Australian Government
Department of Health
Therapeutic Goods Administration

Examples of regulated and unregulated software (excluded) software based medical devices

Version 1.3, October 2021

TGA Health Safety Regulation

The purpose of this guidance is to help manufacturers and sponsors understand how the TGA interprets requirements, and thus indicate how manufacturers and sponsors can comply.

This is a guide only, and manufacturers and sponsors are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia, and if necessary, to seek professional advice. It is the responsibility of each manufacturer or sponsor to understand and comply with these requirements.

Contents

About this guidance

This document presents examples that illustrate the boundaries between regulated and unregulated software.

The process to determine if a software product is a regulated medical device is explained in a separate document Is my software regulated?

Regulatory changes for software

Recent reforms have been implemented to clarify the requirements for regulated software based medical devices, including introducing a number of exclusions and exemptions for specific types of software products.

Excluded products are not medical devices and are not subject to any TGA regulatory requirements. Excluded products do not need to be included in the Australian Register of Therapeutic Goods (ARTG). It is important to note that not all software that is not a medical device is described by an exclusion (i.e., specified in an excluded goods order). The intent of an excluded goods order is to clarify the TGA's position on the regulation of certain products. If your product is not specified in an excluded goods order you still need to consider whether it meets the definition of a medical device. If your product does not meet the legislated definition of a medical device, it is not a medical device, and is not subject to any TGA regulatory requirements.

An exemption has also been introduced for some clinical decision support software (CDSS). **Exempt** software is a medical device but is not subject to all regulatory requirements. The exemption can be found in Part 2 of Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Depending on the intended purpose and functionality, the CDSS will be:

1. A medical device, and either:
   - Exempt (some regulatory requirements apply); or
   - Not Exempt (all applicable regulatory requirements apply); or
2. Not a medical device. It is possible for a CDSS to be excluded if it meets the criteria for any of the exclusions

If a CDSS is **not** a medical device (either does not meet the definition of a medical device or is excluded), you do not need to determine if it is exempt, as it is not subject to any TGA regulatory requirements.

Further detail on the exemption, including which products are covered, and which requirements still apply can be found in the guidance for Clinical Decision Support Software.

Walkthrough examples

There are two determinations that must be made to establish which software products are regulated as a medical device, and those which are not:

Is the software intended to be used for a medical purpose?

This will determine if the product meets the definition of a medical device (as per section 41BD of the Therapeutic Goods Act (1989):

Definition of a medical device:

- Diagnosis, monitoring, prediction, prognosis, treatment or alleviation of disease, injury or disability
- Prevention of disease
- Compensation for an injury or disability
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
- Control or support of conception
- Is an accessory to a medical device (something specifically intended to be used together with a medical device to enable that device to function as intended)

Does the software meet the exclusion criteria?

Some software has been excluded from regulation by the TGA when limited to performing only certain functions. The *Therapeutic Goods (Excluded Goods) Determination 2018* is the legislative instrument that describes these exclusions.

For the purposes of these exclusions, 'serious' is has the meaning defined in the *Therapeutic Goods (medical Devices) Regulations 2002*:

serious, for a condition, ailment or defect, means a condition, ailment or defect that is:

a. generally accepted as not being appropriate to be diagnosed or treated without consulting a medical practitioner, dentist or other kind of health care worker registered under a law of a State or Territory; or

b. generally accepted to be beyond the ability of the average person to evaluate accurately, or treat safely, without supervision by a medical practitioner, dentist or other kind of health care worker registered under a law of a State or Territory.

serious disease means a disease that:

a. may result in death or long-term disability; and

b. may be incurable or require major therapeutic interventions; and

c. must be diagnosed accurately, to mitigate the public health impact of the disease.

Software **is excluded** if it meets the exclusion criteria which means it is limited to performing the following functions:

Consumer health life-cycle prevention, management and follow up:

- Software intended for self-management of an existing disease or condition that is not serious (without providing specific treatment or treatment suggestions).
- Consumer health and wellness products (may be software or a combination of non-invasive hardware and software or wearables), that do not make claims about serious diseases or conditions.
- Behavioural change or coaching software intended to be used to improve general health or wellness factors (such as weight, exercise, sun exposure or dietary intake) that does not provide information to the consumer that would generally be accepted to require the interpretation of a health professional.
- PROMs (patient recorded outcome measures) and patient surveys (including those that form part of an electronic health record).
- Digital mental health tools (including a cognitive behaviour therapy tool) based on established clinical practice guidelines that are referenced and displayed in the software.

Enabling technology for telehealth, health care facility management

- Communication software that enables telehealth consultations, including the transmission of patient information, for the purposes of supporting the delivery of health services.
- Software intended to administer or manage health processes or facilities, rather than patient clinical use cases.
- Systems that are intended only to store or transmit patient images.
- Software intended to provide alerts or additional information to health professionals in relation to patient care. The health professional can exercise their own judgement in determining whether to action the alert or information.
- Software embedded in delivery of health services (clinical workflow management software).
- Middleware that does not control IVD instruments or medical devices and does not recommend a diagnosis or make treatment decisions.

Digitisation of paper based or other published clinical rules or data:

- Simple calculators that use relevant published clinical standards or authoritative sources to make calculations or display calculations and outputs so they may be validated by the user, but do not control the administration of a calculated dosage.
- Electronic Patient Records (EMRs) and Electronic Health Records (EHRs) that use relevant published clinical standards or authoritative sources to make calculations or display calculations and outputs so they may be validated by the user, but do not control the administration of a calculated dosage.

Population based analytics:

- Data analytics that are for the collection and analysis of class, group or population data that are not intended to be used for clinical use cases for individuals.

Laboratory information management systems (LIMS) and Laboratory information systems (LIS)

- LIMS that are not intended to manipulate information or data to generate new, diagnostic outputs (other than automating simple calculations or generating report comments).

The following examples illustrate the decision process followed to determine which software products are regulated as a medical device, and those which are not.

Example 1: Kilojoule counter

A smartphone app intended to inform users of the energy content of foods. The app enables a user to scan a product barcode in the store and receive information on the energy content of the product.

Is the intended purpose of this app likely to be medical?

No - the software is not intended to be used for any of the medical purposes listed in the table on page 5.

Therefore, this software is **not a medical device and is not regulated by TGA**.

Example 2: Software for tracking health information

Software intended to provide the user with tools to self-manage their eczema and monitor the severity and extent through analysis of images and user entered data.

Is the intended purpose of this software likely to be medical?

Yes - the software is intended to be used for monitoring and management of eczema.

Does the software meet any of the exclusion criteria?

Yes – the software is intended to be used for self-management of an existing condition that is not serious (without providing specific treatment or treatment suggestions).

Therefore, this software **is excluded and is not regulated by TGA**.

Example 3: Software that is used to diagnose hypertension and risk of cardiac disease

A software tool intended to track a user's health information, including blood pressure. The software analyses the information in order to provide a diagnosis of hypertension and risk of cardiac disease.

Is the intended purpose of this software likely to be medical?

Yes - the software is intended to be used to diagnose and predict disease (hypertension and predict risk of cardiac disease).

Does the software meet the exclusion criteria?

No - this software does not meet the exclusion criteria since it is intended to diagnose a serious condition i.e. hypertension.

Therefore, the software **is a medical device and must be included in the ARTG**.

Example 4: Software that controls an insulin pump

Software that calculates an insulin bolus based on readings from a blood glucose meter. The software controls an insulin pump to deliver the calculated dose.

Is the intended purpose of this software likely to be medical?

Yes - the software is intended to be used in the treatment of a disease, and to directly control a medical device.

Does the software meet the exclusion criteria?

No - this software does not meet any of the exclusion criteria as it is intended to manage a serious disease (i.e., diabetes) and provide treatment.

Therefore, this software **is a medical device and must be included in the ARTG**.

Examples of excluded software

Note: the use of AI technology in software will not directly dictate whether it is excluded. The intended purpose of the software will determine if the product is in scope of regulation or not. Software that is intended to automate diagnosis, treatment decisions, or otherwise replace the judgment of a health professional, is unlikely to be excluded.

The following are examples of excluded software:

- A consumer health and wellness product not intended to manage serious conditions, such as a wearable that allows the wearer to track their heart rate for fitness.
- Behavioural change or coaching software for improving general health parameters (for example weight, exercise, salt intake), such as a 'sun smart' app that gives user alerts for UV protection to minimise skin cancer risk.
- Patient recorded outcome measures (PROMs) and patient surveys (including those that form part of an electronic health record). For example, an app that digitises an established PROM questionnaire to assess the quality of life of a patient undergoing cancer treatment, similar to a paper-based version.
- Software that replicates paper-based mental health assessments in electronic format. The information must be from authoritative medical sources, as recognised by the relevant field or discipline, and must be cited in the software. The results can be independently reviewed by a health professional.
- Communication software that enables telehealth consultations or supports a clinician in making a remote diagnosis, such as:
  - Software intended to facilitate a video conference with a medical practitioner, with a waiting room facility.
  - Software that communicates information from a health professional to their patient, for example, non-urgent (i.e. not requiring immediate action) test results.
- Software intended to administer or manage health processes or facilities, rather than patient clinical use cases. This includes software for the processing of financial records, claims, billing, appointment schedules, business analytics, admissions, practice and inventory management, utilisation, cost effectiveness, health benefit eligibility, population health management, and workflow.

- Medical image storage and retrieval software, or software that facilitates the communication or transfer of medical images between devices.
- Software intended to be used by health professionals to provide alerts or additional information. The health professional can exercise their own judgement in determining whether to action the alert or information. For example, pharmacy dispensing systems and prescribing software used by GPs – these are not intended to be used by laypeople and are not making decisions.
- Software embedded in delivery of health services such as clinical workflow and support systems that display medical information about a patient or peer-reviewed clinical studies and clinical-practice guidelines.
- Chat-based triage software intended to guide users to the most appropriate form of help based on their medical symptoms.
- Laboratory software that facilitates the electronic transfer of data between medical devices. The software does not control a medical device, or analyse the data transferred in any way.
- Software that calculates a drug dosage based on the dose information provided on that drug's label. The user enters the calculation parameters (e.g., age, gender, weight) and can independently review the calculation.
- Electronic Patient Records (EMRs) and Electronic Health Records (EHRs). A suite of software used to electronically receive, collect, store, manage, display, output, and distribute data, within or between healthcare facilities, to support the electronic registration and documentation of patient clinical data. The software enables healthcare providers to review and update patient medical records, place orders (e.g., for medications, procedures, tests.
- Data analytics that are class- or group-based rather than individual patient-based. For example, software that performs an analysis on a population who are asked via email reminders to report via a website on fever, cough, days off work, and vaccination status. The results are used to generate population statistics and track infections, which may be of use in studying and controlling epidemics. The information is not used to inform interventions for any of the individuals involved.
- Laboratory information management systems (LIMS) and Laboratory information systems (LIS) such as software that allows a laboratory to automate workflows, integrate instruments, and manage samples and associated information, through to delivery of a report. Such report accurately identifies the patient and shows the collected results of assays performed by the instruments but does not recommend a diagnosis or treatment.

Examples of regulated software

Software that is a regulated medical device is classified according to the level of harm it may pose to users or patients. There is a four-tier classification system for medical devices:

- Class I (lowest classification)
- Class IIa
- Class IIb
- Class III (highest classification)

The higher classification level the higher the level of regulatory oversight.

Medical devices are classified according to the medical device classification rules in Schedule 2 of the *Therapeutic Goods (medical Devices) Regulations 2002*.

Note these classification examples are for medical device software only and are not relevant to IVD medical device software. For guidance on IVD software, see Software as in vitro diagnostic medical devices (IVDs).

For further information on classifying software, see the guidance Regulatory changes for software based medical devices.

Class I

This is the lowest risk classification and corresponds to the lowest level of regulatory scrutiny.

Neural network for monitoring shingles

Software that consists of a deep learning neural network that monitors patient recovery from shingles (herpes zoster) using uploaded images of shingles rashes.

The product can be accessed by health professionals or consumers – allowing real-time monitoring of recovery with or without oversight from a health professional.

This software-based medical device is a **Class I** medical device as:

- it is intended to monitor the state or progression of a disease;
- the information provided does not indicate if an individual may be in danger;
- there is a low public health risk.

Other Class I examples

- Analytic app using aggregated population data for a particular condition to make inferences about the most appropriate treatment options for an individual with migraine headaches.

Class IIa

Class IIa medical devices are considered medium risk.

Diabetes diagnosis software

A computer program intended to provide information to a general practitioner (GP) for the purposes of aiding the GP to make a diagnosis of diabetes.

The software is intended to provide the diagnosis to a relevant health professional only. The instructions for use reflect the intended purpose and the software package is only sold to healthcare facilities for use by health professionals.

This software-based medical device is a **Class IIa** medical device as the device provides information to a relevant health professional to inform the diagnosis of a **serious disease**.

Other Class IIa examples

- Risk prediction software that analyses blood pressure information for a health practitioner to assist them in diagnosing hypertension and provides options for a management plan.

- Software that records and communicates readings from a patient monitor to allow the patient's condition to be monitored from a remote location (not intended to indicate if patient is in immediate danger or high public health risk).
- Software that records an image directly from an MRI scanner (does not directly control or influence the MRI scanner)

Class IIb

Class IIb medical devices are considered medium-high risk.

Cardiac MRI analyser

Software that performs an analysis of a cardiac MRI, then provides information intended to be used to make a diagnosis of aortic valve stenosis.

The software is intended to provide the diagnosis to a relevant health professional only. The instructions for use reflect the intended purpose and the software package is only sold to specialist healthcare facilities.

In this instance the software would be a **Class IIb** medical device as it is intended by the manufacturer (the software developer) to provide information to a relevant health professional to inform the diagnosis of a serious disease.

Diagnosis of acute arterial occlusion

Software that performs an analysis of an angiogram and provides this information to a relevant health professional (e.g. a vascular surgeon) to inform the diagnosis of acute arterial occlusion.

This software-based medical device is a **Class IIb** medical device as the device provides information to a health professional to inform the diagnosis of a disease that may lead to the death or a severe deterioration in the health of an individual without urgent treatment.

Recommendation of a treatment or intervention

Software intended to perform an analysis of a coronary angiogram and, based on the results of the analysis, provides a recommendation to a cardiac surgeon to perform coronary artery bypass grafting surgery.

This software is intended only to be used by a relevant health professional (e.g. a cardiac surgeon).

This software is a **Class IIb** medical device as it is:

- intended to recommend a treatment or intervention to a relevant health professional for the purposes of the health professional making a decision about the treatment or intervention;
- a case where the absence of this treatment, or the treatment itself, may lead to the death or a severe deterioration in health of an individual.

Other Class IIb examples

- A wearable that analyses the wearer's cardiac rhythm for the purpose of screening for a serious heart condition.

- A patient questionnaire app that analyses the responses using a novel, unpublished algorithm to predict the risk of depression or an anxiety disorder. The software provides a diagnostic output that the health professional would otherwise not have access to.

Class III

Class III medical devices are considered the highest risk and corresponds to the highest level of regulatory scrutiny.

Specifies a treatment or intervention

Software intended to perform an analysis of a consumer's coronary angiogram and, based on the results of the analysis, specifies coronary artery bypass grafting surgery as the appropriate treatment.

This software is a **Class III** medical device as it is:

- intended to *specify* a treatment or intervention (rather than *recommending* the intervention to a relevant health professional, for the purposes of that health professional making a decision about the treatment or intervention);
- a case where the absence of this treatment, or the treatment itself, may lead to the death or a severe deterioration in health of an individual.

Other Class III examples

- A consumer smart phone app that takes an image of a mole or lesion to screen for and detect malignant melanoma.
- Software for programming an implanted pacemaker.

Excluded software versus regulated software

This section shows examples of products that are excluded, each contrasted with an example of a similar product that remains regulated as it does not meet the conditions of exclusion.

Note:

- These examples are not exhaustive, and there may be other products that are captured by these exclusions.
- Some products may fit into one or more of these exclusions.
- Not all software that is not a medical device is described by an exclusion. You should also check if your software meets the definition of a medical device.

Consumer health life-cycle prevention, management and follow up

	Examples of excluded products	Examples of products that remain regulated
Software intended for self-management of an existing disease or condition that is **not serious** (without providing specific treatment or treatment suggestions).	Software tool to self-manage and monitor tinnitus. An app or wearable that monitors sleep and movement to assess and report on quality and quantity of sleep.	A software tool intended to track a user's health information. The software analyses the information using a novel algorithm to predict risk of diabetes. Software that monitors sleep and predicts risk of sleep apnoea.
Consumer health and wellness products (may be software or a combination of non-invasive hardware and software), which do not make claims about serious diseases or conditions.	A wearable that allows the wearer to track their heart rate for fitness. An app on a smartphone that measures a physiological function such as oxygen saturation and makes no claims about serious diseases or conditions. An app that records and tracks physiological measurements such as blood pressure, blood test results as part of a personal health record.	A wearable that analyses the wearer's cardiac rhythm for the purpose of screening for a serious heart condition (which may include atrial fibrillation, heart attack risk among others). An app on a phone or tablet that analyses blood pressure and diagnoses hypertension. An app that uses the microphone to analyse sounds for the purpose of monitoring or diagnosing asthma. An app that analyses temperature, movement or oxygen saturation to diagnose COVID risk.
Behavioural change or coaching software intended to be used to improve general health or wellness factors (such as weight, exercise, sun exposure or dietary intake) that does not provide information to the consumer that would generally be accepted to require the interpretation of a health professional.	A 'sun smart' app that gives user alerts for UV protection to minimise skin cancer risk. A cognitive behaviour therapy app based on established clinical practice guidelines that are referenced and displayed in the software in a manner that is reviewable by the user.	A smartphone app intended to provide a direction to adjust the dosage of a prescribed medication.

	Examples of excluded products	Examples of products that remain regulated
PROMs (patient recorded outcome measures) and patient surveys (including those that form part of an electronic health record).	An app that digitises an established PROM questionnaire (e.g. to assess the quality of life of a patient undergoing cancer treatment), similar to a paper-based version.	A patient questionnaire app that analyses the responses using a novel, unpublished algorithm to predict the risk of a certain cancer. The software provides a diagnostic output that the health professional would otherwise not have access to.

Digital Mental Health

	Examples of excluded products	Examples of products that remain regulated
Digital mental health tools (including a cognitive behaviour therapy tool) based on established clinical practice guidelines that are referenced and displayed in the software.	Software that replicates paper-based mental health assessments in electronic format. The information must be from authoritative medical sources, as recognised by the relevant field or discipline, and must be cited in the software. The results can be independently reviewed by a health professional. A cognitive behavioural therapy app based on widely accepted clinical practice guidelines that are referenced and displayed in the software in a manner that is reviewable by the user.	A smartphone app for treatment of anxiety that does not show the clinical guidelines on which the treatment is based. An internet-based service that uses a novel machine learning approach to diagnose severe depression from facial expressions and patient movement. Clinical trials have not yet been completed and there are no published guidelines as the approach is so new.

Enabling technology for telehealth, remote diagnosis, health care facility management

	Examples of excluded products	Examples of products that remain regulated
Communication software that enables telehealth consultations, including the transmission of patient information, for the purposes of supporting the delivery of health services.	Video conference with a medical practitioner, with a waiting room facility. Communication of information, for example, non-urgent test results.	Software that records and communicates readings from a patient monitor to allow the patient's condition to be actively monitored from a remote location. The software generates real-time feedback based on measured signals and generates alerts for the clinician if signals are outside an established range.
Software intended to administer or manage health processes or facilities, rather than patient clinical use cases.	Suite of software for the processing of financial records, claims, billing, appointment schedules, business analytics, admissions, practice and inventory management, utilisation, cost effectiveness, health benefit eligibility, population health management, and workflow.	
Systems that are intended only to store or transmit patient images.	Medical image storage and retrieval device, or medical image communication between devices.	Software that records an image directly from an MRI scanner. Software that analyses an MRI scan to screen for potential tumours.
Software intended to provide alerts or additional information to health professionals. The health professional can exercise their own judgement in determining whether to action the alert or information.	Pharmacy dispensing systems and prescribing software used by GPs – these are not intended to be used by laypeople and are not themselves acting as a de facto decision maker. Software module that provides alerts for adverse drug interactions based on established rules and guidelines.	

	Examples of excluded products	Examples of products that remain regulated
Software embedded in delivery of health services (clinical workflow management software).	Clinical workflow and support – including the display of medical information about a patient or peer-reviewed clinical studies and clinical-practice guidelines.	
Middleware that does not control IVD instruments or medical devices and does not recommend a diagnosis or make treatment decisions.	Laboratory software that facilitates the electronic transfer of data between medical devices. The software does not drive or influence a medical device, or analyse the data transferred in any way.	Software that operates an IVD medical device. Software that combines IVD results to calculate and report a result for clinical purposes. For example, software that interprets results from a first trimester screening assessment for foetal risk of trisomy 21.

Digitisation of paper based or other published clinical rules or data

	Examples of excluded products	Examples of products that remain regulated
Simple calculators that use relevant published clinical standards or authoritative sources to make calculations or display calculations and outputs so they may be validated by the user, but do not control the administration of a calculated dosage.	Software that calculates drug dosing based on a published clinical standard. The user inputs the parameters (e.g., age, gender, weight) and can independently review the calculation.	An automated insulin bolus calculator that controls the dose delivered by an insulin pump.

	Examples of excluded products	Examples of products that remain regulated
Electronic Patient Records (EMRs) and Electronic Health Records (EHRs) to be used in clinical practice by healthcare providers to collect, use, disclose and otherwise manage patient clinical data within or between healthcare facilities.	Receive, collect, store, manage, display, output, and distribute data, within or between healthcare facilities, to manage patient clinical data. It typically enables healthcare providers to review and update patient medical records, place orders (e.g., for medications, procedures, tests), and view data from many specialties. A software module included in an EMR that flags if an individual falls within an at-risk population based on established rules or guidelines (e.g. over 50 years of age at increased risk for bowel cancer).	A module integrated into an EMR that directly records readings from a patient monitor to allow the patient's condition to be monitored remotely. An app that connect to an EHR and analyses an individual's mammography data to automatically screen for breast cancer.

Population based analytics

	Examples of excluded products	Examples of products that remain regulated
Data analytics that are for the collection and analysis of class, group or population data that are not intended to be used for clinical use cases for individuals.	Analysis on a population who are asked via email reminders to report via a website on fever, cough, days off work, and vaccination status. The results are used to generate population statistics and track infections, which may be of use in studying and controlling epidemics. The information is not used to inform therapeutic interventions for any of the individuals involved.	Analytic app using aggregated population data for a particular condition to make inferences about the most appropriate treatment options for an individual Analytic app that extracts groups from an EHR database and combines data with other sources to identify high risk of a disease that leads to a direct therapeutic action for an individual.

Laboratory information management systems (LIMS) and Laboratory information systems (LIS)

	Examples of excluded products	Examples of products that remain regulated
LIMS that are not intended to manipulate information or data to generate new, diagnostic outputs (other than automating simple calculations or generating report comments).	Software that automates workflows, integrates instruments, manages samples, reports results of assays - but does not recommend a diagnosis or treatment. Software that allows for pathologists to annotate test results and create notes.	A LIMS software module that takes IVD results and generates new diagnostic data. See Software as in vitro diagnostic medical devices (IVDs) for more detail.

Clinical decision support software

Some clinical decision support software (CDSS) are not medical devices. These may be covered by the above exclusions, and others may not meet the definition of a medical device without being explicitly excluded.

Some CDSS are a medical device, and depending on the intended purpose and functionality, may be either:

- Exempt (some regulatory requirements apply); or
- Not Exempt (all applicable regulatory requirements apply).

Some software may have multiple functions, each with a distinct intended purpose. Some functions may be associated with a medical purpose, and some not. The boundaries of the functions which are subject to the *Therapeutic Goods (Medical Devices) Regulations 2002* should be clearly identified by the manufacturer, based on their intended purpose.

The following are examples of CDS software.

Not a medical device

Software that digitises a clinical guideline decision tree for stroke management. The software guides the health professional user through the steps of the process and prompts when a decision needs to be made by the user (the software does not recommend a decision). The software then presents the recommended management plan to the health professional, based on the decision selections made by that user. The software clearly references the clinical guideline as the basis for the recommendation and is not replacing the clinical judgement of the health professional.

This software is not a medical device, as it is digitising what was previously a paper-based resource through an interactive software interface. The health professional uses information about their patient to decide which path to proceed along the decision tree, and whether to use the resulting recommendation. The software does not allow the clinician to input individualised patient symptoms or test results, but rather provides yes/no prompts (e.g. 'is the patient conscious?').

Exempt medical device

Surgical workflow software that describes the steps of a surgical procedure to a surgeon. The software is based on an accepted clinical guideline and analyses an individual patient's test results to determine which steps of the surgery are or are not required. The software recommends a decision to the surgeon and the surgeon can choose to override the recommendations from the software.

This software is a medical device, as the software has gone beyond digitising the paper-based resource, as it automatically takes patient information and uses this to recommend actions to a health professional. The **software is exempt**, as it meets all three criteria:

- It does not take data directly from a medical device.
- It is intended only for the purpose of providing a recommendation to a health professional.
- It is not intended to replace the clinical judgement of a health professional, as it is based on information (the referenced clinical guideline) that can otherwise be verified.

Medical device (not exempt)

Radiation treatment planning software that takes patient images, and allows a healthcare professional to identify tumours, healthy tissues, and critical organs. The software calculates a plan for the delivery of radiation therapy, and the plan serves as input for medical linear accelerators in the treatment of cancer.

This is a medical device, as the software is for the treatment of a disease.

The **software is not exempt**, as:

- the software specifies a treatment output directly to a medical device.
- the software determines the specified treatment without input from the health professional.

Version history

Version	Description of change	Author	Effective date
Draft V1.0	Original draft	Devices Emerging Technology & Diagnostics Section	January 2021
Draft V1.1	Fixed link Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021 and Included link to Clinical decision support guidance	Devices Emerging Technology & Diagnostics Section	February 2021
V1.2	Update – finalise draft	Devices Emerging Technology & Diagnostics Section	August 2021
V1.3	Minor update	Devices Emerging Technology & Diagnostics Section	October 2021

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Reference/Publication #