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|  | **TGA USE ONLY** |

This form, when completed, will be classified as '**For official use only**'.  
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <<https://www.tga.gov.au/treatment-information-provided-tga>>.

# Manufacturer’s Declaration of Conformity for Class I non-sterile, non-measuring or Class 1 in vitro diagnostic (IVD) medical devices

This Declaration of Conformity (DoC) is required under clause 6.6 (for single devices or kinds of devices) of Schedule 3 of the [*Therapeutic Goods (Medical Devices) Regulations 2002*](https://www.legislation.gov.au/Series/F2002B00237) (the Regulations).

For more information on how to complete this DoC refer to [Guidance for Declaration of Conformity for Class I non-sterile non-measuring and Class 1 in vitro diagnostic (IVD) medical devices](https://www.tga.gov.au/resources/resource/guidance/guidance-declaration-conformity-procedures).

This document can be:

* used for single or multiple devices.
* filled out by hand and then scanned and submitted or filled out electronically.

### Manufacturer’s details

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| Manufacturer’s name |  |
| Manufacturer’s business address |  |

### Classification type

Specify if your device is:

Class I non-sterile, non-measuring device

Class 1 In vitro diagnostic (IVD) medical device

### GMDN code and term

Select the most appropriate Global Medical Device Nomenclature (GMDN) code for this product. GMDN codes and terms are a system of internationally agreed generic descriptors that are used to identify all medical device products. Class 1 IVDs require the use of a level 1 collective term (CT). Please refer to the following link for guidance regarding an appropriate CT for the kind of device: [The use of GMDN codes for IVD medical devices in Australia](https://www.tga.gov.au/publication/use-gmdn-codes-ivd-medical-devices-australia).

GMDN codes are generated by the [GMDN Agency](https://www.gmdnagency.org/).

The GMDN code tables are available on [TGA Business Services (TBS)](https://www.ebs.tga.gov.au/).

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| GMDN Codes and terms |  |

### Standards applied to the device(s)

List any standards used in the manufacturing of the device, including:

* International Standards (ISO)
* Australian Standards (AS)
* [Conformity Assessment Standard Orders (CASO)](https://www.tga.gov.au/medical-devices-notices-standards-orders)
* [Medical Device Standard Orders (MDSO)](https://www.tga.gov.au/medical-devices-notices-standards-orders)

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| Standards |  |

### Name of medical device(s) / IVD(s)

Identify the specific device/s this form relates to for example, the name of the device or model numbers of the device and any variants that are being manufactured for supply in Australia.

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| Name of medical device(s) / IVD(s) |  |

**This declaration is being made under clause 6.6 of Schedule 3 to the Regulations for a Class I non-sterile, non-measuring device or Class 1 IVD medical device.**

**By signing this form, you are agreeing that:**

* You have reviewed the Declaration of Conformity procedures under Part 6 of Schedule 3 of the Regulations and the device complies with the applicable provisions of those procedures.
* The device complies with the relevant essential principles set out in Schedule 1 to the Regulations.
* The device complies with the applicable provisions of the classification rules set out in Schedule 2 to the Regulations.
* You will update the technical documentation when any changes are made in relation to the device.

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| Information | **Important note**  Providing information that is false or misleading to a Commonwealth entity or in connection with a Commonwealth law is a serious offence subject to criminal penalties under the *Criminal Code Act 1995.* |

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| --- | --- | --- | --- |
| Name |  | | |
| Title |  | | |
| Signature |  | Date |  |