Australian Government
Department of Health
Therapeutic Goods Administration

The regulation of medical device software

Webinar

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TGA Health Safety Regulation

Overview

- What is SaMD?
- Reforms to medical device software regulation in Australia
- Is my product regulated?
- What do I need to do?

What is SaMD?

- Software as a Medical Device
  - Software that runs on general purpose platforms
    - On a laptop, tablet or mobile phone
    - On a server
    - Web app
    - Cloud based – software as a service

- Software in a Medical Device
  - Drives a medical device

When is software a medical device?

Software is a medical device when the manufacturer *intends* for its product to be used for:

- diagnosis
- prevention
- monitoring
- prognosis & prediction
- treatment
- alleviation

…of disease, injury or disability

It's not based on…

- what colour it is
- what shape it is
- whether or not it looks good
- what it is called
- whether it is novel or not
- what technology is used
- how it is supplied (online, in hardware, through the sneaker net, …)

Intended purpose is critical…

Medical device software regulation

- Program of reforms
  - broad program of reforms to Medical Device regulation
  - Review of Medicines and Medical Device Regulation (MMDR)

- International alignment
  - International Medical Device Regulators Forum (IMDRF)
  - Health Canada, EU, US FDA

- Software specific consultations

Consultations on software

2019

Regulation of software, including Software as a Medical Device (SaMD).

- regulation changes made Dec 2019 (commences on 25 Feb 2021)

2020

Scope of regulated software-based products (the "carve out")

- closed May 2020
- 48 submissions received from a broad range of respondents
- analysis published on TGA website
- further meetings held with targeted stakeholders

Regulatory change for software

Changes to Essential Principles:

- **EP 12.1** amended to clarify the requirements for:
  - cyber security
  - the management of data and information
  - requirements relating to development, production, and maintenance.
- **EP 13.2(3)** amended to allow information to be provided electronically.
- New **EP 13B** introduced requiring the current version and build number for the software to be made accessible and identifiable to users of software-based medical devices. This information must be in English, however may also be displayed in other languages.

Regulatory change for software

Changes to the classification rules for software intended for:

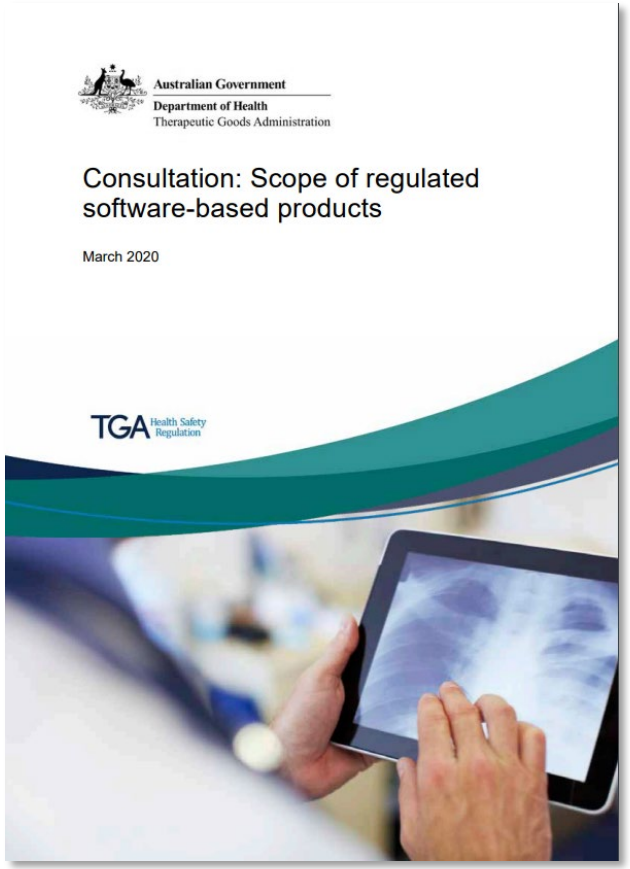
- diagnosing and screening for a disease or condition
- monitoring the state or progression of a disease or condition
- specifying or recommending a treatment
- providing therapy (via provision of information)

- Changes to EPs and classification rules commence on **25 February 2021** - transition period until **1 November 2024**
- Notification required for devices needing classification

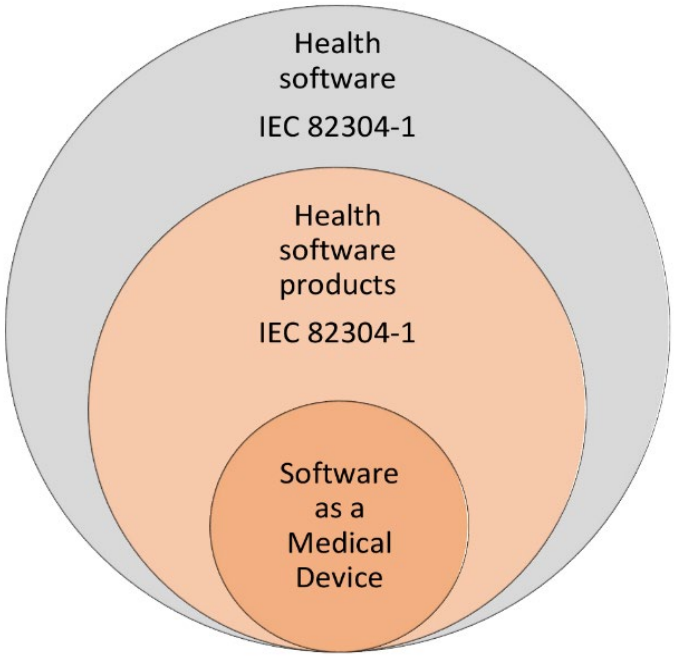
Carve out consultation

- Sought feedback on:
  - Measures to clarify the boundary of regulated products
  - proposal to “carve-out”, certain groups of software medical devices that would normally be regulated by the TGA

- Two primary guiding considerations for the carve-out:
  - Device presents a low risk to safety
  - Alternative oversight schemes or systems are in place



Carve-out consultation



- **Software as a Medical Device (SaMD) is a subset of health software**
  - The scope of ‘health software’ is broader than ‘medical device software’
  - Most health software is not a medical device and is not regulated by the TGA.

Carve-out mechanisms: Exclusion vs Exemption

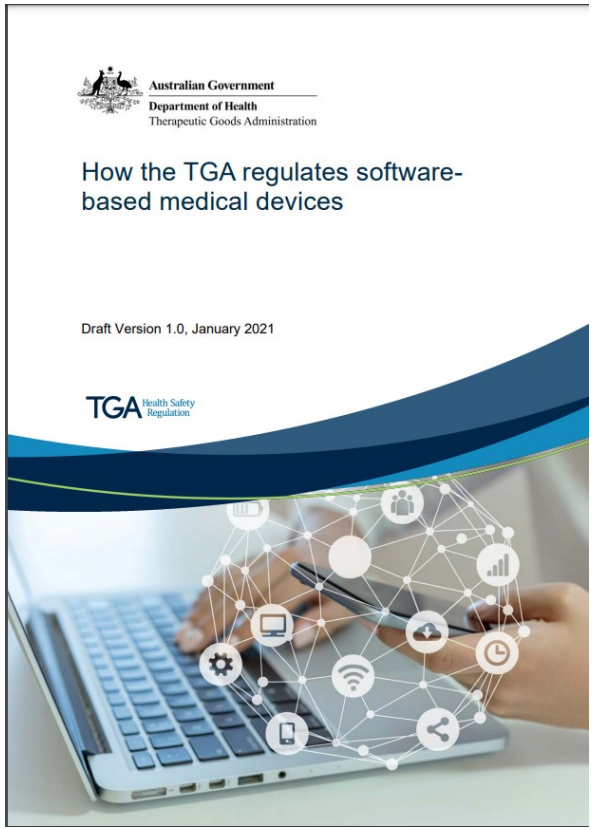
Exclusion	Exemption
means that the devices are completely unregulated by TGA	means that TGA retains some oversight for advertising, adverse events and notification Registration of the devices is not required.

Carve-out mechanisms: Exclusion vs Exemption

- **Excluded products** are not subject to any TGA oversight
- **Exempt products** are
  - Not required to be in the ARTG
  - Do not have pre-market evaluation by the TGA
  - Must meet the relevant essential principles for safety and performance
  - Must report adverse events to the TGA
  - Are subject to recalls or hazard alerts in the event of a problem
  - Are subject to the Therapeutic Goods Advertising Code

Carve out consultation - outcomes

- clarification of boundary
- *exemption* for Clinical Decision Support Systems
- *exclusion* for a range of products
- guidance to illustrate boundary and changes – guidance now published on TGA website
- commences on **25 Feb 2021**



Software to be carved-out - Excluded

15 Exclusions grouped into 5 categories:

- **Consumer** health products - prevention, management and follow up devices that do not provide specific treatment or treatment suggestions
- **Enabling** technology - for telehealth, remote diagnosis, healthcare or dispensing
- **Digitisation** - of paper based or other published clinical rules or data including simple dose calculators and Electronic Patient Records
- **Analytics** - population based
- **Laboratory Information Management Systems**

Clinical decision support software

Exemption for clinical decision support software that is:

a) intended to be for the sole purpose of providing or supporting a recommendation to a health professional about preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; and

b) not intended by its manufacturer to directly process or analyse a medical image or signal from another medical device; and

c) not intended by its manufacturer to replace the clinical judgement of a health professional in relation to making a clinical diagnosis or decision about the treatment of patients

Is my product carved-out?

You need to consider the following.

The order is important:

- Is it a medical device (according to the definition)?
- Does it meet any of the exclusions?

If it is a medical device, determine if it meets the exemption for clinical decision support

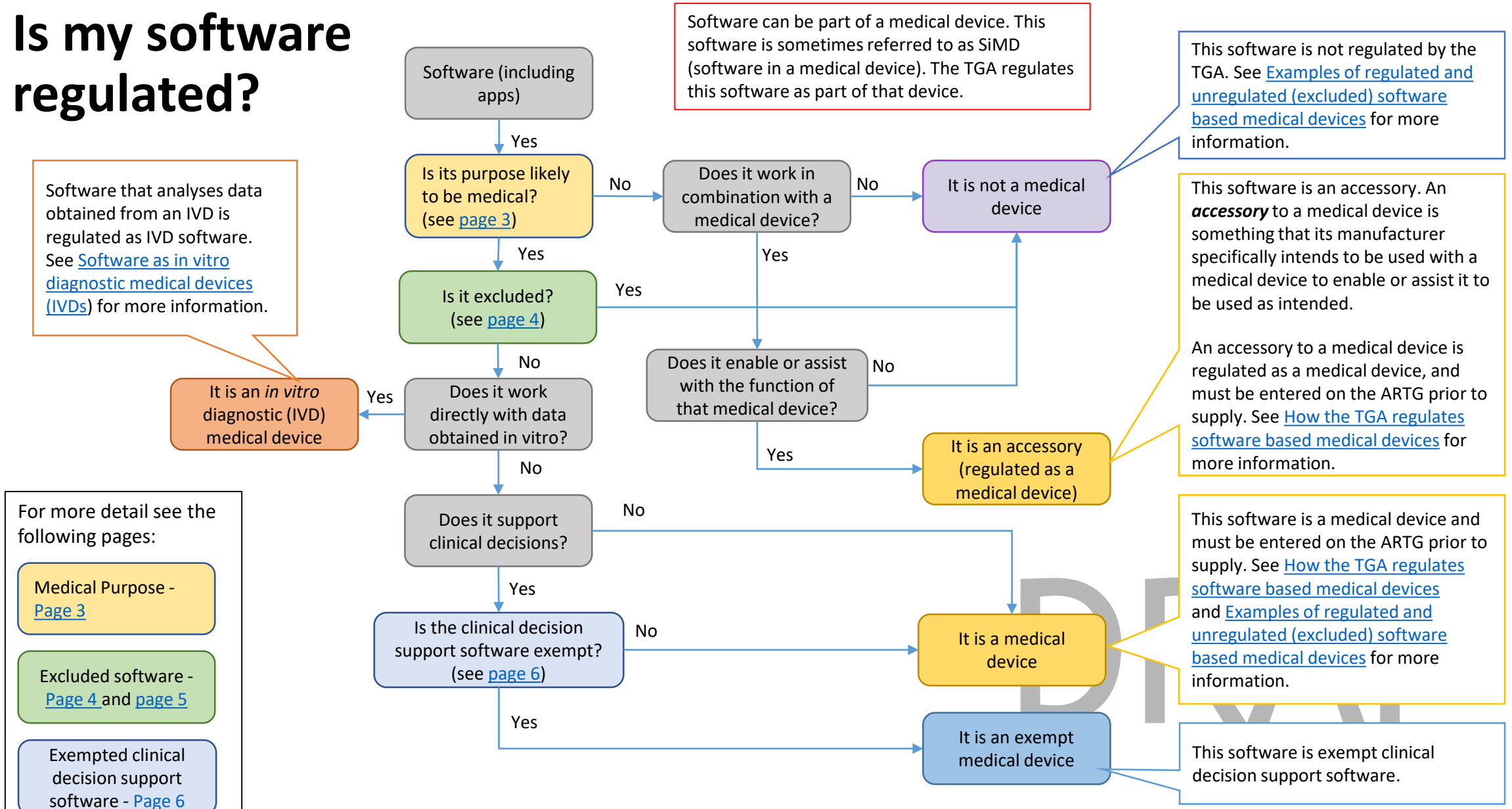
Is my product regulated?

Need to consider

- Who is the manufacturer?
  - may be software developer, vendor, integrator…..
- Is it a medical device?
  - what is the intended purpose
- Does it meet exemption or exclusion criteria?

Flowchart and other guidance published on the TGA website

Is my software regulated?



We’re answering your questions

Regulation of software based medical devices

https://www.tga.gov.au/regulation-software-based-medical-devices

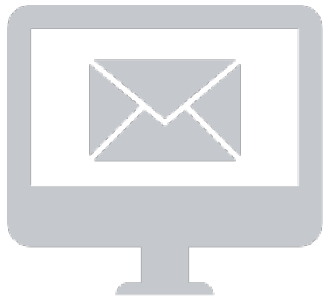
General medical device enquiries

devices@tga.gov.au

1800 141 144

The TGA’s Digital Devices team

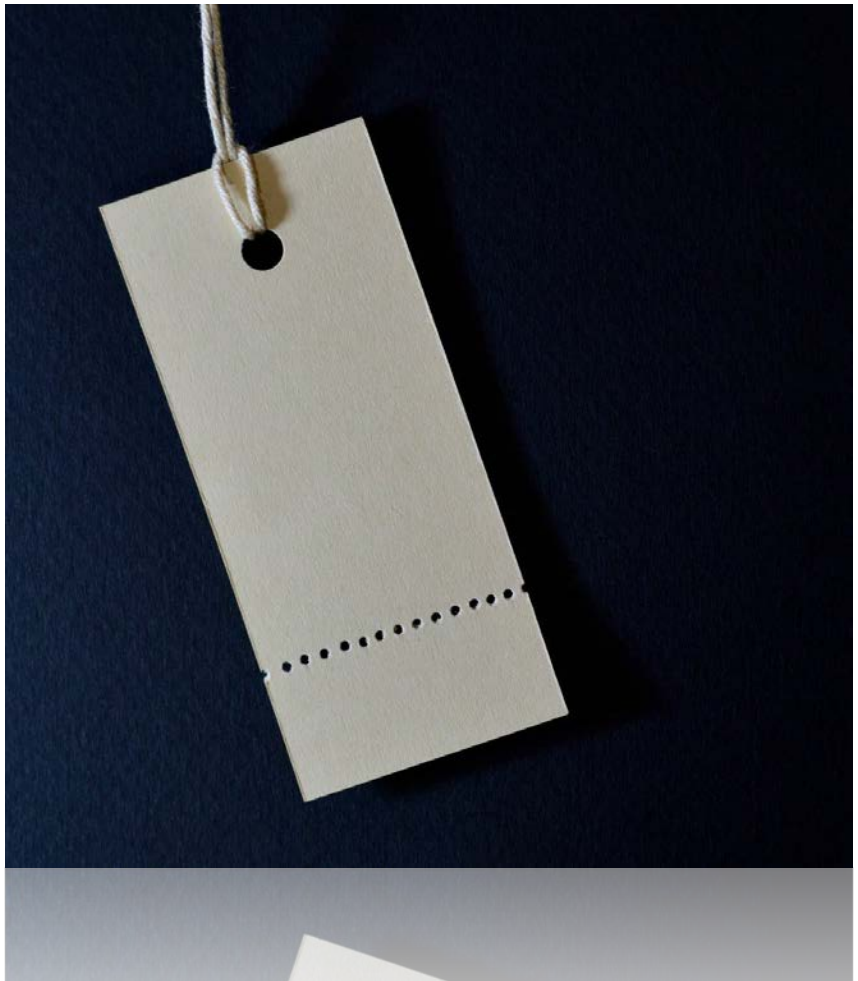
digital.devices@tga.gov.au



www.tga.gov.au

Introduction to medical device regulation

Who is the manufacturer?

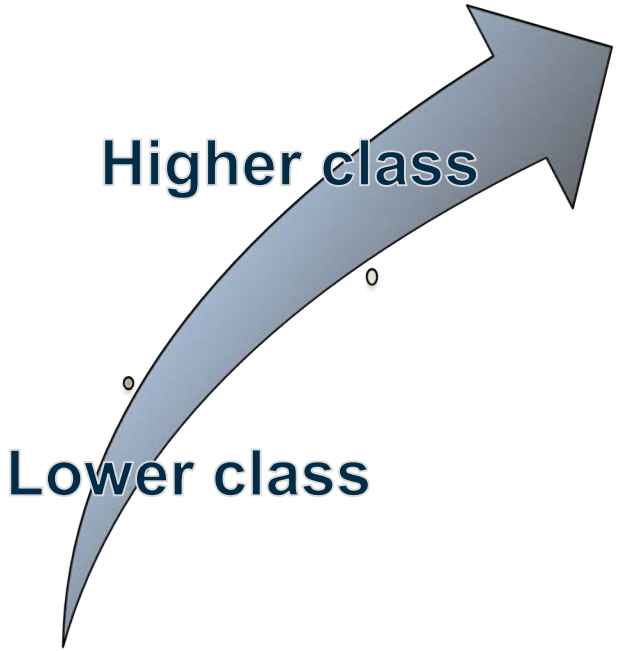


- It’s not necessarily who physically makes the device.
- It’s who has their name on the label

What do I need to do?

- Determine if your product is a medical device!
- Determine the **classification**
- Hold **evidence of compliance** with the **essential principles** for safety, quality, and performance
- Obtain **3rd-party certification** (if required)
  - assessment of technical files
  - inspection of QMS, manufacturing site(s)
- Apply for inclusion in the ARTG
- Follow post-market requirements
  - Monitor post-market performance
  - Report problems to the TGA
  - Annual manufacturing inspections

Regulatory classification



Classification	Requirements	Degree of oversight
Class III	✓✓✓	3rd-Party, High
Class IIb	✓✓✓	3rd-Party, Medium
Class IIa, Im, Is	✓✓	3rd-Party, Low
Class I	✓	Self-certification

The Essential Principles of Safety and Performance

Schedule 1, *Therapeutic Goods (Medical Devices) Regulations (2002)*

General principles

1. Use of medical devices not to compromise health and safety
2. Design and construction of medical devices to conform to safety principles
3. Medical devices to be suitable for intended purpose
4. Long-term safety
5. Medical devices not to be adversely affected by transport or storage
6. Benefits of medical devices to outweigh any side effects

Principles about design and construction

7. Chemical, physical and biological properties
8. Infection and microbial contamination
9. Construction and environmental properties
10. Medical devices with a measuring function
11. Protection against radiation
12. Medical devices connected to or equipped with an energy source
13. Information to be provided with medical devices
14. Clinical evidence
15. Principles applying to IVD medical devices only

www.legislation.gov.au

The Essential Principles – software requirements

Evidence generally expected for software

Some of the evidence required:

- Quality management (QMS) records
- Release & version management
- Design control and validation
- Defect reporting and correction
- Clinical evidence
- Benefit must outweigh the risks

Evidence of compliance

Some of the standards you need to consider

IEC 62304 – Medical device software — Software life cycle processes

ISO 13485 – Medical devices — Quality management systems — Requirement for regulatory purposes

ISO 14971 – Medical devices — Application of risk management to medical devices

Plus other standards that you identify as applicable to your product

3rd-party certification

Involves an independent review

- Manufacturer must meet certain requirements
- Inspection/audit by 3rd party against those requirements

Manufacturers are certified against the requirements

- Certificates issued for a certain scope of manufacture or design/type

Certification options in Australia

- European Union
- MDSAP + US FDA / Health Canada
- MDSAP/QMS + Japan
- TGA
- EU–Aus MRA

Evidence of compliance

Beyond standards

- Risk and quality management
  - Total product lifecycle (TPLC)
- State-of-the-art
  - Standards published and unpublished
- Best practice
  - Software engineering, clinical, other
- Product validation
  - Engineering, clinical, other

What is a quality management system?

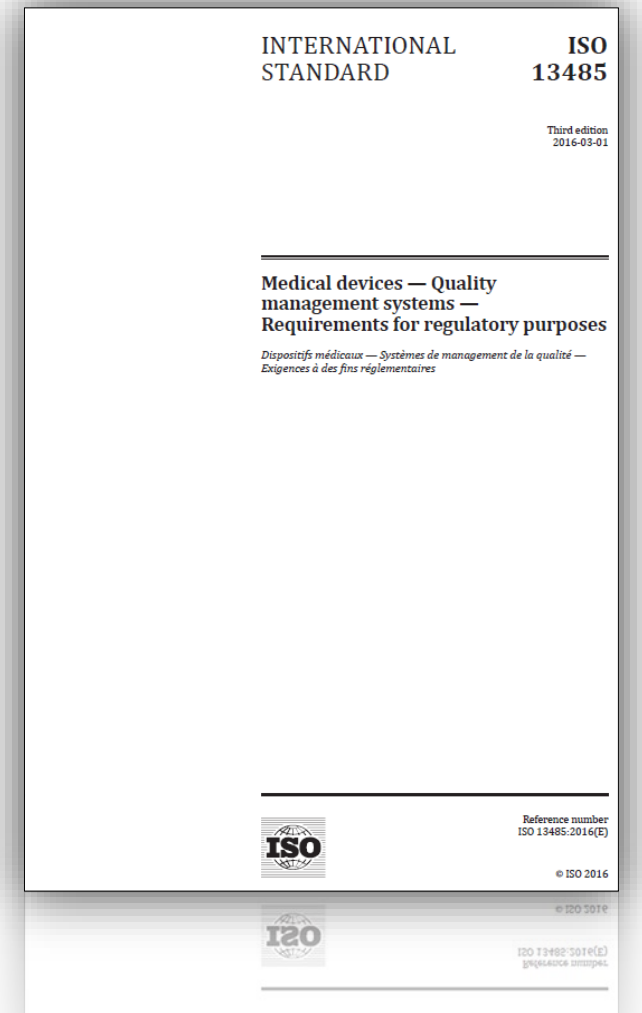
Simply put, it is a system to assure quality in manufacturing.

More broadly, it's also a means for manufacturers to meet customer and regulatory requirements.

In therapeutic goods regulatory schemes, a QMS is used for the management of **quality** but also for the management of **safety** and **performance/efficacy** of therapeutic goods.

It's up to you, as a manufacturer, to put in place a system that works for you and your business.

Quality management - introducing ISO 13485



ISO 13485 is…

- a technical standard
- based on ISO 9001
- recognised by regulatory jurisdictions the world over
- principles based
- not mandatory in most jurisdictions (including Australia)

Medical devices—Quality management systems—Requirements for regulatory purposes — ISO 13485: 2016

Post-market requirements

Work doesn't stop when a product reaches the market - it continues over the lifetime of every medical device

Adverse events - when things go wrong:

- Monitor
- Respond, report
- Change control

Recalls or hazard alerts in the event of a problem

Compliance with the Therapeutic Goods Advertising Code

Inspections of manufacturing facilities

Inspections of software manufacturers

The manufacturer is expected to:

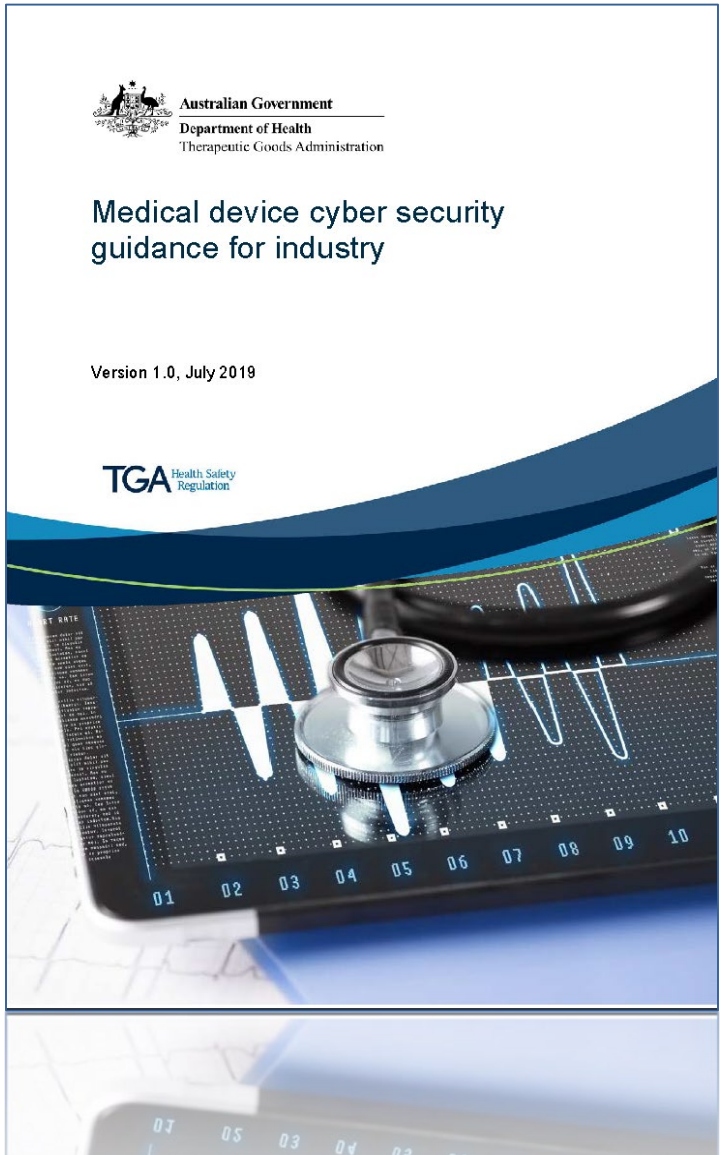
- **design** for safety and performance
- **develop** for quality, robustness, resilience, and predictability
- **monitor**, **report**, and **improve**

using appropriate, sufficient, robust, and defensible tools, approaches, and methods.

Cyber security

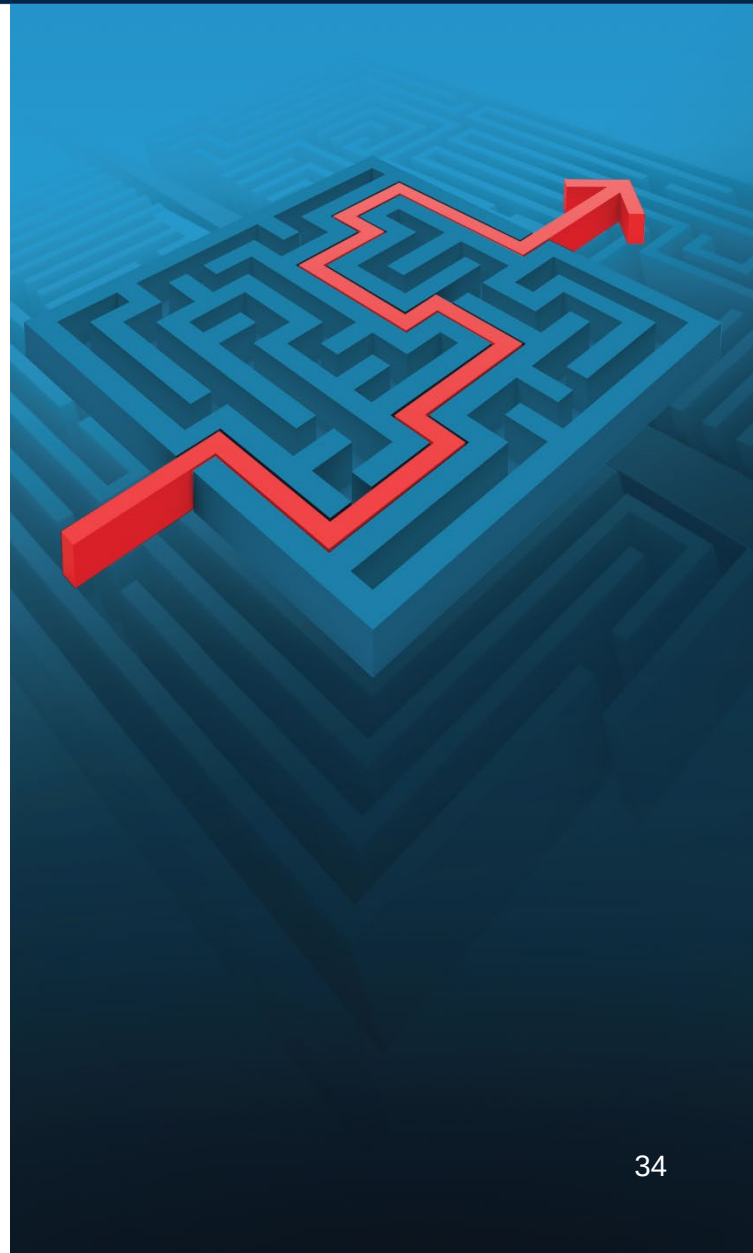
Regulatory guidance

- https://www.tga.gov.au/sites/default/files/medical-device-cyber-security-guidance-industry.pdf
- Total product life cycle
- Applying the Essential Principles
- Relevant standards
- Strategies for risk management
- Design and testing considerations
- Supply chain and platform security
- Post market monitoring, response and change control



SME Assist

- **Targets** the needs of small to medium enterprises (SMEs), start-ups, researchers and those unfamiliar with therapeutic goods regulation
- **Assists** users with navigating the 'regulatory maze'
- Offers:
  - Guidance articles
  - Interactive decision tools (including 'What classification is my medical device?')
  - Educational face-to-face workshops across Australia (including a dedicated medical device focus session)
  - Email and phone support
  - A subscription service to keep up-to-date with news and events



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