

Application for consent for unapproved medical devices that are non-compliant with the Essential Principles



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Medical Devices Surveillance Branch
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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



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Slido

How to access and use Slido



Through the Slido application in Webex



- Click on the **Apps** icon
- Select **Slido**
- Open the **Q&A** tab to ask questions
- Live Poll (use survey tab when prompted)



Using the QR code



Scan the QR code to access Slido from your mobile device



Application for consent for unapproved medical devices that are non-compliant with the Essential Principles

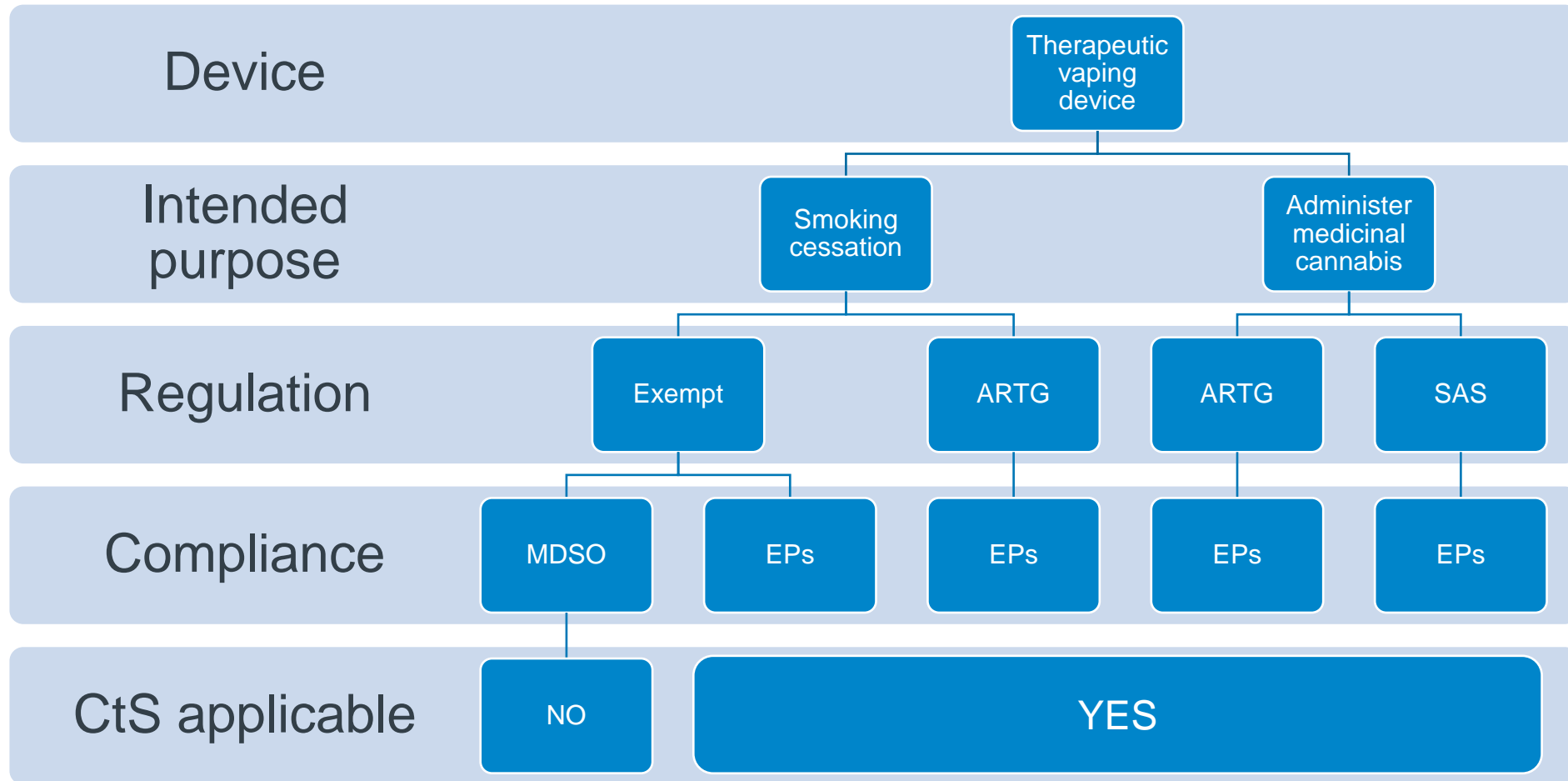


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When to apply for consent for non-compliance with the essential principles



Scope	Vaping device and device accessory including reusable vaping device, or an unfilled cartridge, capsule, pod, or other vessel for use in or with a reusable vaping device intended to administer a therapeutic vaping substance whose only purpose is for smoking cessation or the management of nicotine dependence.
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Pathways for nicotine substance:

[Application for consent to import, supply or export goods that do not comply with standards - section 14/14A](#)

Criminal offences under section 41MA and civil penalties under section 41MAA of the *Therapeutic Goods Act 1989* for importing, supplying, or exporting medical devices that do not meet the Essential Principles (EPs) unless consent has been granted by the Secretary of the Department of Health and Aged Care

- Applications for consent are considered on case to case basis
- Consent is granted for a limited time of period
- When there are no safety and performance concerns

Aim:

Guidance on how to apply for consent to import, supply or export medical devices that are not included in the ARTG and are non-compliant with the Essential Principles

Home > PMR Compliance Dashboard

PMR Compliance Dashboard

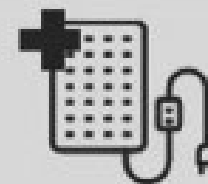
Services



Post Market
Reviews



Consent for Non-
compliance
Applications



Custom-made
Medical Devices
Notifications



[Home](#) > Consent for Non-compliance Dashboard

Consent for Non-compliance Dashboard

Please select a service below



New Application
for Consent for
Non-compliance


- Draft**
- Submitted
- Notifications

Reference Number ↓	Title	Created On	Modified On	
CTS-2025-01556	Application 01	07/01/2025 12:30 PM	13/01/2025 1:13 PM	<ul style="list-style-type: none">EditPreviewDelete
CTS-2024-01548	bbbb	10/12/2024 11:54 AM	10/12/2024 11:54 AM	
CTS-2024-01547	bty	26/11/2024 7:32 AM	26/11/2024 8:29 AM	
CTS-2024-01546	1039801 - Capitalisation	22/11/2024 6:26 AM	22/11/2024 6:29 AM	

Home > Consent for Non-compliance Dashboard

Consent for Non-compliance Dashboard





Please select a service below



New Application
for Consent for
Non-compliance

Draft **Submitted** Notifications

Reference Number	Title	Status	Created On	Modified On	Submitter	
CTS-2021-01053	test	Submitted	12/11/2021 9:28 AM	24/03/2022 9:00 AM	Amanda Craig	  View details Preview Withdraw application
CTS-2021-01058	20211112 1432 - J&J By Chin Perera (Imporeted)	Submitted	12/11/2021 2:02 PM	24/03/2022 9:00 AM	Tyrel Perera	
CTS-2021-01072	UAT 20211115 PBI Number: 161071 #3	Submitted	15/11/2021 2:44 PM	24/03/2022 9:00 AM	Jake Fernandez	
CTS-2022-01170	TEST_LUCY	Withdrawn	22/02/2022 12:32 PM	29/03/2022 3:49 PM	TESTCTS TESTNEW	

Please select a service below



New Application for Consent for Non-compliance

Draft

Submitted

Notifications

Notification ID	Application name	Notification type	Notification status	Response due date ↓	Received date	
CTS-2024-01535 - Imposing conditions on approval - 06	QA1111_01	Imposing conditions on approval	Completed	10/11/2025 11:30 PM	16/12/2024 8:29 AM	▼
CTS-2024-01544 - Imposing conditions on approval - 12	Consent Withdrawal	Imposing conditions on approval	Sent/Awaiting Response	18/03/2025 11:30 PM	23/12/2024 1:18 PM	▼
CTS-2022-01321 - Approved - 01	Suspension revocation_Response due hidden in portal	Consent approved	Sent/Awaiting Response	07/02/2025 7:30 AM	22/07/2022 11:39 AM	
CTS-2024-01516 - Approved - 01	Srini 2910 - Non ARTG	Consent approved	Sent/Awaiting Response	30/01/2025 11:30 PM	20/12/2024 8:39 AM	▼

▼

- Draft
- View details
- Preview



Questions are now open



Through the Slido application in Webex



- Click on the **Apps** icon
- Select **Slido**
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- Live Poll (use survey tab when prompted)



Using the QR code



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New Application
for Consent for
Non-compliance

New Application for Consent for Non-compliance

Provide a relevant name for your application. It will enable you to differentiate multiple applications over time. *

This application seeks consent for non-compliance for: *

- Device(s) included in the ARTG
- Device(s) included in Application(s) for Inclusion
- Device(s) NOT included in the ARTG or Application(s) for Inclusion

Select device category *

Select ▼

- Select
- Vaping device
- Other

Back

Create

Create application

Consent for Non-compliance Application Draft

Application 01

For guidance on how your information will be treated by the TGA see:
Treatment of the information provided to the TGA at <https://www.tga.gov.au/privacy>

i **Are your correspondence details up to date?**
To update your correspondence details (postal, email, phone or mobile), please email the Therapeutic Business Service (TBS) at ebs@health.gov.au or contact your account administrator. Please see [Questions and Answers for Administrators](#) for more information.

Expand All

Collapse All

Application details !

-

Non-compliant Essential Principles !

+

Device groups !

-

Declaration !

+

Back

Save

Application details 

Reference number

CTS-2025-01556

If you would like to change the name of this application, you can do so in the field below. *

Application 01

Sponsor *

Johnson & Johnson Pacific Pty LTD

This application seeks consent for non-compliance for:

Device(s) NOT included in the ARTG or Application(s) for Inclusion

Device category

Vaping device

Are you seeking consent for your device(s) to be: *

Select one or more application type(s) from the list below.

Imported?

Exported?

Supplied?



What is the reason for not conforming to the Essential Principle(s)? *

Select



Select

Is this a result of EU MDR implementation?

Is this a result of EU IVD R implementation?

Is this a result of Australian Regulation changes?

Other

What are the real or potential risks associated with the non-conformance if the non-conforming device(s) were to be imported, exported or supplied? *

Please type your answer in box provided or upload a document by using the "add files" button. If you are providing your explanation in an attached document, please write "document attached" in the box below.

Documents attached

Before uploading supporting documentation, please check that folders have been created. To provide supporting documentation, please click the 'Add files' button or click on the relevant folder.

Sometimes there is a delay in creating the folders. If they do not appear after a few minutes or refreshing the page, refer to the guidance document for some quick trouble shooting.

Documents uploaded before folders have been created will not be included in your submission.

Add files

Name ↑	Modified	
CTS-2025-0155601	2 months ago	📄
CTS-2025-0155602	13/01/2025 10:53 AM	📄

Non-compliant Essential Principles !

Identify all the Essential Principles (EPs) that the device(s) are non-compliant with. You will need to select one EP at a time and provide details as to why the device(s) are non-compliant with each EP.

Non-compliant EP ↑

How device(s) do not conform to the selected EP?

Add breached Essential Principle

There are no records to display.



Add breached Essential Principle

Add Non-compliant Essential Principle



Essential Principle *

EP 13 - Information to be provided with medical devices - EP 13.4 - Instructions for use



Detail how the device(s) is non-compliant with this selected EP *

Lorem ipsum dolor sit amet



Save and Close

Non-compliant Essential Principles

Identify all the Essential Principles (EPs) that the device(s) are non-compliant with. You will need to select one EP at a time and provide details as to why the device(s) are non-compliant with each EP.


Add breached Essential Principle

Non-compliant EP 

How device(s) do not conform to the selected EP?

EP 13 - Information to be provided with medical devices - EP 13.4 - Instructions for use	Lorem ipsum dolor sit amet
------------------------------------------------------------------------------------------	----------------------------

EP 14 - Clinical evidence	abcdef
---------------------------	--------

 Edit
Delete

Device groups

You can group the unapproved devices with the same proposed start and end dates, and the same implementation plan for this consent application.

[Add device group](#)

Group name 	Unapproved device(s) linked to the group	Notification number(s) linked to the group	Proposed start date	Proposed end date	Group data completed	Created on
----------------------------------------------------------------------------------------------	------------------------------------------	--------------------------------------------	---------------------	-------------------	----------------------	------------

There are no records to display.

Add device group

Add Device Group ✕


Provide a name of the group, to aid you in identifying different groups you may have in this application. *

Save and Close

Device groups

You can group the devices with the same proposed start and end dates, and the same implementation plan for this consent application.

Add Device group

Group name 	Device(s) linked to the Group	Proposed start date	Proposed end date	Group data completed	Created On	
Application 01 - Group 1				No	25/02/2025 11:33 AM	 Edit Delete

Edit Device group ✕

The provided device group name is shown below, please edit if required. *

Application 01 - Group 1

Add device group

Must add at least one device to the device group.

Add device

Unique ID	Notification number	Manufacturer name	Device name ↑
There are no records to display.			

Proposed consent duration



Edit device group

Add devices to the device group

Proposed consent duration

Edit Device group

The provided device group name is shown below, please edit if required. *

Add device group

Must add at least one device to the device group.

Add device

Unique ID	Notification number	Manufacturer name	Device name ↑
There are no records to display.			

Proposed consent duration

Add device

You can 'add existing device' if it was part of a previous consent for non-compliance application or you may 'add new device' *

Add existing device

Add a new device



Edit device group

Add devices to the device group

Add existing device

Proposed consent duration

Add device

You can 'add existing device' if it was part of a previous consent for non-compliance application or you may 'add new device' *

Add existing device

Add a new device

Device name *

Lookup records

Search

Choose one record and click Select to continue

Select	<input checked="" type="checkbox"/>
Unique ID	MD-25-001053
Manufacturer name	XXX
Good Name	BBB
Device type	Reusable vaporizer

Select	<input type="checkbox"/>
Unique ID	MD-24-001009

< 1 2 3 4 >

Select Cancel Remove value

Edit device group

Add devices to the device group

Proposed consent duration

Add existing device

Add device ✕

You can 'add existing device' if it was part of a previous consent for non-compliance application or you may 'add new device' *

Add existing device
 Add a new device

Device name *

BBB
✕
🔍

Device name: BBB

Unique ID: MD-25-001053

Device type: Reusable vaporizer

Manufacturer name: XXX

Manufacturer address: 123

Manufacturer country: Albania

Please provide a notification number

This is the number assigned to your device after you submitted "Sponsor notice to import or supply in Australia therapeutic goods" form. If the number did not pre-fill above then please add it here.

VG-2025-NTF-XXXXX

Add device ✕

Current stock level

500

Future stock level

1000

Stock level - units of measurement

Box
▾

Expected depletion date of stock, including current and future stock

01/07/2025
📅

Will there be any supply shortage, if the consent to supply is not granted?

Select
▾

Any additional impact(s) to Australian consumers if the consent is not approved?

Select
▾

Save and Close



Edit device group

Add devices to the device group

Proposed consent duration

Add a new device

Add device ✕

You can 'add existing device' if it was part of a previous consent for non-compliance application or you may 'add new device' *

Add existing device

Add a new device

Device name *

Device type *

Select ▾

- Select
- Battery
- Charging unit
- Coil
- Complete vaping device
- Mouthpiece
- Unfilled pod or cartridge
- Vaporiser
- Wick
- Other

Add device ✕

Manufacturer name *

Manufacturer address *

Manufacturer country *

Edit device group

Add devices to the device group

Proposed consent duration

Add a new device

Lookup records ✕

Search

Choose one record and click Select to continue

Select	<input checked="" type="checkbox"/>
Short Description	Afghanistan
Code	AFG
Select	<input type="checkbox"/>
Short Description	Aland Islands
Code	ALA
Select	<input type="checkbox"/>

< 1 2 3 4 5 6 7 8 ... 25 >

Add device ✕

Manufacturer country *

Please provide a notification number
This is the number assigned to your device after you submitted "Sponsor notice to import or supply in Australia therapeutic goods" form.

Current stock level

Future stock level

Stock level - units of measurement

Expected depletion date of stock, including current and future stock

Edit device group

Add devices to the device group

Proposed consent duration

Edit Device group ✕

The provided device group name is shown below, please edit if required. *

Application 01- Group 1

Add device group

Add device

Unique ID	Notification number	Manufacturer name	Device name ↑
		ZZZZ	ABCD
MD-25-001053	VG-2025-NTF-XXXXX	XXX	BBB

Proposed consent duration

Edit Device
Remove Device



Edit device group

Add devices to the device group

Proposed consent duration

Edit Device group

Proposed consent duration

Proposed start date *

Proposed end date (must be within 3 years of proposed start date) *

Provide a reason for proposed duration of consent *

Batches affected

Edit Device group

Strategies to rectify non-compliance

What are the strategies to be implemented, or proposed to be implemented, to rectify the non-conformance for this device group? *

You must provide an explanation in the box below or attach supporting document(s). If you are providing supporting document(s), please write "document attached" in the box.

Documents

Before uploading supporting documentation, please check that folders have been created. To provide supporting documentation, please click the 'Add files' button or click on the relevant folder.

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Add files




Name	Modified	
Implementation Plan	about 2 hours ago	
Other supporting documents	about 2 hours ago	
PIC documents	about 2 hours ago	
PIL documents	about 2 hours ago	

Save and Close

Device groups 

You can group the devices with the same proposed start and end dates, and the same implementation plan for this consent application.

[Add Device group](#)

Group name 	Device(s) linked to the Group	Proposed start date	Proposed end date	Group data completed	Created On	
Application 01 - Group 1	BBB,ABC	08/03/2025	23/07/2026	Yes	25/02/2025 11:33 AM	
Application 01 - Group 2				No	25/02/2025 3:19 PM	 Edit Delete

Declaration

I declare that the information provided in this application is true and correct. I understand that providing false or misleading information is an offence. *

[Back](#)[Save](#)[Submit](#)

Application 01

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Treatment of the information provided to the TGA at <https://www.tga.gov.au/privacy>



Are your correspondence details up to date?

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Your application has been saved successfully



Expand All

Collapse All

Application details



Non-compliant Essential Principles



Device groups



Declaration



Back

Save

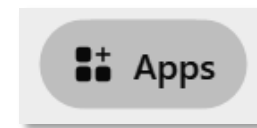
Submit

How did we go?

Take a moment to complete our survey, and we'll be back with you shortly for Q&A



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration



Use the app in Webex



Use the QR code

Website and Reference links

Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023

<https://www.legislation.gov.au/F2023L01686/latest/text>

[Requirements for unapproved therapeutic vaping devices and accessories in Australia](#)

Essential Principles

<https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/quality-safety-and-performance-requirements-medical-devices-essential-principles>

<https://www.tga.gov.au/sites/default/files/2024-03/standards-therapeutic-vaping-devices-checklist.docx>

Consent under section 14/14A

<https://www.tga.gov.au/resources/resource/forms/application-consent-import-supply-or-export-goods-do-not-comply-standards-section-1414av>

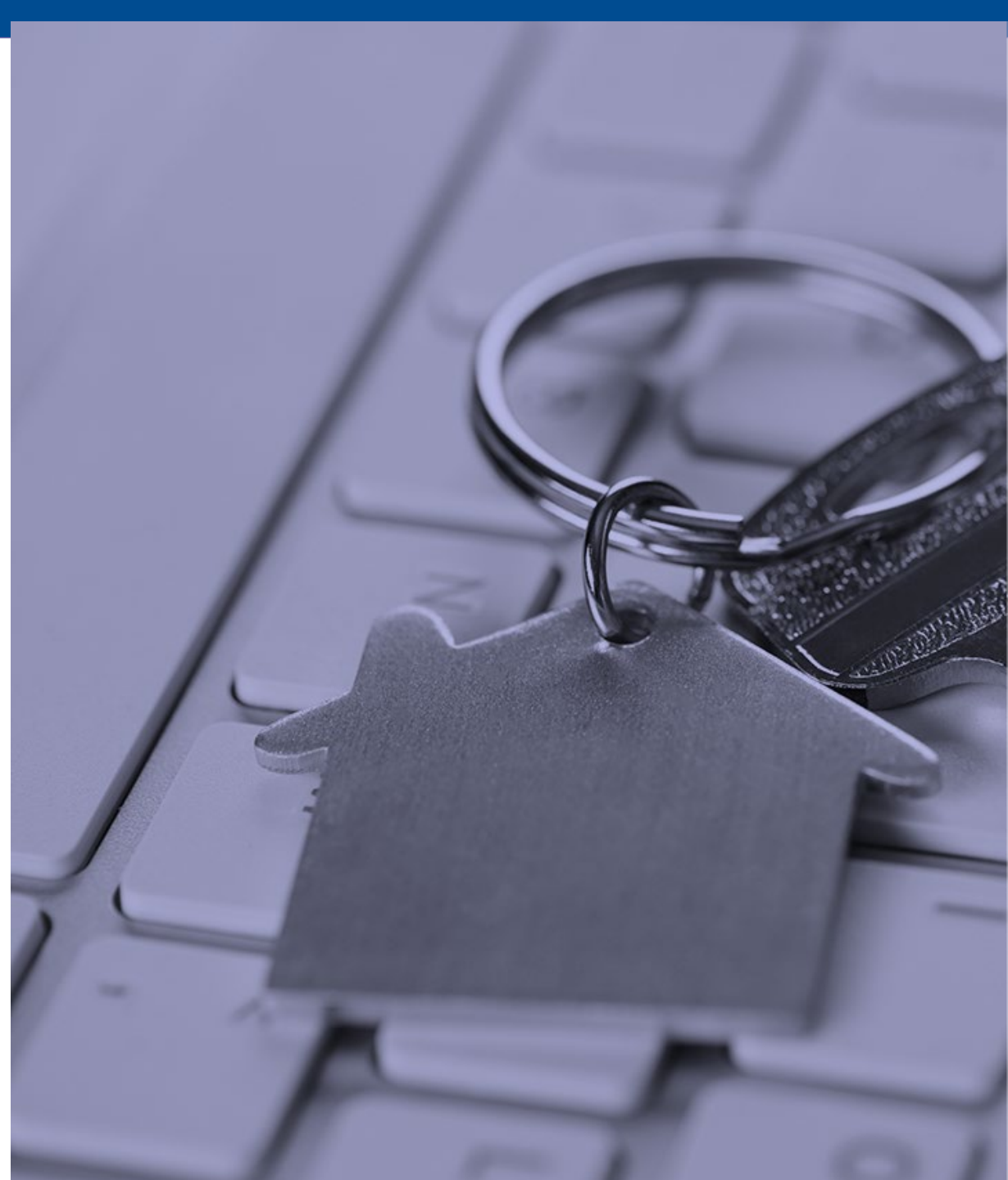
Consent for non-compliance with the Essential principles

<https://www.tga.gov.au/resources/resource/forms/essential-principles-consent-non-compliance>

Contact us

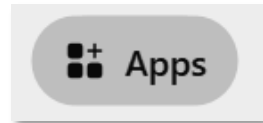
Email

mdconsent@health.gov.au



Questions?

Ask us through Slido



Use the app in Webex



Use the QR code



Racheal Aye

A/g Assistant Director,

Medical Devices Surveillance Branch

Department of Health and Aged Care, TGA

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