Australian Government
Department of Health
Therapeutic Goods Administration

Regulation of software, including software as a medical device

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Housekeeping

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  - 2. Enter Pass Code **133 024 7191**
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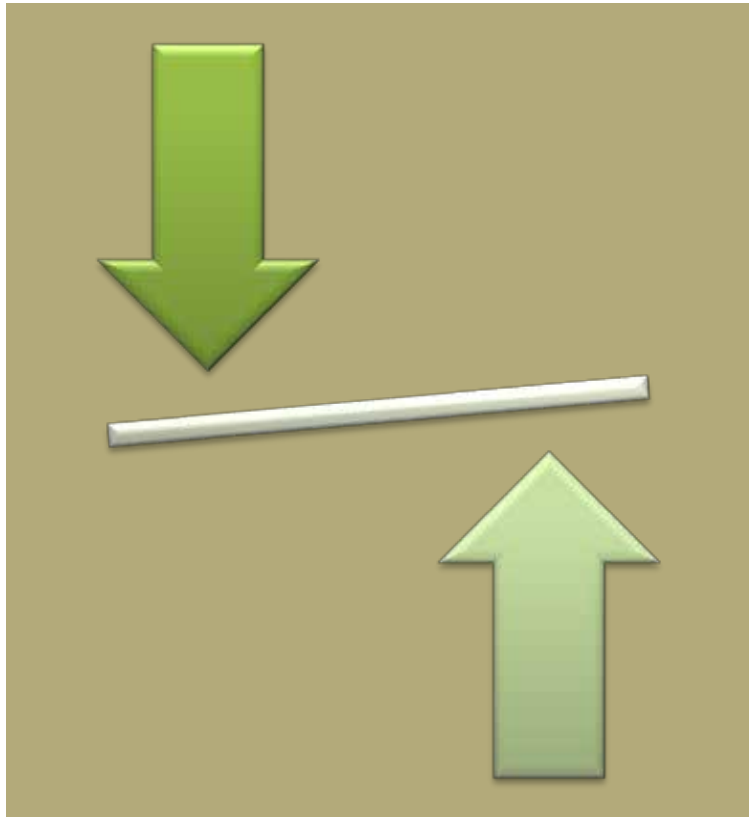
- This event will be published on the TGA website
  - News room [tab]
  - Presentations

- Medical Device Regulation for Market Authorisation
- Considerations for Software
- International Approaches and Australian Regulatory Reforms
- Questions

Medical Device Regulation for Market Authorisation

The benefit versus risk approach

- No therapeutic good is **risk free**
- The work of the TGA is based on **applying scientific and clinical expertise** to **decision making**
- We ensure that the **benefits outweigh any risks**



Medical device legislation

- Therapeutic Goods Act 1989 (Chapter 4)
  - Therapeutic Goods (Medical Devices) Regulations 2002

What is a medical device?

Defined in s41BD of the *Therapeutic Goods Act 1989*

Any instrument, apparatus, appliance, material or other article intended to be used for human beings for the purpose of one or more of the following

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability

(iii) investigation, replacement or modification of the anatomy or of a physiological process

(iv) 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

- Bandages
- Dental implant
- Breadt implant
- Gluscose monitor

What is a manufacturer?

41BG Manufacturers of medical devices

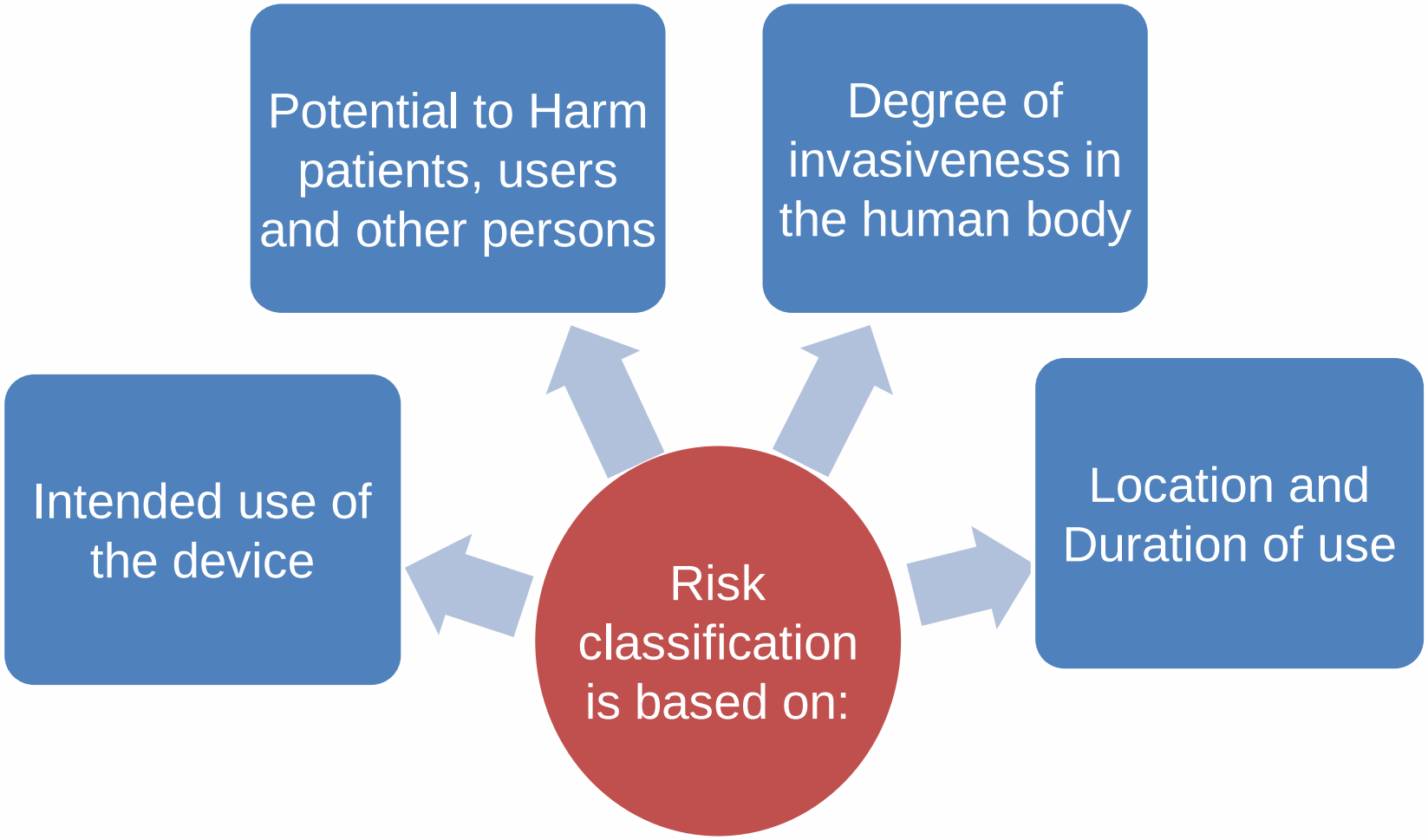
(1) The ***manufacturer*** of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations.

- […]

Regulatory requirements - 4 Steps

1. Risk based classification system
   - Classification determines minimum CA procedure(s)
2. Conformity assessment (CA) procedures
   - Manufacturing requirements
   - Essential principles (EP)
3. Inclusion in the Australian Register of Therapeutic Goods
4. Post market monitoring and reporting

Step 1 - Risk based classification



Regulatory oversight increases with increasing risk category

	Regulatory Scrutiny
Class III	✔✔✔✔
Class IIb	✔✔✔
Class IIa	✔✔
Class I	✔

(IVD Device Classes – Class 1 to Class 4)

Step 2 - Conformity assessment

Requirements for manufacturers

Quality Management System	• Quality management system in compliance with ISO 13485 (except for Class I devices)
Technical documentation	• Technical documentation for the design of the device including evidence of testing
Declaration of Conformity	• Declaration that the device complies with the regulatory requirements
Post market surveillance	• Surveillance of product performance in the market

The essential principles

Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 1

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

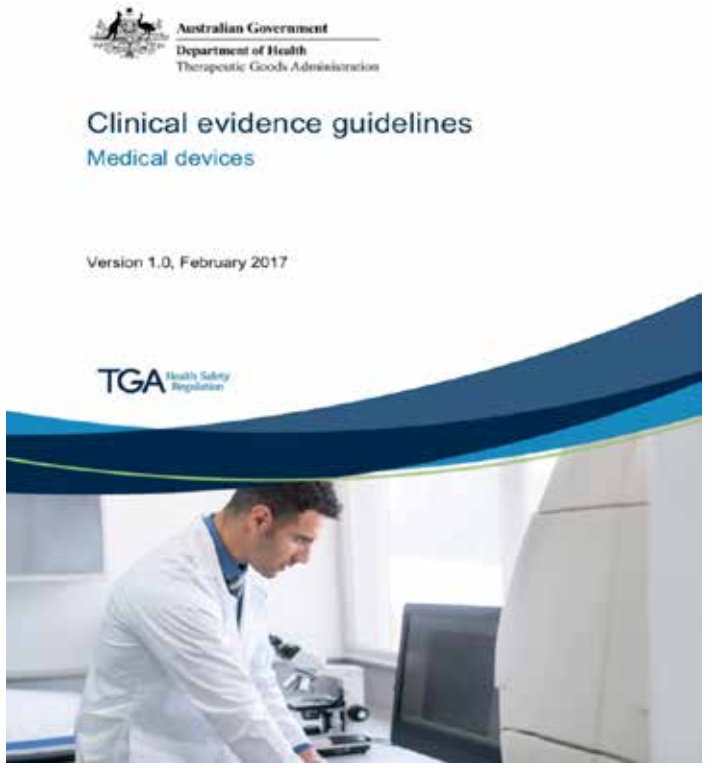
Principles about design and construction

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

What is clinical evidence for a medical device?

Clinical evidence guidelines: Medical devices



Step 3 - Inclusion in the ARTG

Evidence Requirements

- **Class I** Self-assessment and declaration
- Class Is, Im, IIa
  - Manufacturing certification including technical file review
- Class IIb
  - Manufacturing certification including technical file review
  - Mandatory application audit for some Class IIb devices
- Class III
  - Manufacturing certification
  - Device design examination certification
- Mandatory application audit

Step 4 - Postmarket obligations

For higher risk devices: an AIMD, Class III or implantable Class IIb device

Three consecutive annual reports to the TGA required

Monitoring of product performance

Adverse event reporting to the TGA

Environmental scanning

Review of medical & scientific literature, regulatory news, media and other sources

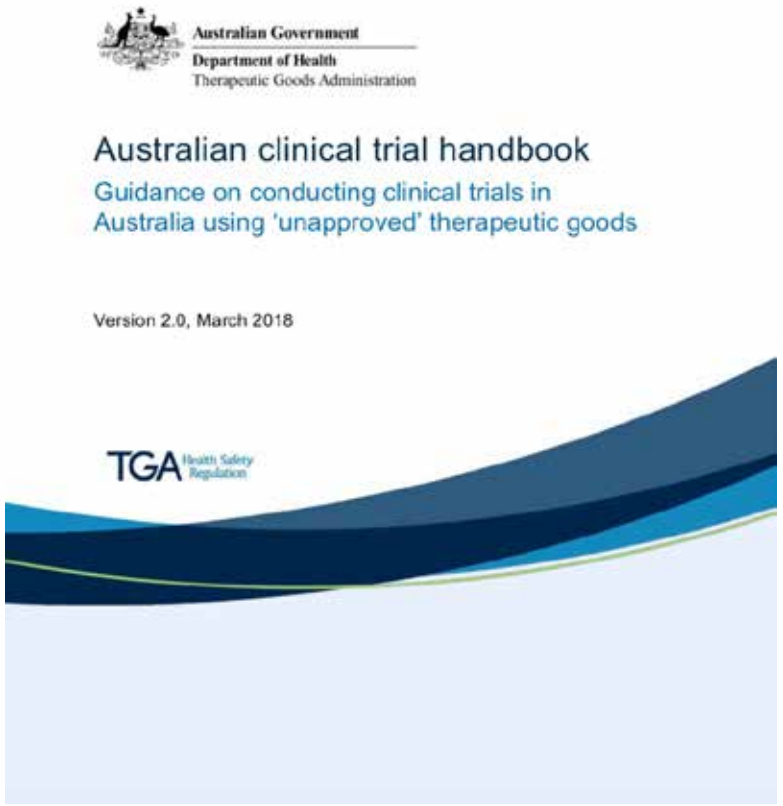
Some exceptions

The following are not required to be in the ARTG:

- Special Access Scheme for Unapproved Goods
- Experimental Product Exemptions
- Custom Made Medical Devices
- In-House In Vitro Diagnostic Devices

Australian clinical trial handbook

Clinical Trials	
CTN	CTX
HREC	HREC
Notification to TGA	Approval by TGA



Considerations for Software

Is it regulated?

Software is regulated by the TGA

- When it is part of a hardware medical device or medical device system
- When it controls a medical device
- When it meets the definition of a medical device.

That is, when the legal manufacturer intends for the software to be used for:

- diagnosis,
- prevention,
- monitoring,
- treatment, or
- alleviation, of disease, injury or disability

Software as a Medical Device (SaMD)

Software that is intended to run on general purpose computing platforms and is also a medical device[1]

- Platforms could include computers, tablets, phones, web browsers
- Examples:
  - Image processing for diagnosis or pathology
  - Software that collects information and makes a clinical decision or referral
  - Apps that calculate drug dose

1. As defined in 41BD of the *Therapeutic Goods Act 1989*.

Software as a Medical Device (SaMD)

- Does **not** include:
  - general health and lifestyle apps (not a MD)
  - software that is part of a device (not regulated separately)
  - apps that control a medical device (accessory and MD)
  - apps that rely on hardware in addition to a general purpose computing platform, eg – sensors, to achieve their intended purpose

Classification rules for software

4.1 Active medical devices - general

An active medical device is classified as Class I, unless the device is classified at a higher level under another clause in this Part or in Part 2, 3 or 5.

Regulation 3.3

(5) If a medical device is driven, or influenced, by an item of software, the software has the same classification as the medical device.

Most software is Class I under the current rules

Evidence of compliance

- QMS
- Version control
- Release management
- Design validation
- Bug/issue reporting and correction
- Clinical evidence
- Benefit must outweigh the risks

Document it

Evidence of compliance

Important standards

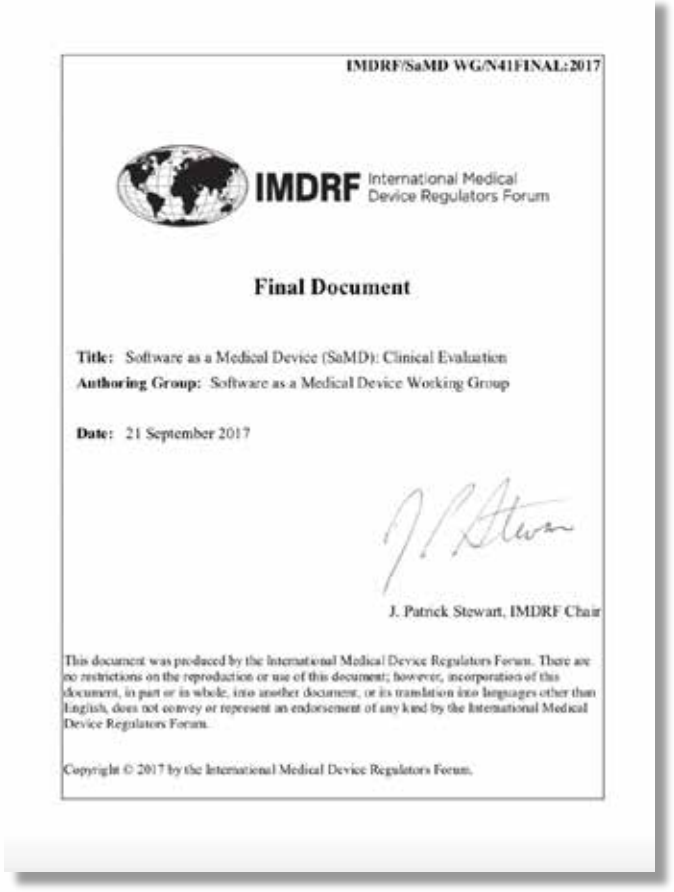
ISO 13485 - Medical devices - Quality management systems - Requirement for regulatory purposes

ISO 14971 - Medical devices - Application of risk management to medical devices

IEC 62304 - Medical device software - Software life cycle processes

What is clinical evidence for a software medical device?

www.imdrf.org



IMDRF/SaMD WG/N41FINAL:2017

IMDRF International Medical Device Regulators Forum

Final Document

Title: Software as a Medical Device (SaMD): Clinical Evaluation
Authoring Group: Software as a Medical Device Working Group

Date: 21 September 2017

J. Patrick Stewart, IMDRF Chair

International approaches and Australian regulatory reforms

Differences in regulatory schemes

Jurisdiction	Self Assessed	Premarket Product Assessment	Premarket Manufacturer Assessment	Premarket Manufacturer Certification	Premarket Product Certification
Australia, Europe, FDA Class I					
Australia and Europe Class IIa, IIb					
FDA Class II					
Australia and Europe Class III				ü	ü
FDA Class III		ü	ü		ü

Differences in regulatory schemes

Recent Regulatory Reforms

- Europe
  - Higher Classification for Software that provides information for clinical decision making
- FDA
  - Premarket assessment and certification of manufacturers for software products
- Australia
  - Current consultation for higher classification for software for clinical decision making, therapy

New requirements in Europe

- The EU MDR 2017/745 has introduced the following new classifications for software:

- Software that provides information to be used in making decisions for diagnosis or treatment is:

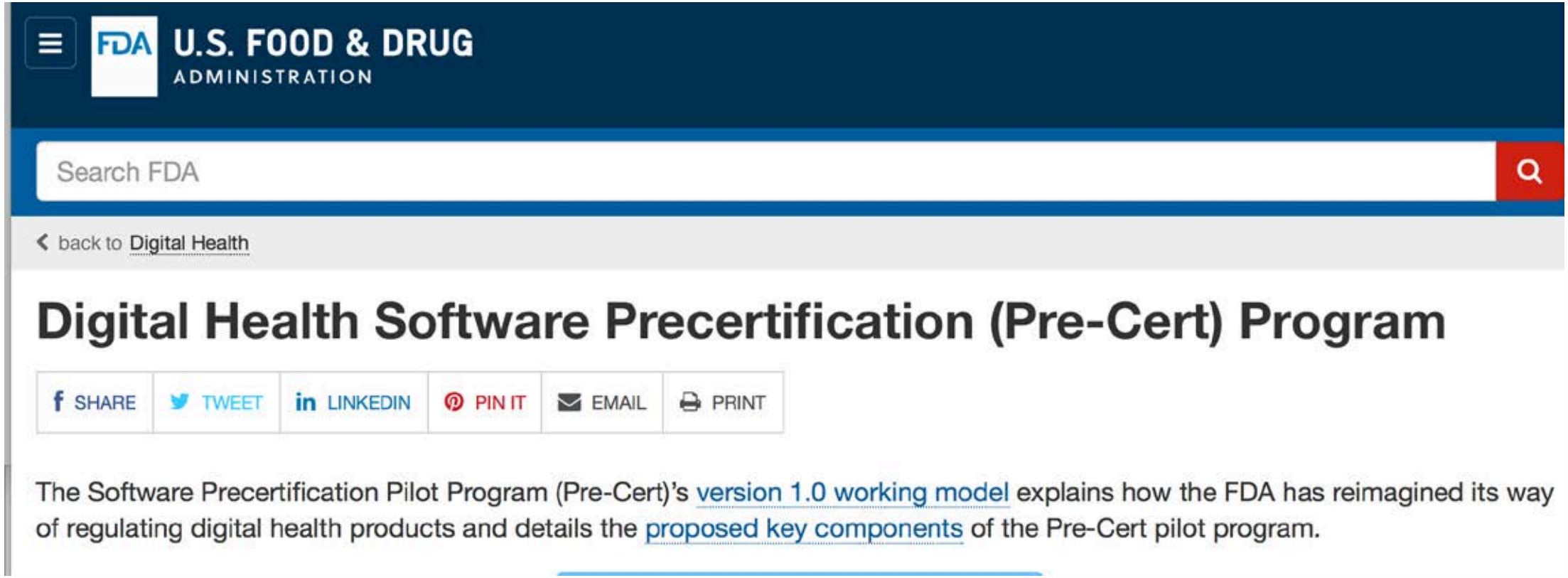
  - Class III if the decisions have an impact that may cause death or an irreversible deterioration of a person's state of health
  - Class IIb if the decisions have an impact that may cause a serious deterioration of a person's state of health or a surgical intervention
  - Class IIa in any other case

NOTE: The EU already has an additional classification rule applicable to software compared with Australia:

Rule 16 (MDD 93/42/EEC)

Devices specifically intended for recording of X-ray diagnostic images are in Class IIa.

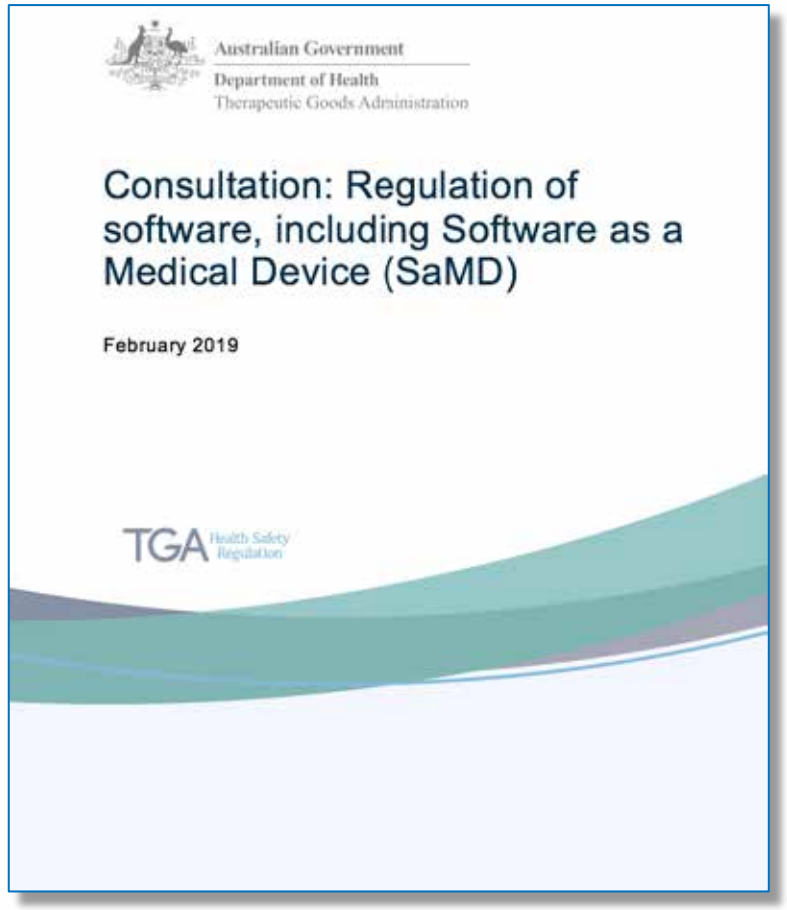
New Requirements in the USA



https://www.fda.gov/medicaldevices/digitalhealth/digitalhealthprecertprogram/default.htm#program

Proposed new requirements in Australia

- New rules to **appropriately classify SaMD products according to the potential harm they could cause to patients**
- **Exclude SaMD products from the personal importation provisions** so that SaMD products will be required to be included in the ARTG and have an Australian sponsor
- Ensure the **essential principles for medical devices include clear and transparent requirements for demonstrating the safety and performance of SaMD and other regulated software**.



https://www.tga.gov.au/consultation/consultation-regulation-software-including-software-medical-device-samd

Website references and contacts

Medical device regulation basics: http://www.tga.gov.au/medical-devices-regulation-basics

Regulation of Software as a Medical Device (SaMD): https://www.tga.gov.au/regulation-software-medical-device

Premarket medical device enquiries: devices@tga.gov.au

The TGA's Digital Devices team: digital.devices@tga.gov.au

For more on TGA visit……

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Youtube https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw

Questions?

Australian Government

Department of Health

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