# Reclassification of some medical devices

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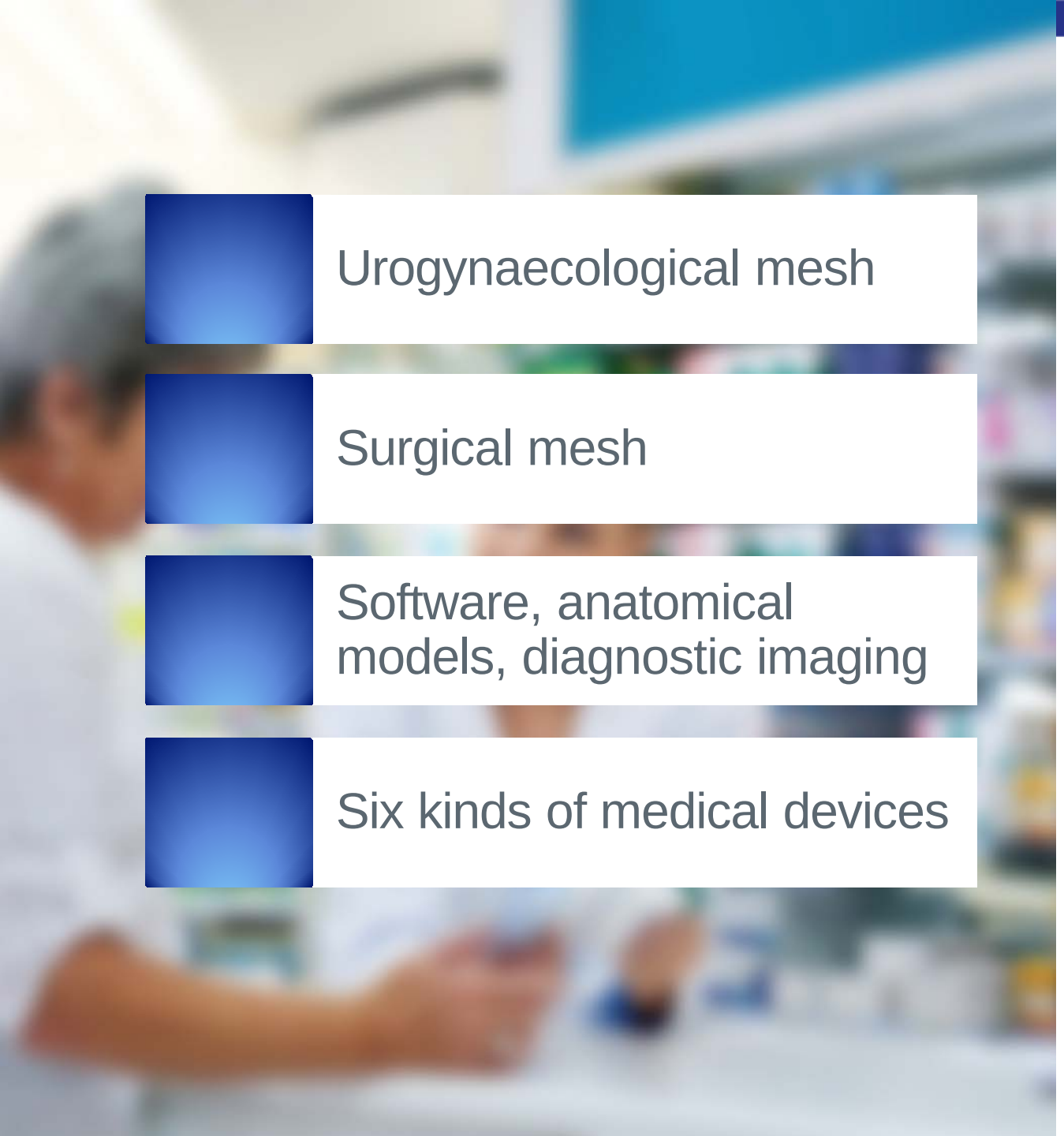


- Urogynaecological mesh
- Surgical mesh
- Software, anatomical models, diagnostic imaging
- Six kinds of medical devices

# Several new and amended classification rules

# Software, anatomical models, and diagnostic imaging

01 Provides a diagnosis or screen for a disease or condition

02 Monitor the state, progression, or parameters of a disease or condition

03 Specify or recommend a treatment or intervention

04 Provide therapy through the provision of information

05 Record patient images using energy outside the visible spectrum, used in diagnosis or monitoring of disease or condition

06 Virtual or physical anatomical models, or software used to generate the virtual models, used in diagnosis or monitoring of disease or condition

# When is software a medical device?

## *Intended purpose is critical…*

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, cloud portal …)

# Clinical decision support software

## Exemption under particular requirements:

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

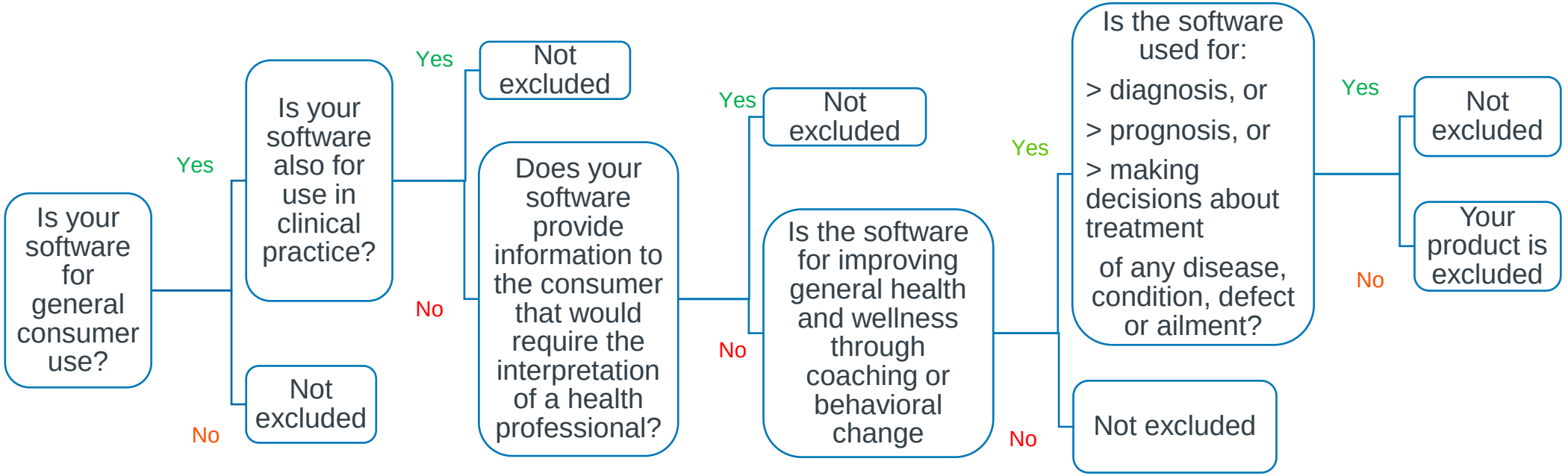
c) not intended by its manufacturer to replace the clinical judgement of a health professional in relation to making a clinical diagnosis or decision about the treatment of patients

Sponsors/suppliers **must** notify the TGA of their exempt CDSS devices using the Notification form: Clinical decision support software exemption

Note: must meet all 3 criteria

# Excluded software

## Exclusions are conditional:

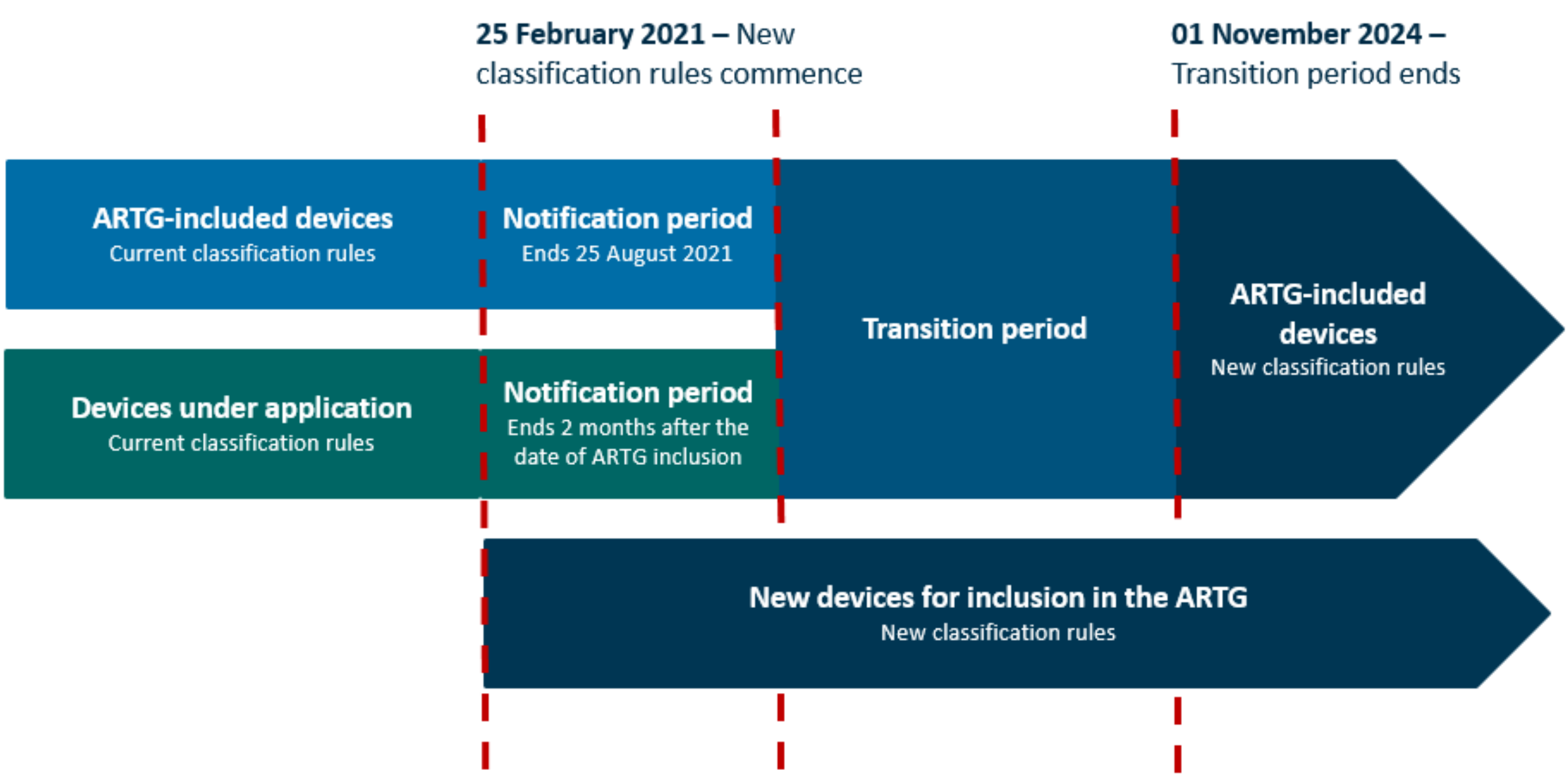



**Examples of excluded software:**

A ‘sun smart’ app that gives user alerts for UV protection to minimise skin cancer risk.

**Examples of software that is not excluded:**

A smartphone app intended to provide a direction to adjust the dosage of a prescribed medication.


25 February 2021 – New classification rules commence
01 November 2024 – Transition period ends
ARTG-included devices
Current classification rules
Notification period
Ends 25 August 2021
Transition period
ARTG-included devices
New classification rules
Devices under application
Current classification rules
Notification period
Ends 2 months after the date of ARTG inclusion
New devices for inclusion in the ARTG
New classification rules

# Reclassification of certain medical devices

01 Spinal Implantable medical devices

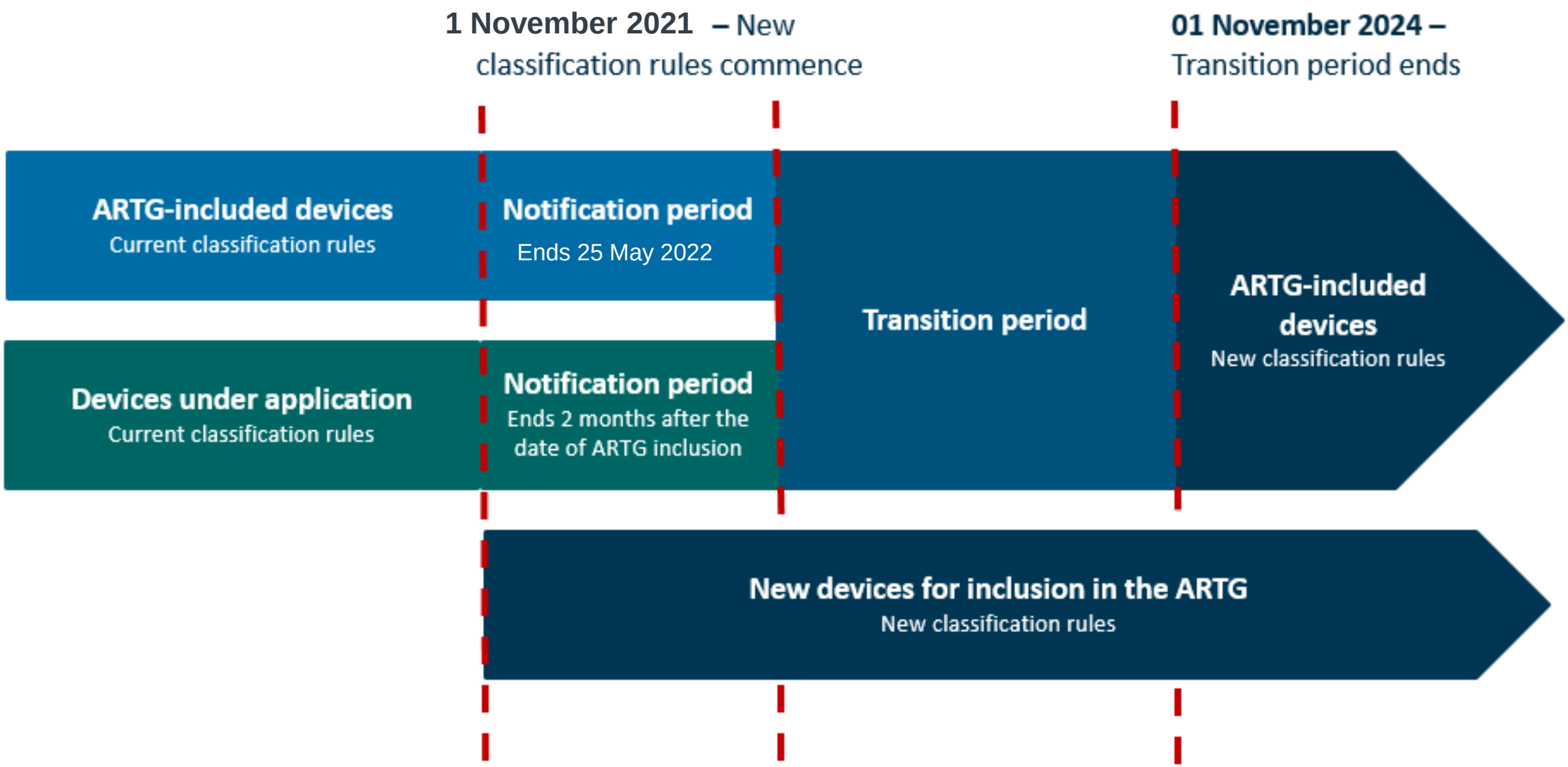
02 Active Implantable medical devices (AIMD)

03 MD administer medicines or biologicals by inhalation

04 MD substances for introduction into body via body orifice or applied to the skin

05 Active medical devices for therapy with diagnostic function

06 MD in direct contact with the heart, CCS, or CNS


1 November 2021 – New classification rules commence
01 November 2024 – Transition period ends
ARTG-included devices
Current classification rules
Notification period
Ends 25 May 2022
Transition period
ARTG-included devices
New classification rules
Devices under application
Current classification rules
Notification period
Ends 2 months after the date of ARTG inclusion
New devices for inclusion in the ARTG
New classification rules

# EU MDR Transition Extension

The European Parliament agreed the following key elements:

- extend the transition for qualifying medical devices from 26 May 2024 to:
  - 26 May 2026 for class III implantable custom-made devices
  - 31 December 2027 for class III and implantable class IIb devices
  - 31 December 2028 for non-implantable class IIb and lower risk devices
- remove the “sell-off” deadline of 25 May 2025 from the MDR and IVDR.

# Spinal Implantable Medical Devices

https://www.tga.gov.au/resource/reclassification-spinal-implantable-medical-devices

**Old classification**
**Class IIb**

**New Classification**
**Class III**

## Schedule 2 Part 3 Classification rule 3.4 (4B)

**3.4 Surgically invasive medical devices intended for long term use and implantable medical devices**

- (4B) If the device is intended by the manufacturer to be a motion preserving device for the spine (such as a spinal disc replacement), the device is classified as Class III.

## Review snapshot

36 GMDNs in the review – 9 additional GMDNs identified through notifications

# Active Implantable Medical Devices (AIMD)

https://www.tga.gov.au/resource/reclassification-active-implantable-medical-devices-aimd

**Old classification**
**AIMD**

**New Classification**
**Class III**

## Schedule 2 Part 5 Classification rule 5.7

**5.7 Active implantable medical devices**

(1) An active implantable medical device is classified as Class III.

(2) An implantable accessory to an active implantable medical device is classified as Class III.

(3) An active medical device that is intended by the manufacturer to be used to control or monitor, or directly influence, the performance of an active implantable medical device is classified as Class III.

## Review snapshot

All candidates notified and are transitioning

# Medical Devices that administer medicines or biologicals by inhalation

https://www.tga.gov.au/resource/reclassification-medical-devices-administer-medicines-or-biologicals-inhalation

**Old classification**
**Class I or IIa**

**New Classification**
**Class IIa or Class IIb**

## Schedule 2 Part 5 Classification rule 5.10

**5.10 Medical devices that administer medicines or biologicals by inhalation**

If a medical device is intended to be used to administer medicines or biologicals by inhalation:

(a) if the mode of action of the device has an essential impact on the efficacy and safety of the medicines or biologicals—the device is classified as Class IIb; or

(b) if the device is intended to treat a life threatening condition—the device is classified as Class IIb; or

(c) if paragraphs (a) and (b) do not apply—the device is classified as Class IIa

## Review snapshot

109 GMDNs in the review – 51 additional GMDNs identified through notifications

# MD that are substances for introduction into body via body orifice or applied to the skin

https://www.tga.gov.au/resource/reclassification-medical-devices-are-substances-introduced-human-body-body-orifice-or-applied-skin

**Old classification**
**Class I or IIa**

**New Classification**
**Class IIa, Class IIb**

## Schedule 2 Part 5 Classification rule 5.11

**5.11 Medical devices that are substances to be introduced into the body or applied to and absorbed by the skin**

If a medical device is composed of substances, or combinations of substances, that are intended to be:

(a) introduced into the human body through a body orifice; or

(b) applied to and absorbed by the skin;

the device is classified as follows:

(c) if the device is introduced into the nasal or oral cavity as far as the pharynx, or is applied to and absorbed by the skin, and achieves its intended purpose in that cavity or on the skin—Class IIa;

(d) in any other case—Class IIb.

## Review snapshot

95 GMDNs in the review – 54 additional GMDNs identified through notifications

# Active medical devices for therapy with diagnostic function

https://www.tga.gov.au/resource/reclassification-active-medical-devices-therapy-diagnostic-function

**Old classification**
**Class IIa or Class IIb**

**New Classification**
**Class III**

## Schedule 2 Part 4 subclause 4.2(4)

**Subclause 4.2(4):**

(4) An active medical device for therapy that includes a diagnostic function the purpose of which is to significantly determine patient management by the device is classified as Class III.

## Review snapshot

29 GMDNs in the review – 71 additional GMDNs identified through notifications

# Medical Devices in direct contact with the heart, CCS or CNS

https://www.tga.gov.au/resource/reclassification-active-implantable-medical-devices-aimd

**Old classification**
**Class IIa**

**New Classification**
**Class III**

## Schedule 2 Part 3 subclauses 3.2 and 3.3

**Subclause 3.2(3A):**

(3A) If the device is not a reusable surgical instrument and the device is intended by the manufacturer specifically to be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient, the device is classified as Class III.

**Subclause 3.3(4)(b):**

(4) If the device is intended by the manufacturer:

… (b) specifically, to be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient;

… the device is classified as Class III

## Review snapshot

79 GMDNs in the review – 61 additional GMDNs identified through notifications

# NEXT STEPS…..

## Non-transitioning devices

Assess non-transitioning devices - s41JAs

**Affected:**

* Monitor / assess potential supply issues
* Provide feedback on classification rule - sponsors requested to cancel their entry and cease supply until they have an approved inclusion at the higher classification.
* Alternatively, TGA can cancel the affected non-transitioning devices

**Not affected:**

Provide feedback and confirm no need to reclassify
Close out of the review

# NEXT STEPS…..

## Transitioning devices

- Reminders to be sent for reclassification applications
- Previous ARTG entries cancelled after a decision is made on applications for the higher classification
- Cancellation of devices that fail to submit application for correct class by 1 Nov 24
- Communication with stakeholders including state and territory health departments, Prothesis List, etc
- Monitor / assess potential supply issues

# Website references

| | |
|---|---|
| TGA website | www.tga.gov.au |
| Notification form: Clinical decision support software exemption | https://consultations.health.gov.au/medical-devices-and-product-quality-division/clinical-decision-support-exemption/ |
| Reclassification of spinal implantable medical devices | https://www.tga.gov.au/resource/reclassification-spinal-implantable-medical-devices |
| Active Implantable Medical Devices (AIMD) | https://www.tga.gov.au/resource/reclassification-active-implantable-medical-devices-aimd |
| Medical Devices that administer medicines or biologicals by inhalation | https://www.tga.gov.au/resource/reclassification-medical-devices-administer-medicines-or-biologicals-inhalation |
| MD that are substances for introduction into body via body orifice or applied to the skin | https://www.tga.gov.au/resource/reclassification-medical-devices-are-substances-introduced-human-body-body-orifice-or-applied-skin |
| Active medical devices for therapy with diagnostic function | https://www.tga.gov.au/resource/reclassification-active-medical-devices-therapy-diagnostic-function |
| Medical Devices in direct contact with the heart, CCS or CNS | https://www.tga.gov.au/resource/reclassification-active-implantable-medical-devices-aimd |

# Therapeutic Goods Administration (TGA)

## Exhibition booth **No.1**

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# Questions?

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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration