory agencies and the medical devices industry of member countries. The principles of the GHTF framework are embodied in the Therapeutic Goods Act 1989 and the associated Therapeutic Goods (Medical Devices) Regulations 2002.

The foundation elements of the framework are

- A classification system for medical devices based on the risk the device presents to the user, the patient and the environment
- A set of Essential Principles setting out requirements for safety and performance of a medical device
- A set of conformity assessment procedures, used by the manufacturer of a medical device, to demonstrate the device is in compliance with the essential principles of safety and performance

These elements of the framework are applicable to all medical devices.

The Australian regulations for medical devices recognizes three broad 'types' of medical devices –

- Finished medical devices, ready for use 'off the shelf'
- Customized medical devices,
- Custom made medical devices manufactured from 'base' materials, to a prescription, for an individual patient

The regulation of medical devices is intended to ensure that all devices have been shown, by the manufacturer, to comply with the Essential Principles of Safety and Performance before the device is used for humans.

This requirement establishes a clear basis for distinguishing whether a device is custom made or customized. Devices that are assembled, adapted, processed etc or used in accordance with the manufacturer's intentions will comply with the Essential Principles when used for humans as it is an incumbent upon the manufacturer to verify compliance for the stated range of operating conditions. Hence a person who customizes such a device from components supplied by others is not required to perform the relevant investigations to determine if the finished product complies with the Essential Principles.

The purpose of this document is to outline the Australian medical devices regulatory framework as it applies to custom made and customized devices.

Key Definitions

These definitions are reproduced from the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Medical Devices) Regulations 2002*, and are provided here for convenience.

Manufacturer is:

- the person who is responsible for the design, production, packaging and labeling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations; or
- the person who, with a view to supplying the device under the person's name, does one or more of the following using ready-made products:
  - assembles the device;
  - packages the device;
  - processes the device;
  - fully refurbishes the device;
  - labels the device;
  - assigns to the device its purpose by means of information supplied, by the person, on or in any one or more of the following:
    - the labeling on the device;
    - the instructions for using the device;
    - any advertising material relating to the device.

However, a person is not the manufacturer of a medical device if:

- the person assembles or adapts the device for an individual patient; and
- the device has already been supplied by another person; and
- the assembly or adaptation does not change the purpose intended for the device by means of information supplied by that other person, on or in any one or more of the following:
  - the labeling on the device;
  - the instructions for using the device;
  - any advertising material relating to the device.

Sponsor to therapeutic goods means:

- a person who exports, or arranges the exportation of, the goods from Australia; or
- a person who imports, or arranges the importation of, the goods into Australia; or
- a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

but does not include a person who:

- exports, imports or manufactures the goods; or
- arranges the exportation, importation or manufacture of the goods;

on behalf of another person who, at the time of the exportation,

importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

Supply includes:

- supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase; and
- supply, whether free of charge or otherwise, by way of sample or advertisement; and
- supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons or animals; and
- supply by way of administration to, or application in the treatment of, a person or animal.

A ***medical device*** is:

- any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
  - investigation, replacement or modification of the anatomy or of a physiological process;
  - control of conception;
  - and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or
- an accessory to such an instrument, apparatus, appliance, material or other article.

Custom made medical device means a medical device that:

- is specifically made in accordance with a request by a health professional specifying the design characteristics or construction of the medical device; and
- is intended to be used only in relation to a particular individual.

Conformity Assessment procedures are:

- requirements set out by regulations relating to the obligations of manufacturers of medical devices;
- the conformity assessment procedures, or any part of the conformity assessment procedures, may:
  - be limited in their application to one or more medical device classifications; or
  - apply differently to different medical device classifications, different kinds of medical devices or different manufacturers.

Interpretations

The Therapeutic Goods Act does not define the term customised medical device, however the interpretation below is supported by the second part of the definition of a manufacturer, which excludes a person from the definition in specific circumstances.

A ***customised medical device*** can therefore be regarded as a medical device prepared/assembled by a person who is not the manufacturer of a medical device but:

- the person assembles or adapts the device for an individual patient; and
- the device has already been supplied by another person; and
- the assembly or adaptation does not change the purpose intended for the device by means of information supplied by that other person, on or in any one or more of the following:
  - the labeling on the device;
  - the instructions for using the device;
  - any advertising material relating to the device.

The role of manufacturers and sponsors

In supplying medical devices to the market, the regulatory framework for therapeutic goods, recognizes two possible entities, the device manufacturer and the device sponsor.

Where a medical device is manufactured in Australia, the device manufacturer is also considered to be the device sponsor and has an obligation to comply with all regulatory requirements imposed on both the manufacturer and the sponsor, including providing identifying information in relation to their role to the device user/wearer.

Where a device manufacturer is not resident in Australia, the medical device is required to have a device sponsor. The sponsor is the person or organization responsible for importing, or exporting, the custom made medical device. The sponsor is required to ensure the manufacturer is aware of, and has complied with their obligations in relation to the regulatory framework. The sponsor is also required to comply with other requirements, such as providing information to the TGA, reporting adverse events, etc, imposed by the regulations.

In relation to custom made medical devices, this has the effect of making any organization, or practitioner, who arranges for the offshore manufacture of a custom made medical device, for supply to a patient/client, the sponsor of the device for the purposes of regulation and demonstrating compliance with the requirements of the Therapeutic Goods Act 1989

It should be noted the definition of ‘supply’ in the Therapeutic Goods Act 1989 also includes ‘ ….supply …… by way of administration …..’ within its scope. Healthcare practitioners who create and provide custom made medical devices to their patient/client are therefore considered manufacturers of custom made medical devices – unless the device provided is a mass produced medical device, which has been customized, within the scope provided by the device manufacturer, to suit the needs

of the individual patient. The difference between a **custom made** and a **customized** medical device is discussed further on in this guidance document.

Characteristics of custom made and customized medical devices

A Custom made medical device or **Customized medical device** has three defining characteristics.

They are -

- Manufactured in accordance with a request from a health care professional
- That request specified the design characteristics of the device
- The device is manufactured for a named individual

In considering these characteristics, it is necessary to consider the broad range, from simple to complex, of custom made and customized devices provided for users, and the processes by which they are prescribed.

Typical examples of custom made, or customized, medical devices include

- A finger splint, moulded from a piece thermoforming plastic sheet, used to immobilize or support the finger to allow a bone fracture to heal
- A Hearing aid used to compensate for mild to moderate hearing loss
- Dental appliances such as crowns, bridges and dentures used to replace the natural teeth
- Prosthetic or glass eye used to cosmetically replace the eye after it is removed
- Orthopaedic and pedorthic footwear crafted for an individual to compensate for foot or gait problems caused by disease, injury or malformation
- Artificial limbs used to aid in patient mobility after partial or total amputation
- Orthoses applied externally to a part of the body to correct deformity, improve function, or relieve symptoms of a disease by supporting or assisting the wearer
- Joint replacement implants or other skeletal structures (such as partial skull plates used in cranioplasty) constructed specifically to accommodate the anatomical structures of the patient

- Powered artificial limbs controlled by connecting the system controlling movement of the limb either peripherally to the wearer with peripheral electrodes, or directly to residual nerves in the arm or leg

Note that with many of the examples cited above, the device may be considered **customized**, or **custom made** depending on the manufacturing process and components used in the construction of the device.

More will be explained regarding these categorizations of devices below.

The Health Care Professional

It is also necessary, because of the broad range of custom made devices available, to consider the range individuals of who may be considered the 'health care professional' for the purposes of specifying a custom made device, and the form such a specification may take. For the purposes of custom made devices, the health care professional is taken to be the treating practitioner best suited and informed to specify the design characteristics of the device.

In many instances, the health care professional may be a single individual, for example the audiologist who undertakes the hearing test, and prescribes the specifications of the hearing aid, based on the identified hearing loss of the patient, or the physiotherapist who determines the configuration of a splint best suited to immobilize a finger.

However, in other circumstances the role may be 'shared' – for example where an orthopaedic surgeon commences the prescribing process by requesting an artificial limb for an amputee, but the limb, including the components used in its construction, are specified by the orthotist, taking into account physical characteristics of the patient such as weight, height, agility, desired mobility, etc.

The Design Specification

Similarly, the 'design specification' of the device must be interpreted in the broader sense. Because of the range and nature of custom made devices, the form of the 'design specification' will vary widely.

In many instances the design specification will simply be an instruction from the health care professional, for example '….. a rigid, straight splint to immobilize the finger with respect to movement of the hand or wrist.' The decision regarding material, shape, size, immobilization technique etc is made by the person charged with construction and fitting of the splint.

In other circumstances, such as when an audiogram is used to describe the compensation curve to be incorporated into a hearing aid, the design specification will be a precise description of the required characteristics of the device, as generally defined by the audiogram.

With many devices, it is possible the design specification is not embodied so much in the written word, but in a facsimile or reverse moulding of the required anatomical structure – such as an impression of the patient's teeth taken by a dentist and forwarded to a dental laboratory to construct a dental appliance.

It should also be noted that the development of the design specification may be a combined effort between multiple healthcare professionals.

Customised medical devices

A **customized medical device** shares many of the same characteristics as a custom made medical device.

There is, however, one fundamental difference. A customized medical device is considered to be a medical device assembled from components, mass produced by the component manufacturer **with the intent these components be assembled into a finished medical device**, constructed to a prescription for an individual patient. As the limits of therapeutic use have already been established by the manufacturer of the components, the assembly of these components into a finished medical device will result in a device that should perform as intended, if the assembly has been in accordance with the component manufacturer's instructions. It is expected that the finished good will comply with the Essential Principles.

Typical examples of customized medical devices include -

- Fully manufactured hearing aids, where only the hearing compensation characteristics are adjusted, and an ear mould manufactured to fit the wearer's ear canal. In this instance the aid is a customized device, but the ear mould associated with it is a custom made device
- Artificial limbs where the appliance is constructed from component ankle and knee joints, a sole plate and leg pylon, etc. In this case the bulk of the artificial limb is a customized device, but the socket in to which the stump of the limb is fitted, is a custom made component of the device
- Dentures constructed from artificial teeth, and dental PMMA resin
- A dental bridge constructed from a 'dental grade' alloy
- Spectacles constructed by preparation of a pair of lenses to the patient's optical prescription and mounting the lenses on a frame.
- Plaster or fibre glass cast or splint used to support and immobilize a fracture, using materials specifically intended for this purpose
- cushioning shaped to accommodate user specific seating and positioning requirements – may be fixed seating, may be used in a wheelchair

Custom made medical devices

A **custom made medical device**, on the other hand, is constructed from various materials, components or elements, where there was no specific intention by the manufacturer that the materials be used in the manufacture of a medical device. Such materials may include metals, adhesives, plastics, fiberglass, glass, etc acquired by the manufacturer of the custom made device from commercial sources.

Typical examples of custom made medical devices include –

- Artificial eye constructed of various coloured glasses to aesthetically match the colours and hues in the wearer's residual eye.
- Maxilliofacial prostheses used to replicate and replace surgically removed tissues
- Orthopaedic or pedorthic footwear constructed from leather and other readily available materials to the shoemaker.
- 'In the ear' hearing aids where the electronic components are selected to compensate for the wearer's hearing loss, and assembled in the moulding taken of the ear canal.
- A dental bridge constructed of 'jewelry' or other non-dental grade alloy
- Plaster cast using commercially available plaster (eg Plaster of Paris) and gauze bandage material
- A complete wheelchair specifically constructed to accommodate the seating and positioning of the user, and mobility requirements

Status as a manufacturer

Note: In all instances, a **customized** medical device is assembled from, or constructed from components intended by their manufacturer to be assembled in to a finished medical device.

In manufacturing these component parts, the manufacturer must be able to demonstrate that, as far as possible, when assembled according to the manufacturer's instructions, the finished device will be in compliance with the Essential Principles of safety and performance contained within the regulatory framework for medical devices.

The manufacturer of these components is also required to apply an appropriate conformity assessment procedure to the process used to manufacture these

components. Depending on the classification of the devices, the manufacturer may need to have those processes and their quality management system assessed by a conformity assessment body.

Because the manufacturer of the component parts is required to apply an appropriate conformity assessment procedure to the components, and provide instructions and direction on how to either further process, or assemble, the components into a finished device, the person undertaking the final steps of processing or assembly before making the device available to the patient or wearer is **not** considered a manufacturer of a medical device, and their activities are not controlled by the medical devices regulatory framework.

It must be noted however, the sponsor supplying the components for a customised medical device must have the components included on the Australian Register of Therapeutic Goods.

Custom made medical devices, however, are manufactured using many different materials or components, most of which were not originally intended to be used in the construction of a medical device by their manufacturer. As a consequence, there is no evidence that these materials, either in their raw form, or finished form when assembled in to a medical device, are in compliance with the Essential Principles of safety and performance.

The responsibility therefore, for ensuring both the finished medical device is in compliance, as far as possible, with the Essential Principles of safety and performance and applying the appropriate conformity assessment procedure to the device and the processes used to manufacturer the device resides with the person manufacturing the custom made medical device. The medical devices regulatory framework **does consider such a person to be a manufacturer** within the definition provided in the Act.

It should be noted, that in some of the examples of customized medical devices provided in this document, there is also an element of custom making associated with the customized device. Examples include –

- The manufacture of a fiberglass (or other material) socket to accommodate the remaining stump of a limb to connect with the customized artificial limb

- The manufacturer of a moulding to allow close fitting or coupling of a hearing aid to the ear canal

Organisations and persons undertaking the assembly of customized medical devices should examine the activities and devices they produce to determine if they may be considered a manufacturer in these circumstances.

Application of the Essential Principles to Custom Made Medical Devices

Although a custom made medical device is manufactured to the prescribed requirements of a health care professional, it must be fit for its intended purpose, and it must meet, as far as possible, all the Essential Principles of safety and performance detailed in Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002. In preparing the documentation outlined below, the manufacturer must prepare an essential principles checklist detailing essential principles applicable to the device, and how compliance has been demonstrated.

The Essential Principles cover, amongst other things –

- Design and construction
- Safety and performance
- Handling and storage
- Chemical, physical and biological properties
- Infection and microbial contamination
- Sterility
- Handling and packaging
- Risks associated with any internal energy source
- Environmental compatibility
- Labeling and Instructions for Use
- Supporting clinical evidence demonstrating compliance with the Essential Principles

Details of the requirements of the Essential Principles of safety and performance, including a template checklist can be found in *Guidance Document …….*

It is recognized, however, that a manufacturer may not be able to demonstrate compliance with some of the essential principles, for example where demonstration would require a ‘test to destruction’ approach as often applied in material standards. In such circumstances the prepared checklist should record the inability to demonstrate compliance and the reason why.

For many manufacturer’s of custom made medical devices where, although the device is custom made for an individual, the manufacturing process and materials used are the same for all devices, it is sufficient to develop an overarching checklist for each different type of device for the records, rather than a checklist for every device manufactured.

Risk management

The use of any medical device entails some risk, to the healthcare professional, the user or the environment.

Manufacturers should make judgements relating to the safety of a medical device including the acceptability of risks, in order to determine the probable suitability of a medical device to be supplied for its intended use.

In doing so, a manufacturer must establish and maintain a process for identifying potential hazards associated with their custom made medical device, estimating and evaluating the associated risks, controlling these risks and monitoring the effectiveness of these control measures.

This process should be documented as part of the technical documentation prepared by the manufacturer described below. The process should include the following elements -

- Risk analysis (intended use identification, hazard identification, risk estimation),
- Risk evaluation (risk acceptability decisions),
- Risk control (protective measures for reducing risks to specified levels), and
- Post production information (post-production experience and review of risk management experience)
- Use of a risk management strategy, for example as outlined in either Australian Standard *AS/NZS 4360 – Risk Managem*ent or *AS ISO 14971 – Medical Devices, Application of risk management to medical devices*.

The risk management process undertaken should be appropriate to the complexity of the custom made medical device.

Responsibilities of a manufacturer of Custom Made Medical Devices

The manufacturer of custom made medical device has an obligation to prepare, and keep up to date, documentation in relation to the device or device types produced.

The documentation must detail information in relation to the design, production and intended performance of the device.

Typically, this requires the manufacturer to have documented procedures relating to

- The process applied in taking the requirements detailed in the prescription or specification from the health care professional and producing a design for the custom made medical device
- Specifications for the components or materials used in the device, including verification that materials used in the manufacture of the device meet the documented specifications
- Manufacturing processes used in the manufacture of the device, including verification procedures to demonstrate that application of those processes results in a device or devices complying with the Essential Principles of safety and performance

- Production records indicating the continued application of the documented manufacturing processes in the manufacture of all devices produced.
- Verification procedures, and the results of application of those procedures to ensure the device, or devices, comply with the design and intended performance of the product.
- Patient/client specific records identifying the patient, the prescribing health care professional and the design characteristics or construction of the supplied device to the patient/client.

Manufacturing records held by the manufacturer, and used to demonstrate on-going compliance with documented procedures, depending on the type of device manufactured, may also typically consist of -

- Name, and if applicable model number of the device,
- General description of the product,
- Rationale for classification using the risk based classification rules,
- Considerations and outcome of the application of Risk management principles to the design and application of the device,
- Intended use, indications for use and contra-indications,
- References if the device requires connection to another device to function correctly,
- Design drawings and specifications,
- Design verification and quality control procedures,
- Raw material and/or component specifications,
- Biocompatibility testing of materials, if applicable,
- Clinical evidence of performance and efficacy of the device or device type,
- Labelling and Instructions for Use,
- Equipment/procedures and records kept to monitor and control the raw materials or components used in the manufacturing process,
- Packaging specifications,
- Sterilisation method , if applicable,
- Equipment/procedures and records kept to monitor and ensure the compliance of finished devices with their design specification,
- List of standards used, in whole or in part, to demonstrate compliance or test raw materials, components or finished devices,
- Procedures to ensure a review of the prescribing healthcare professional's written prescription to ensure adequate information has been supplied to document the finished device requirements,
- Procedures to ensure the final product has been reviewed against the prescription, prior to supplying the device,
- Procedures which ensure the traceability from the manufacturer through the practitioner to the patient,

Prior to supply, the manufacturer of the custom made medical device is also required to prepare a written statement in relation to the device including the following:

- the name and business address of the manufacturer;
- sufficient information to enable the user to identify the device or, if relevant, the contents of packaging;
- a statement to the effect that the device is intended by the manufacturer to be used only in relation to a particular individual;
- the name of the individual in relation to whom the device is intended to be used;
- the name and business address of the health professional who provided the specification for the device;
- the particular design characteristics or construction of the device as specified by the health professional who provided the specification for the device;
- a statement to the effect that the device complies with the applicable provisions of the essential principles or, if the device does not comply with all applicable provisions of the essential princiles, a statement explaining which provisions of the essential principles the device does not comply with and the reasons for the non-compliance.

The statement must be signed by a person authorised by the manufacturer of the device identifying the name and position of the person signing the statement and include the date when the statement is signed.

A copy of the statement should be supplied to the user of the device, and a further copy filed with the patient/client specific record held by the manufacturer.

Labelling of Custom Made Medical Devices

The conformity assessment procedure for custom made medical devices imposes a number of particular requirements for the labeling applied to custom made devices.

The labeling requirements for custom made medical devices is detailed in three parts of the Therapeutic Goods (Medical Devices) Regulations 2002.

- Regulation 10.2 identifies the need for information to be provided with a medical device to allow the user of the device to identify the sponsor of the product.

- Essential Principle 13 identifies the particular information to be provided on or with the device, the possible location of that information, and the additional information to be provided in the Instructions for Use for the device.

- Part 7.2 of Schedule 3 – Custom made medical devices

Essential Principle 13 divides information to be provided with a medical device in to two parts –

- Information identifying the manufacturer, the device and any special characteristics of the device
- Information to be contained in the *Instructions for Use* to allow the device to be used safely.

It is important to note that, in the context of the total information which must be supplied with the device, it is an obligation on the Manufacturer to provide the information referenced in Part 7.2 of Schedule 3 **in addition** to the requirements of Essential Principle 13. The Sponsor is obligated to ensure that the device complies with Regulation 10.2.

The Sponsor should note that is not an offence to import a product that does not comply with Regulation 10.2 or Essential Principle 13 however it is an offence for the Sponsor to supply such a non-complying product. If a Sponsor needs to take steps to comply with Essential Principle 13 or Part 7.2 of Schedule 3 then they will regarded as a manufacturer and must comply with the obligations on a manufacturer of a medical device under Chapter 4 of the Act .

Location of Information

In recognition of the large range of medical devices, and variations in physical size, the medical device labeling requirements have a 'layered' approach to where information which must accompany a device may be located.

Unless it is impractical or inappropriate to do so, it is required that the information required to be provided, must be provided **on the device itself**.

If, because of size or other constraints, it is not practical to include all the requisite information on the device, the information must be provided either

- on the packaging for the device, where the device is supplied individually, or
- when multiple devices are packaged together, on the packaging for the devices.

Where it is not possible to provide the requisite information either on the device or on the packaging, or a combination of both of these locations, the information must be provided on a leaflet supplied with the device.

This flexibility allows a manufacturer to vary the location of where the information is provided to accommodate physical and other constraints of the device. It is not, for example, practical to include any information on an 'in the ear canal' hearing aid other than possibly identifying the manufacturer by way of a logo, for example. In such circumstances the required information, or most of the required information, is contained on the individual packaging of each device.

However, recognizing that with such a small device label space is limited, a manufacturer may choose to put some of the information on the individual packaging

for the devices, and other information, storage conditions, warning statements or instructions for use on the outer carton in which multiple devices are supplied.

On the other hand, it would be expected that there is likely to be sufficient surface area on a piece of equipment such as a wheelchair and all information could be incorporated on the device without the need to utilize space on the packaging or an accompanying leaflet. Note this does not preclude duplication of information on the packaging or leaflet/instructions for use.

Size of Text

Any number, letter, symbol or letter or number in a symbol, used in the information must be legible and at least one millimeter high.

Language

The information provided with the device, and the information provided in the instructions for use **must** be in English. To facilitate the use of 'international' labeling by manufacturers, the information may also be provided in any other language.

Use of Symbols

Many manufacturers use symbols on labeling to convey information about the device. The most commonly used symbols are defined in the international standard ISO 15223-1:2007 -Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements. This standard identifies requirements for the development and use of symbols that may be used to convey information on the safe and effective use of medical devices. It also lists symbols applicable to a broad spectrum of devices that satisfy the requirements of the standard. These symbols may be used on the device itself or its package or in the associated documentation.

Manufacturers should note that, to date, this standard has **not** been adopted by the TGA in a Medical Device Standards Order. Accordingly, the meaning of **all** symbols or colour coding used in labeling or instructions for use **must** be explained in the information provided with the device or the instructions for use of the device.

Information to be Provided with the Device

Essential Principle 13 requires that the information in the following table, when applicable to the custom made medical device, **must** be provided with the device.

Item	Information to be provided
	The manufacturer's name, or trading name, and address
	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 (if this information is not obvious)
	Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging
	Any particular handling or storage requirements applying to the device
	Any warnings, restrictions, or precautions that should be taken, in relation to use of the device
	Any special operating instructions for the use of the device
	If applicable, an indication that the device is intended for a single use only
	An indication that the device has been custom-made for a particular individual and is intended for use only by that individual
	If applicable, an indication that the device is intended to be used only for clinical or performance investigations before being supplied
	For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device
	The batch code, lot number or serial number of the device
	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
	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)

Information About the Sponsor to be Provided With the Device

In addition to the information provided by the manufacturer to accompany the custom made medical device, where a medical device is not manufactured in Australia, the regulations also require information be provided with a medical device to allow the intended user of the device to identify the sponsor of the product. (Regulation 10.2)

The intention of the regulation is to identify the **sponsor** to the user, not other organisations who may be in the supply chain between the sponsor and the user such a wholesaler, distributor or retailer where these organisations are not the device sponsor, to ensure the user of the device is provided with sufficient information to enable contact to be made with the sponsor in the event further information is being

sought regarding the device, to report an adverse event or reaction when using the device, etc.

For custom made medical devices, the patient or wearer is considered the user, and the information required by Essential Principle 13, Part 7.2 of Schedule 3 of the Regulations and Regulation 10.2 must be made available to them.

Supply Chain Considerations

In providing information identifying the sponsor to the user, consideration must also be taken of the supply chain existing between the sponsor and the intended user.

Consideration must be given to how the information will be conveyed to the patient/wearer in circumstances such as –

- Supply direct from the sponsor to the intended user
- Supply to the user through a third party – for example a clearing house which collects orders for custom made devices and facilitates manufacture of the devices by either a manufacturer who may be located either in Australia, or overseas.

In circumstances where the supply is **direct** from the sponsor to any of the users identified above, the invoice accompanying the goods identifies the sponsor and could be considered a means of complying with the requirements.

However, where the sponsor, such as a clearing house or importer, supplies the device through an intermediary such as a health care professional, and there is no direct interaction between the sponsor and the user at the time of supply to the user, a labelling strategy must be adopted that ensures the name and address of the sponsor is provided in compliance with the regulation.

The sponsor is at liberty to determine how compliance will be achieved, but typically this could be by -

- The manufacturer incorporating the name of the sponsor in labelling provided with the device
- The sponsor applying a label to the device – as often occurs with large items of equipment such as diagnostic imaging devices, monitoring and diagnostic electromedical equipment and infusion therapy equipment.
- The sponsor applying a label to the packaging of the device (or devices, when packed in multiples), or the *Instructions for Use* of the device
- The sponsor providing a supplementary leaflet with the device

If the strategy applied involves the sponsor over labelling either the device or the packaging, the label must not in any way adulterate the device or obscure any of the

information provided with the device by the manufacturer. The label applied must also comply with previously outlined requirements for language, size of text and use of symbols.

Instructions for use

In most circumstances, instructions must accompany the device which will allow the safe use of the device.

The only exceptions to this requirement are –

- the device is a Class I medical device or a Class IIa medical device; **and**
- the device can be used safely for its intended purpose without instructions.

As with information which must accompany the device, the regulations allow for a layered approach as to how this information is provided.

Unless it is impractical or inappropriate to do so, it is required that the instructions for use required to be provided, must be provided on the device itself.

If, because of size or other constraints, it is not practical to include all the requisite instructions for use on the device, the information must be provided either

- on the packaging for the device, where the device is supplied individually, or
- when multiple devices are packaged together, on the packaging for the devices.

Where it is not possible to provide the instructions for use either on the device or on the packaging, or a combination of both of these locations, the information can be provided separately with the device.

When supplied separately with the device, there is provision for the instructions to be provided in printed form, or using other appropriate media, for example CD-ROM, DVD or other electronic media. Where a manufacturer chooses to use a media other than the printed form, they must also be able to supply the information in printed form if requested by the user.

It should be noted that the TGA does not consider providing this information only through a website identified on the device labeling as being in compliance with this requirement.

Essential Principle 13 requires that, subject to the need for instructions for use to be provided, that where applicable, the information in the following table **must** be supplied in the instructions for use -

Item	Information to be provided
	The manufacturer's name, or trading name, and address
	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
	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 imaging devices)
	Information about the intended performance of the device and any undesirable side effects caused by use of the device
	Any contra-indications, warnings, restrictions, or precautions that may apply in relation to use of the device
	Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging
	Any particular handling or storage requirements applying to the device
	If applicable, an indication that the device is intended for a single use only
	If applicable, an indication that the device has been custom-made for a particular individual and is intended for use only by that individual
	If applicable, an indication that the device is intended to be used only for clinical or performance investigations before being supplied
	For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device
	For a device that is intended by the manufacturer to be supplied in a sterile state: (a) an indication that the device is sterile; and (b) information about what to do if sterile packaging is damaged; and (c) if appropriate, instructions for resterilisation of the device
	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
	Any special operating instructions for the use of the device
	Information to enable the user 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

Item	Information to be provided
	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
	Information about any treatment or handling needed before the device can be used
	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
	For an implantable medical device — information about any risks associated with its implantation
	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
	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
	Information about precautions that should be taken by a patient and the user if the performance of the device changes
	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
	Adequate information about any medicinal product that the device is designed to administer, including any limitations on the substances that may be administered using the device
	Information about any medicine (including any stable derivative of human blood or blood plasma) that is incorporated, or is intended to be incorporated, into the device as an integral part of the device
	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
	Information about the degree of accuracy claimed if the device has a measuring function
	Information about any particular facilities required for use of the device or any particular training or qualifications required by the user of the device

Record keeping requirements

Manufacturers have a requirement to keep particular records in relation to custom made medical devices.

Manufacturers are required to maintain documentation and records relating to -

- The process applied in taking the requirements detailed in the prescription or specification from the health care professional and producing a design for the custom made medical device
- Specifications for the components or materials used in the device, Manufacturing processes used in the manufacture of the device,
- Records of materials used in the manufacturing process of the device,
- Production records,
- Finished device test records
- Patient/client specific records identifying the patient, the prescribing health care professional and the design characteristics or construction of the supplied device to the patient/client.
- a written statement in relation to the device including -
    - the name and business address of the manufacturer;
    - sufficient information to enable the user to identify the device or, if relevant, the contents of packaging;
    - a statement to the effect that the device is intended by the manufacturer to be used only in relation to a particular individual;
    - the name of the individual in relation to whom the device is intended to be used;
    - the name and business address of the health professional who provided the specification for the device;
    - the particular design characteristics or construction of the device as specified by the health professional who provided the specification for the device;
    - a statement to the effect that the device complies with the applicable provisions of the essential principles or, if the device does not comply with all applicable provisions of the essential principles, a statement explaining which provisions of the essential principles the device does not comply with and the reasons for the non-compliance.

These records must be kept, and made available to the TGA if so requested, for a period of **5 years** after the manufacture of the last medical device to which either the documentation, verification results or device specific written statement relates

Sponsors are strongly recommended to maintain distribution records of all custom made devices supplied by their organisation/practice.

In relation to each custom made device, such records should include –

- Device details, including prescription details/specification as appropriate
- Manufacturer
- Batch/model/serial number of the device
- Date of manufacture and date of supply
- Prescribing healthcare professional
- Patient details

Such records would be useful in the event any remedial action, such as under the Uniform Recall Procedure for Therapeutic Goods, is necessary after the products have been supplied to the market.

Adverse event reporting obligations for Manufacturers and Sponsors

The regulatory framework for medical devices imposes requirements on both sponsors and manufacturers of custom made medical devices to report to the TGA any adverse events they become aware of, associated with a particular device, or devices of a particular type.

In particular, manufacturers and sponsors are required to provide information to the TGA about any malfunction or deterioration in the characteristics or performance of the medical device or any inadequacy in the design, production, labelling, instructions for use or advertising materials for the medical device, or any use in accordance with, or contrary to, the use intended by the manufacturer that:

- led to the death of a patient or a user of the medical device or a serious deterioration in their state of health, or another person, within 10 days after becoming aware of the event or occurrence, or
- led to a serious threat to public health, within 48 hours of becoming aware of the event, or
- that might lead to the death of a patient or a user of the medical device or a serious deterioration in their state of health, or another person, within 30 days of becoming aware of the event.

Note: A serious threat to public health is considered as a systemic failure of a medical device that may lead to the death of, or serious injury to a patient, user of the device or another person and the severity of the harm caused by the hazard was not previously known or anticipated by the manufacturer, and the manufacturer will be required to take prompt action to eliminate, or reduce the risk, of the hazard.

Note: A serious deterioration in the state of health of a person means a life-threatening illness or injury or a permanent impairment of a bodily function, permanent damage to a body structure, or a condition requiring medical or surgical intervention to prevent the permanent impairment or damage.

This also includes information relating to any technical or medical reason that has led

the manufacturer to take steps to recover the medical devices.

Postmarket monitoring of product performance

It is not a requirement of the regulatory framework for custom made medical devices, but it is advisable for manufacturers to have in place a procedure to review the experience gained from their custom made devices in the market and to implement any necessary corrective action to improve product performance and reliability.

Sponsors can assist overseas manufacturers of custom made medical devices by providing feedback received from users, or details of adverse event reports received, to the manufacturer.

Custom made medical devices and the Australian Register of Therapeutic Goods

NOTE: These requirements exist in the Regulations, but have not yet been implemented.

Custom made medical devices are exempted from requiring an entry on the Australian Register of Therapeutic Goods (ARTG).

However, the regulatory framework does require manufacturers and sponsors of custom made medical devices to advise the TGA of their details, and the range of custom made medical devices they manufacture/supply.

Australian manufacturers of custom made medical devices are required to notify the TGA of –

- The manufacturer's name and address,
- responsible contact person within the organization, and
- a description of the kinds of medical devices being custom made by the manufacturer – identified using the Global Medical Device Nomenclature System code

Australian sponsors of imported custom made medical devices are required to notify the TGA of –

- The sponsors name and address
- responsible contact person within the organization,
- The manufacturer's name and address, and

- a description of the kinds of medical devices being custom made by the manufacturer – identified using the Global Medical Device Nomenclature System code

This notification is made using the Devices Electronic Application Lodgement (DEAL) system available on the TGA's e-business website.

New users to the DEAL system will first need to establish an e-business account with the TGA. This is done on http://www.tgasime.health.gov.au - the SIME Home page and e-business site for the TGA. Click on the New User section of the page and down load the file 'user form.zip'. This contains the instructions for completing the following forms:

- Client Details Form - only to be completed if, as a sponsor you do not already have a CLIENT identification number. For first time sponsors, the form needs to be completed for both the sponsor and the overseas manufacturer.
- E Business Access Form - needs to be completed to establish an e-business account with the TGA and obtain an account name and password.

Complete these forms and fax them to the TGA on 02 6232 8581. An account name and password will be sent to the email address specified on the form within a couple of days.

Users can then access the DEAL notification system through the **Medical Devices** link on the same web page.

Full instructions on completing this electronic notification can be found in the DEAL user instructions, which can also be downloaded from the **Medical Devices** home page of the website.

NOTE:

The TGA operates two websites –

www.tga.gov.au for general information
http://www.ebs.tga.gov.au for all e-business applications