Proposed changes to IVD medical device classifications and definitions

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

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Today’s showcase on the proposed changes to IVD medical device classifications and definitions consultation

Background

- IVD medical device classification
- Proposed changes
- Why they are changing

Overview of the consultation

- Our approach
- Benefits of proposed changes
- Impacts

Q&A

What are the IVD medical device classifications?

IVD medical device classification

Aus	EU	Examples	Risk
Class 1	**Class A**	• Specimen collection containers • Microbiological culture media	No public health risk or low personal risk
Class 2	**Class B**	• Pregnancy and fertility self-tests • Cholesterol tests	Low public health risk or moderate personal risk
Class 3	**Class C**	• Tests to detect a sexually transmitted disease (e.g. chlamydia, gonorrhoea) • Human genetic tests	Moderate public health risk or high personal risk
Class 4	**Class D**	• Blood donor screening tests for HIV • ABO blood grouping tests	High public health risk

See Classification of IVD medical devices for more information. These classification rules are written within Schedule 2A of the *Therapeutic Goods (Medical Devices) Regulations 2002.*

Approaches for the alignment

Proposed changes:

- ü Amend IVD classification rules and principles to align with the classification and implementation rules (Annex VIII) of the EU IVD Regulations (2017/746)
- ü Australian classification rules adopt certain terminology from EU to cover the new and emerging technologies and improve clarity on specific IVD terms currently not defined in the Australian regulations.

- Classification rule for self-test IVDs are excluded.

Proposed NO changes:

- ü Australian classification rules and principles **already align** with the relevant EU classification.
- ü Australian classification for certain devices retained.

Benefits

- Increase alignment between Australian and EU requirements
- Result in greater consistency in regulatory requirements of IVD medical devices
- Shorten the time for products to enter the Australian market
- Improve clarity and transparency
- Reduce public health and safety risks
- Increase consumer confidence in the regulation of IVD medical devices

Proposed changes

A. Classification changes with an impact on approved IVDs

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Proposed changes with impact

A. Cancer tests

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
2.3 Rule 3 Devices are classified as Class C if they are intended:	1.3 An IVD medical device is classified as a Class 3 IVD medical device or a Class 3 in-house IVD medical device if it is intended for any of the following uses:	**The TGA proposes to include 'screening' and 'staging' in addition to 'diagnosis of cancer'**, to ensure the classification is proportionate to the risk posed to the patient and this also aligns with the EU rule.
(h) to be used in **screening**, diagnosis, or **staging** of cancer;	(f)(iii) in the diagnosis of cancer	

Rationale: IVD medical device used to detect cancer is appropriate to be classified as a Class 3 IVD medical device when used either for screening, diagnosis or staging as cancer is a life-threatening disease and poses a high personal risk.

Impact: The proposed change will result in re-classification of devices intended for cancer screening to Class 3 IVD.

Examples: faecal occult blood (FOB), total prostate specific antigen (PSA), Carcinoembryonic Antigen (CEA)

Proposed changes with impact

B. Preliminary testing and monitoring devices

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
No equivalent note.	Note for paragraph (f): An IVD medical device would be classified as Class 2 if: (a) a therapy decision would usually be made only after further investigation; or (b) the device is used for monitoring.	**The TGA proposes to remove 'Note for paragraph (f)'** to ensure the classification is proportionate to the risk posed to the patient.

Rationale: The devices used for selective therapy and management, disease staging, and cancer diagnosis (Rule 1.3(f)) pose similar personal health risks when used for initial investigation or monitoring and should have consistent classification.

Impact: Re-classification of these devices, when used for preliminary testing or monitoring, to Class 3 IVD medical devices.

Examples: Immunohistology cell marker IVD medical devices

Proposed changes with impact

C. Devices used to manage life-threatening conditions

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
2.3 Rule 3 Devices are classified as Class C if they are intended:	1.3 An IVD medical device is classified as a Class 3 IVD medical device or a Class 3 in-house IVD medical device if it is intended for any of the following uses:	**The TGA proposes to replace 'life-threatening infectious disease' with 'life-threatening disease or condition'** to ensure the classification is proportionate to the risk posed to the patient and this also aligns with the EU rule.
(k) for management of patients suffering from a life-threatening **disease or condition**;	(i) the management of patients suffering from a life-threatening **infectious** disease;	

Rationale: Life-threatening diseases and conditions, irrespective of whether they are infectious or non-infectious, pose a high personal health risk and are critical for patient management decision.

Impact: Re-classification of these devices to Class 3 IVD.

Examples: HbA1c and blood glucose tests, D-Dimer in patients with thrombotic disorders, monitoring anticoagulant therapy with PT (partial thromboplastin time)

Proposed changes with impact

D. Newborn screening devices

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
2.3 Rule 3 Devices are classified as Class C if they are intended: (m) for screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.	No equivalent rule.	**The TGA proposes to adopt this rule** to ensure the classification is proportionate to the risk posed to the patient and this also aligns with the EU rule.

Rationale: An erroneous test result in newborn screening could lead to a failure to detect and treat such birth disorders, which could result in life-threatening situation or severe disability of the patient and hence pose a high personal health risk.

Impact: Re-classification of some non-genetic tests used for newborn screening of life-threatening conditions from Class 2 to Class 3.

Examples: HPLC for newborn screening of haemoglobinopathies, phenylketonuria (PKU) tests and tests for congenital hypothyroidism and congenital adrenal hyperplasia

Proposed changes with impact

E. Control materials

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
2.7 Rule 7 Devices which are controls **without a quantitative or qualitative assigned value** are classified as class B.	1.5 Despite clauses 1.1 to 1.4, an IVD medical device that is intended to be used as non-assay-specific quality control material is classified as a Class 2 IVD medical device or a Class 2 in-house IVD medical device.	**The TGA proposes to classify controls based on assigned values** to ensure the classification is appropriate to the current use and risks posed to the patient and this also aligns with the EU rule.

Rationale: Controls used for one assay (assay-specific), or multiple assays (non-assay-specific) where values are assigned by the manufacturer and not the user are used to monitor performance of devices of various classes and have similar risks as the devices therefore should be classified in the same class as the device.

Impact: Re-classification of some non-assay specific control materials with assigned values to Class 3 or 4 based on the associated IVD medical devices**.**

Examples: Control materials with assigned values used to verify the performance of HIV assays (Class 4), syphilis assays (Class 3), TSH assays (Class 2)

Proposed changes with impact

F. Instruments

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
2.5 Rule 5 The following devices are classified as class A:	1.6 (2) **Despite clauses 1.1 to 1.5,** the following IVD medical devices are classified as Class 1 IVD medical devices or Class 1 in-house IVD medical devices:	**Remove 'Despite clauses 1.1 to 1.5' from statement 1.6 (2)** to ensure the classification is appropriate to the current use and risks posed to the patient and this also aligns with the EU rule**.**
(b) Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures	(a) an instrument, intended by the manufacturer, to be specifically used for in vitro diagnostic procedures;	

Rationale: The reagents and kits associated with the instruments are classified and assessed based on their intended purpose. Hence, the instrument with an independent measuring function which does not use any additional reagents with critical characteristics should be classified based on its intended purpose and the risk posed.

Impact: Re-classification of some Class 1 instruments / analysers with an independent measuring function

Examples: Cell counting analysers, COVID breath analysers, instruments measuring blood gas, electrolytes, glucose via sensors, specific gravity measurements in urine analysis

Proposed changes with impact

G. Software

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
Annex VIII, 1.4 Software, which drives a device or influences the use of a device, shall fall within the same class as the device. **If the software is independent of any other device, it shall be classified in its own right.**	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.	**The TGA proposes to classify software that does not exclusively drive or influence the device based on its intended purpose** to ensure the classification is appropriate to the current use and risks posed to the patient and this also aligns with the EU rule.

1. **Independent** IVD Software has its own intended medical purpose. These devices are currently classified on their own, based on their intended purpose.

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Proposed changes with impact

G. Software

2. IVD software intended to **drive or influence** the use of an IVD device. This software may be an integral component of the IVD device or may be supplied separately.

    a. **IVD software exclusively drives or influences an instrument:** It has the same classification as the IVD device.

    b. **Software does more than only driving or influencing an IVD device:** It has analytical or interpretative functionality and should be classified based on its own intended purpose and risk.

Proposed changes with impact

G. Software

- **Impact:** Re-classification of some IVD software which does more than only driving or influencing an instrument; i.e. has analytical/interpretive functions and generates new diagnostic information.

- **Examples**:

– AI-driven cervical smear analysis software (Class 3)
– Flow cytometry analysis software with interpretive function that generates new diagnostic information (Class 3)
– Digital imaging viewer software with subsequent analysis, such as cell identification (Class 2)
– Software driving/influencing an ELISA microplate washer (Class 1)

Questions

Question 1: Proposed changes to classification rules and principles that have an impact on approved products

(a) Do you agree with the proposals to change the Australian classification rules and principles as specified in Section A, noting the changes are reflective of the regulatory scrutiny based on the associated health risks?

(b) If no, which of the proposed changes do you not agree with? Please provide your reasons.

(c) Are there any other classification rules and principles, relating to the IVD medical devices, that need to be considered as part of this proposal?

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Proposed changes

B. Classification changes with no impact on approved IVDs

Proposed changes

B. Classification changes with no impact on approved IVDs

- **Purpose**

To improve clarity and capture emerging technologies

- **Example**

Adding ‘Cell administration’ for CAR T-cell therapies

- **Impact**

No impact on approved IVDs anticipated

Key proposed changes:

- Adding '**suspected** high risk of propagation'
- Including '**cell administration**'
- Adding '**embryo**'
- Including '**individual's offspring**'
- Removing the statement **'the selection of patients'**
- Removing **'imminent/immediate'**
- Replacing 'specific characteristics' with **'no critical characteristics'**

Questions

Question 2: Proposed changes to classification rules and principles that have no impact on approved products

(a) Do you agree with the proposals to adopt certain terminology in the Australian classification rules as specified in Appendix A, noting the changes are to improve clarity?

(b) If no, which of the proposed changes do you not agree with? Please provide your reasons.

(c) Do you agree the proposed changes in Appendix A, would not result in any impact on existing ARTG entries of IVD medical devices?

(d) Are there any other classification rules, relating to the IVD medical devices, that need to be considered as part of this proposal?

Classification rules proposed to retain

Differences between EU IVDR and Aus classification rules

Examples:

- SARS-CoV-2 IVDs
- Influenza IVDs
- HIV monitoring IVDs

Proposed changes

C. Definition changes with no impact on approved IVDs

Proposed changes

C. Definition changes with no impact on approved IVDs

- **Purpose**

To improve clarity and capture emerging technologies

- **Example**

Including ‘predisposition to a medical condition or a disease’ in the IVD device definition

- **Impact**

No impact on approved IVDs anticipated

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Key proposed changes:

- Including IVD-specific definitions: *'Performance Evaluation*', *'Analytical Performance*', *'Calibrator*', and '*Control Material*'

- Adding the following purposes to the definition of IVD device:
  - Concerning the predisposition to a medical condition or a disease
  - To define or monitor therapeutic measures

- Removing the following statements from the definition of IVD device:
  - Not intended for general laboratory use; and
  - Manufactured, sold or presented for use as an IVD medical device.

- Adding '**not intended for self-testing**' to the definition of point-of-care testing (PoCT)

- Replacing 'a particular medicine' with **'corresponding medicine or biological products'** in CDx definition

Questions

Question 3: Proposed changes to the IVD definitions

(a) Do you agree with the proposal to amend the Australian definitions as specified in Appendix B?

(b) If no, which of the proposed changes do you not agree with? Please provide your reasons.

(c) Are there any other definitions, relating to the IVD medical devices, that need to be considered as part of this proposal?

Impacts

What would change for sponsors?

- Verify the classification of their included devices;
- Ensure to have the supporting evidence;
- Apply for reclassification of their impacted devices in accordance with the transition arrangements.

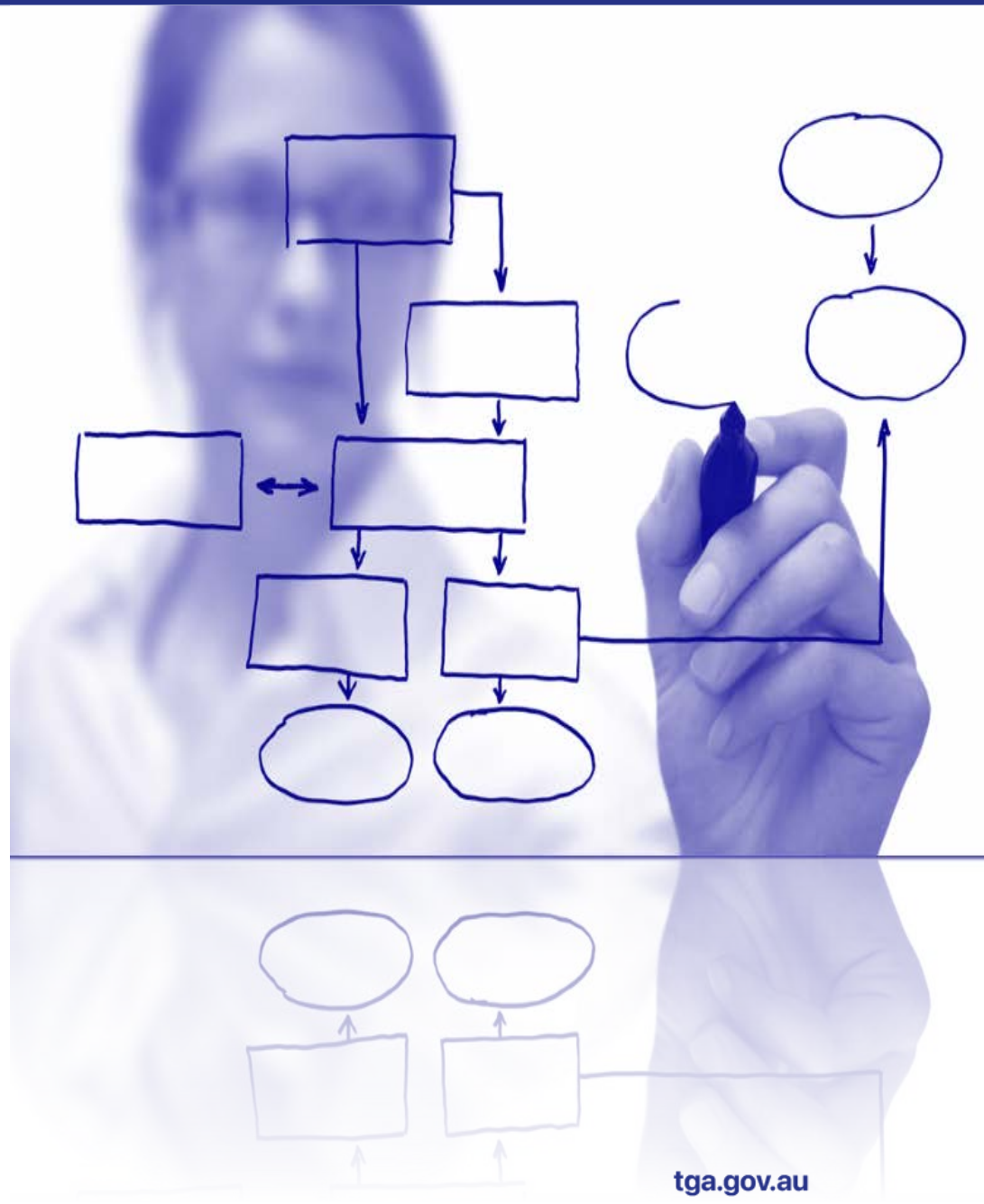
What would change for manufacturers?

- Reassess the compliance of their IVD medical devices with any revised classification rules;
- Ensure to have all appropriate evidence to comply with any relevant regulatory requirements.

Transition arrangements

- Transition timelines for re-classification of impacted existing applications and ARTG entries to be six months after the current EU IVDR transition deadlines.

- Deadlines for each Class of IVDs:
  - Until 30 June 2028 for Class 4 IVDs
  - Until 30 June 2029 for Class 3 IVDs
  - Until 30 June 2030 for Class 2 IVDs



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Question

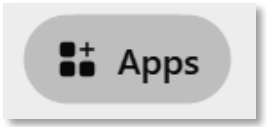
Question 4: Transition period

(a) Do you agree with the proposal to apply a 6-month transition period after the EU IVDR transition timelines for the proposed Australian amendments to take effect?

(b) Provide reasons for your position (optional).

How did we go?

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



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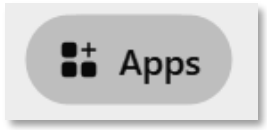

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Website and Reference links

Consultation page and online survey	Consultation: Proposed changes to the IVD medical device classifications and definitions - Therapeutic Goods Administration - Citizen Space
Consultation paper	Consultation Proposed changes to the IVD medical device classifications and definitions.pdf

Contact us

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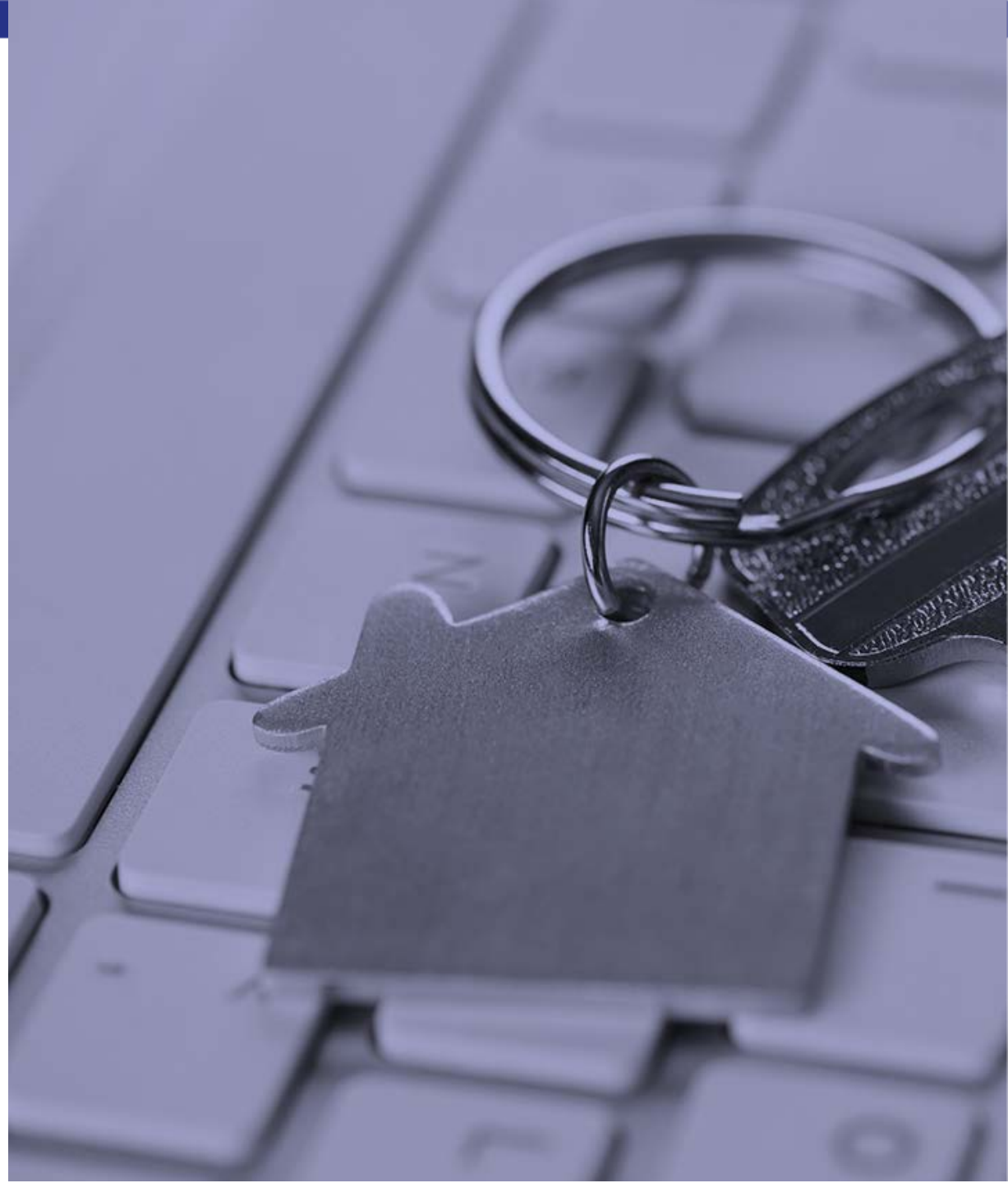

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