# Webinar on the Essential Principles Consultation

**Jennie Robinson**

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Devices Reforms Taskforce

Therapeutic Goods Administration

# Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today.

# Welcome

## Housekeeping

This webinar is being recorded for data and analytics ONLY. Presentation slides will be made available in the upcoming weeks.

**Closed captions are available**

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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# Today’s webinar on the Essential Principles consultation

## Introduction

- How we got here
- Scope
- Our approach
- Benefits and potential impacts

## Panel discussion on the Essential Principles

- Pre-webinar submitted questions
- Open questions (Slido)

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# How we got here

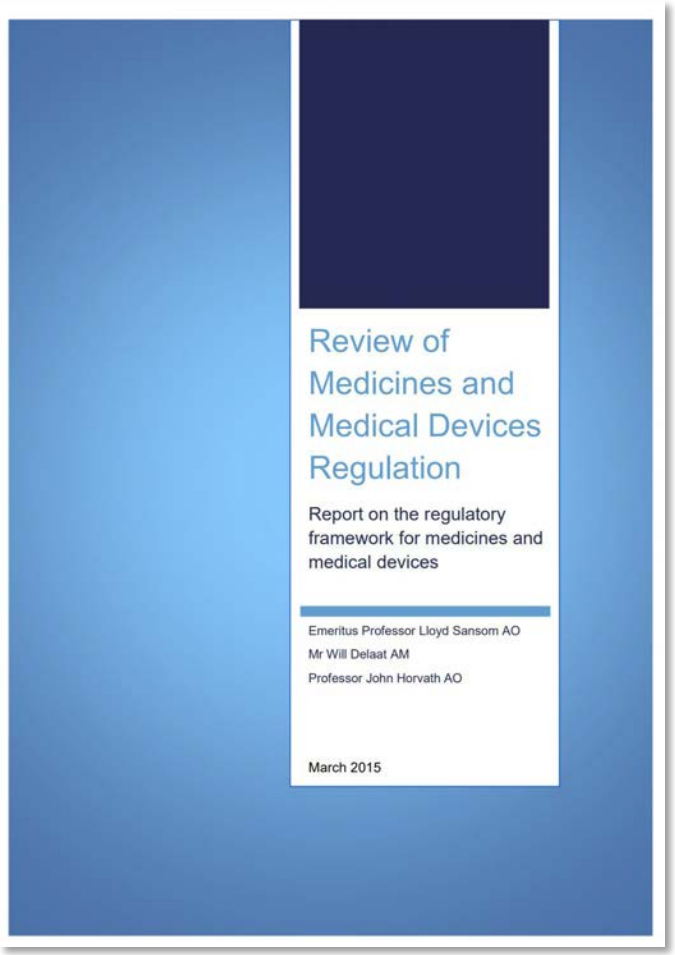
## Medical Devices Regulatory Frameworks: Australia vs Europe

### Historical similarity in regulatory frameworks

- Minor difference in:
  - Classification systems
  - Essential Principles/EU requirements

### Advantages of maintaining harmonisation

- Australia to remain as a desired global market
- Opportunities for Australian manufacturers in the global market



# How we got here

2015 Review of medicines & medical devices

- **Government accepted the recommendation to align wherever possible with the EU Regulations for:**
  - Essential Principles
  - Classification of medical devices
  - Risk-based approach to variations to medical devices

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**PART 1** 2019 EP Consultation

- Proposed alignment with the IMDRF ***and*** EU Regulations
- Feedback indicated strong support for alignment with the EU General Safety and Performance Requirements (GSPR)

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COVID

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**PART 2** 2024 EP Consultation

- Proposed alignment with the EU Regulations for medical devices (MDR) and in vitro diagnostic medical devices (IVDR)

# Scope of this consultation

**In scope**

- Essential Principles
- Alignment with the EU GSPRs
  - Add clarity
  - Introduce new requirements
  - Introduce new terminology
- Sponsor requirements
  - Regulation 10.2

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# Scope of this consultation

## Out of scope

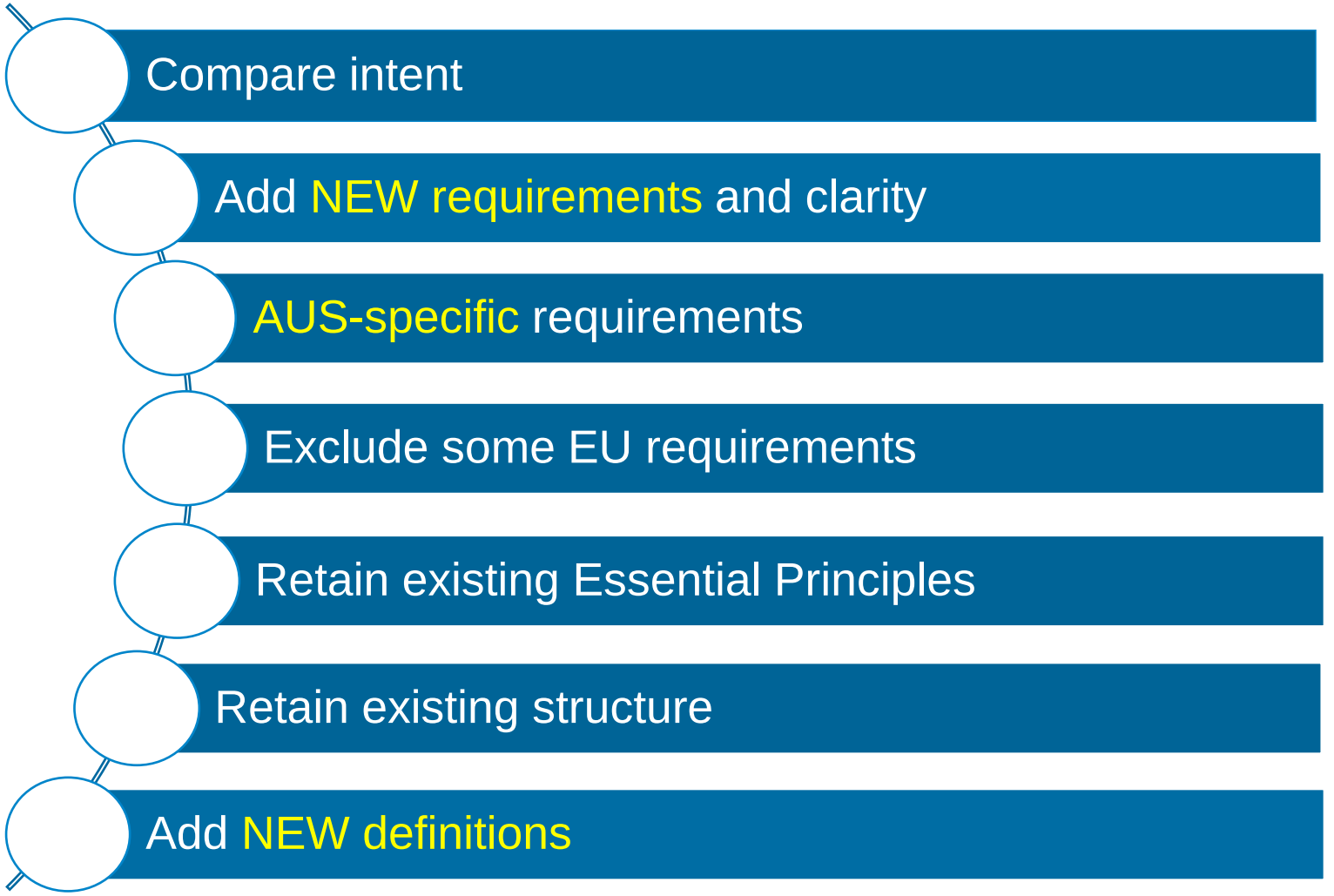
### Essential Principles related to ongoing reforms

- Unique device identification (UDI)
- Software as a medical device reforms
- Electronic IFU
- Devices with no specified therapeutic function (EU GSPR 9)

### Essential Principles with no equivalent EU GSPR

- AUS EP 14 – Clinical evidence
- AUS EP 13A – PICs/PILs

# Our approach to the proposed changes

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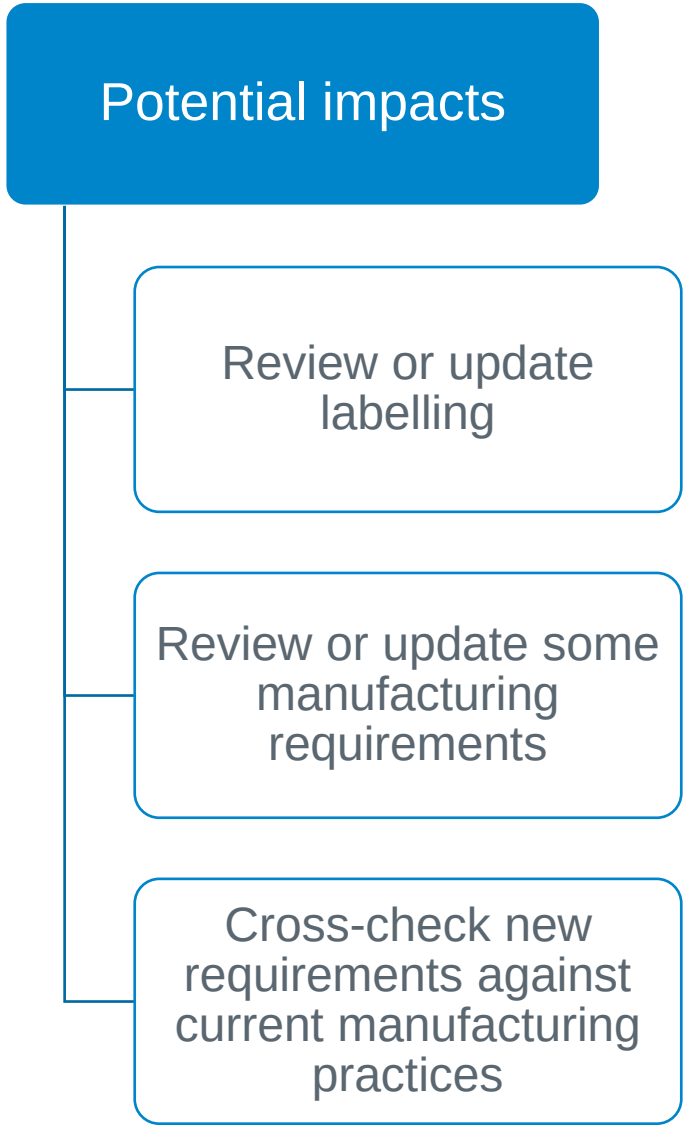
# Potential benefits of proposed changes

The purpose of regulation is to protect public health and safety.

- Improved safety and performance of medical devices
- Improved risk management for design and manufacture of devices throughout the life cycle
- Clarity on regulatory expectations for compliance
- Simplify regulatory compliance for medical devices that utilise European manufacturer evidence
- Simplify regulatory compliance for Australian manufacturers wanting to export to Europe

# Potential impacts of proposed changes

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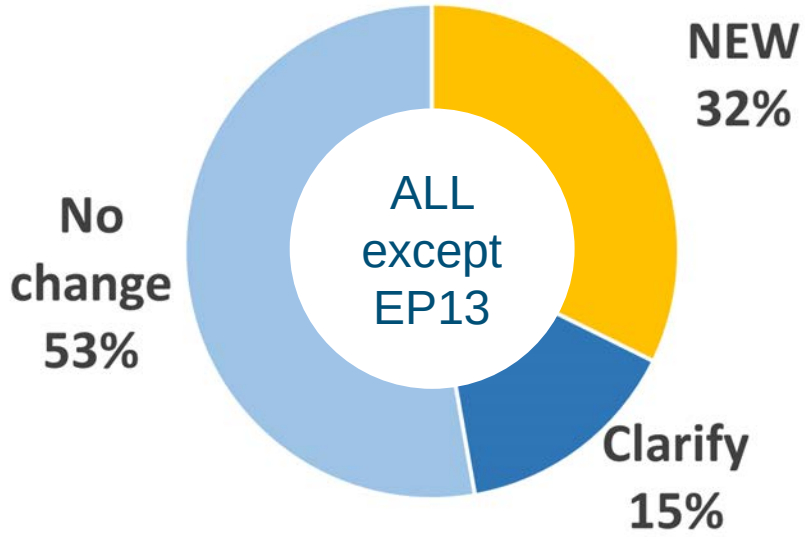
# Potential impacts of proposed changes

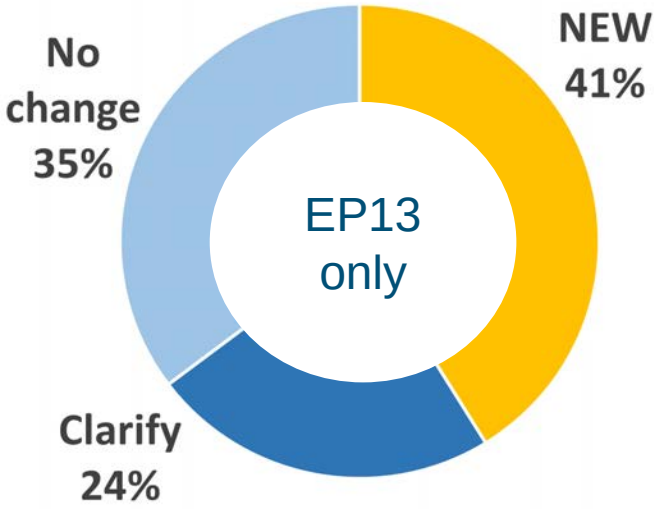
**Potential impacts**

- Review or update labelling
- Review or update some manufacturing requirements
- Cross-check new requirements against current manufacturing practices

## Degree of impact

| Which EPs apply to a device | Type of changes proposed |
|---|---|
| EP | New requirement |
| EP | Clarity |
| EP | |



# Mitigating potential impacts

## Proposed transitional arrangements for any adopted changes

**New ARTG entry** → 4-year transition

**Existing ARTG entry** → 6-year transition

- The transition periods would apply from the date any amendment takes effect.
- Existing ARTG entries will not have to reapply but would need to comply with any revised Essential Principles by the end of the transition period.

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# Mitigating potential impacts

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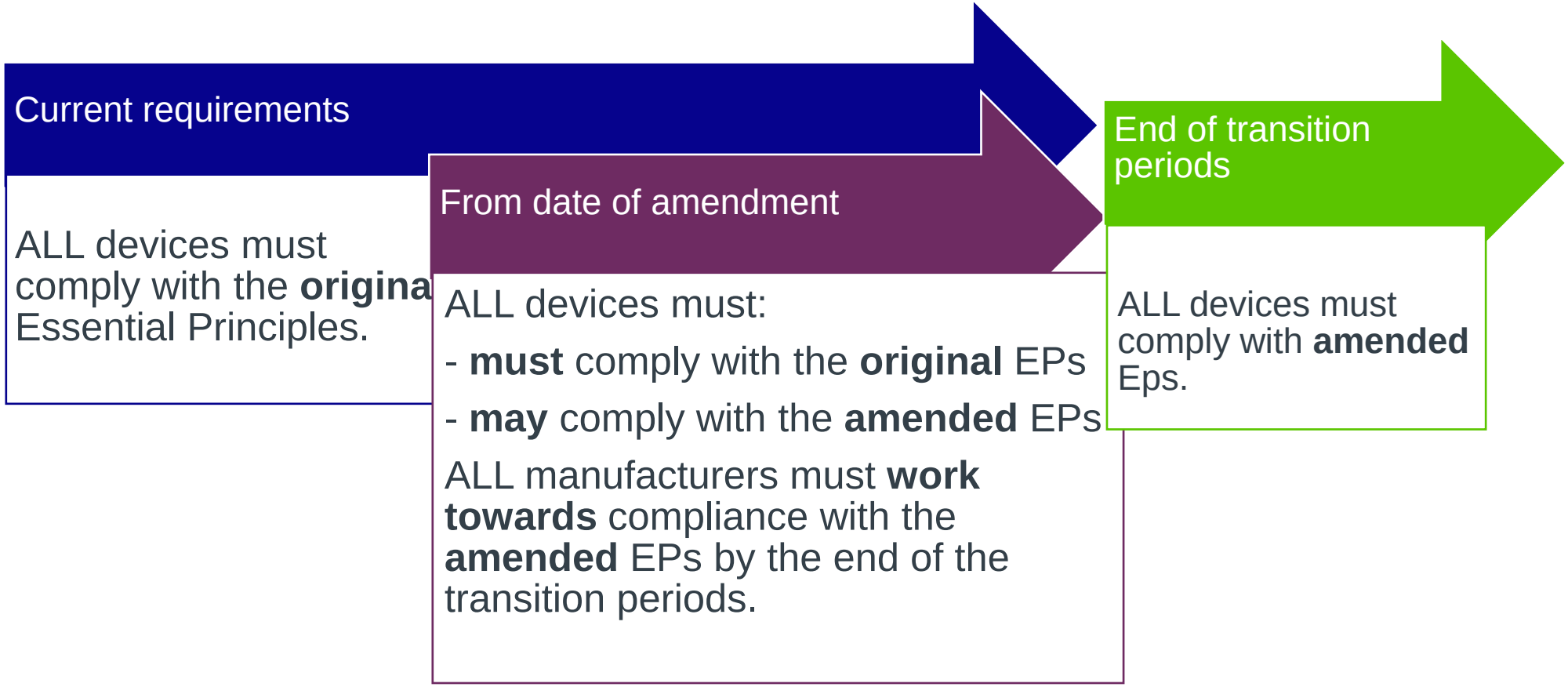


## Additional support through education and guidance

# Exempt devices – Regulatory obligations

## Market authorisation

**s41HA:** Devices exempt from inclusion in the Register

**Exempt from**: Division 3 of Part 4-11 of the Act

Listed in Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*

## Ongoing responsibilities

- Comply with all relevant Essential Principles
- Comply with any relevant conformity assessment procedures
- Comply with the Advertising Code
- Report adverse events
- Conduct recall actions through the URPTG

https://www.tga.gov.au/resources/resource/guidance/regulatory-obligation-exempt-medical-devices

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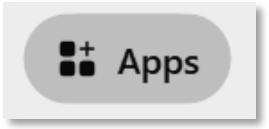
# How did we go?

Take a moment to complete our survey

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# Questions?

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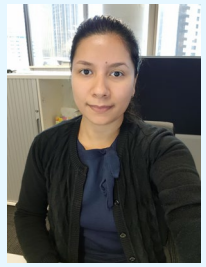
## Device Reform Taskforce TGA



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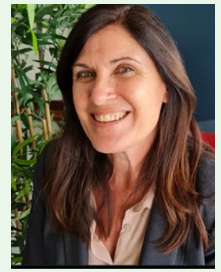
**Director**

**Susan Barker**
**Director**

## Medical Device Surveillance Branch TGA



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**Director**
**Devices Post Market Review Section**

## Medical Device Authorisation Branch TGA

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**Device Application and Triage Section**

**Jane Shum**
**A/g Director**
**Medical Device Authorisation Executive Section**

**Claudio Mastronardi**
**Evaluator**
**Devices in vitro Diagnostic Section**

**Christine Gee**
**Medical Officer**
**Devices Clinical Evaluation Section**

# Useful information and resources

| | |
|---|---|
| Regulatory obligation of exempt medical devices | https://www.tga.gov.au/resources/resource/guidance/regulatory-obligation-exempt-medical-devices |
| Disinfectants, sterilants and sanitary products | https://www.tga.gov.au/resources/resource/guidance/disinfectants-sterilants-and-sanitary-products |
| Personalised medical devices (and adaptable medical devices) | https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/manufacture-specific-types-medical-devices/personalised-medical-devices |
| Review of Medicines and Medical devices Regulation, March 2015 | https://oia.pmc.gov.au/sites/default/files/posts/2020/10/independent_review_-_review_of_medicines_and_medical_devices_regulation_-_stage_one_report_0.pdf |
| Australian Government Response to the Review of Medicines and Medical Devices Regulation, May 2016 | https://www.health.gov.au/sites/default/files/response-review-of-medicines-and-medical-devices-regulation.pdf |

# Contact us

**Device Reforms Taskforce**

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