Australian Government
Department of Health
Therapeutic Goods Administration

# Declaration of conformity templates (IVDs)

12 January 2017

As part of the conformity assessment procedures, the manufacturer of an IVD medical device is required to make a Declaration of Conformity which declares that the device complies with:

- the applicable provisions of the Essential Principles
- the classification rules
- an appropriate conformity assessment procedure

The declaration also requires the manufacturer to provide details that are relevant to the conformity assessment procedure and the manufacture of the IVD medical device covered by the declaration.

It should be noted that these templates are published to assist in the preparation of declarations of conformity. It is the responsibility of the manufacturer signing a declaration to ensure that it is drawn up correctly and meets all the legal requirements.

How to access an RTF document (//www.tga.gov.au/accessing-documents-website)

Template: Manufacturer's declaration of conformity - Class 4 in-house IVD medical devices (rtf,72kb) (//www.tga.gov.au/sites/default/files/ivd-forms-declaration-conformity-class4.rtf)

Declaration made under Clause 6B.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002. Please note, if applying Full Quality Assurances procedures under Schedule 3, Part 1, use the alternative template below

Template: Manufacturer's declaration of conformity - full quality assurance procedure (rtf,18kb) (//www.tga.gov.au/sites/default/files/ivd-forms-declaration-conformity-fullqa.rtf)

Declaration made in accordance with the requirements of Clause 1.8 of

Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002

Template: Manufacturer's declaration of conformity - production quality management system (rtf,15kb) (//www.tga.gov.au/sites/default/files/ivd-forms-declaration-conformity-productionqms.rtf)

Declaration made in accordance with the requirements of Clause 4.7 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002

Template: Manufacturer's declaration of conformity - Clause 6.6 (rtf,14kb) (//www.tga.gov.au/sites/default/files/ivd-forms-declaration-conformity-clause6.rtf)

Declaration made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002

Template: Manufacturer's declaration of conformity - procedure pack or system (rtf,42kb) (//www.tga.gov.au/sites/default/files/ivd-forms-declaration-conformity-procedurepack.rtf)

Declaration made under Clause 7.5 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002

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**Category:** Manufacturing, Medical devices/IVDs
**Tags:** forms, conformity assessment, in vitro diagnostic medical devices (IVDs)
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