Australian Government
Department of Health
Therapeutic Goods Administration

Declaration of conformity templates (medical devices)

5 February 2013

As part of the conformity assessment procedures, the manufacturer of a 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 medical device covered by the declaration.

The following table outlines which declaration of conformity requires completion.

Class of medical device	Conformity assessment procedure required under Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)	Directive 93/42/EEC on Medical Devices - European Union equivalent	Declaration of conformity required under Schedule 3 of the Regulations
Class I	Part 6 (Declaration of conformity procedures)	nil	Schedule 3, Part 6, clause 6.6

Class of medical device	Conformity assessment procedure required under Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)	Directive 93/42/EEC on Medical Devices - European Union equivalent	Declaration of conformity required under Schedule 3 of the Regulations
Class I (measuring)	Part 1 excluding clause 1.6 (Full quality assurance procedures) OR	Annex II.3 OR	Schedule 3, Part 1, clause 1.8 OR
	Part 6 (Declaration of conformity procedures) + Part 3 (Verification procedures) or Part 4 (Production quality assurance procedures) or Part 5 (Product quality assurance procedures)	nil + Annex IV or Annex V or Annex VI	Schedule 3, Part 6, clause 6.6
Class I (sterile)	Part 1 excluding clause 1.6 (Full quality assurance procedures) OR	Annex II.3 OR	Schedule 3, Part 1, clause 1.8 OR
	Part 6 (Declaration of conformity procedures) + Part 4 (Production quality assurance procedures)	Nil + Annex V	Schedule 3, Part 6, clause 6.6

Class of medical device	Conformity assessment procedure required under Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)	Directive 93/42/EEC on Medical Devices - European Union equivalent	Declaration of conformity required under Schedule 3 of the Regulations
Class IIa	Part 1 excluding clause 1.6 (Full Quality Assurance Procedures) OR	Annex II.3 OR	Schedule 3, Part 1, clause 1.8 OR
	Part 6 (Declaration of conformity procedures) + Part 3 (Verification procedures) or Part 4 (Production quality assurance procedures) or Part 5 (Product quality assurance procedures)	Nil + Annex IV or Annex V or Annex VI	Schedule 3, Part 6, clause 6.6
Class IIa (sterile)	Part 1 excluding clause 1.6 (Full quality assurance procedures) OR	Annex II.3 OR	Schedule 3, Part 1, clause 1.8 OR
	Part 4 (Production quality assurance procedures) (excluding clause 4.7)	Annex V	Schedule 3, Part 6, clause 6.6

Class of medical device	Conformity assessment procedure required under Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)	Directive 93/42/EEC on Medical Devices - European Union equivalent	Declaration of conformity required under Schedule 3 of the Regulations
Class IIb	Part 1 excluding clause 1.6 (Full quality assurance procedures) OR	Annex II.3 OR	Schedule 3, Part 1, clause 1.8 OR
	Part 3 (Verification procedures) + Part 2 (Type examination procedures) OR	Annex IV + Annex III OR	Schedule 3, Part 3, clause 3.5 OR
	Part 4 (Production quality assurance procedures) + Part 2 (Type examination procedures OR	Annex V + Annex III OR	Schedule 3, Part 4, clause 4.7 OR
	Part 5 (Product quality assurance procedures) + Part 2 (Type examination procedures)	Annex VI + Annex III	Schedule 3, Part 5, clause 5.7
Class IIb (sterile)	Part 1 excluding clause 1.6 (Full quality assurance procedures) OR	Annex II.3 OR	Schedule 3, Part 1, clause 1.8 OR

Class of medical device	Conformity assessment procedure required under Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)	Directive 93/42/EEC on Medical Devices - European Union equivalent	Declaration of conformity required under Schedule 3 of the Regulations
	Part 4 (Production quality assurance procedures) + Part 2 (Type examination procedures)	Annex V + Annex III	Schedule 3, Part 4, clause 4.7
Class III	Part 1 (Full quality assurance procedures) + clause 1.6 (Examination of design) OR	Annex II.3 + Annex II.4 OR	Schedule 3, Part 1, clause 1.8 OR
	Part 3 (Verification procedures) + Part 2 (Type examination procedures) OR	Annex IV + Annex III OR	Schedule 3, Part 3, clause 3.5 OR
	Part 4 (Production quality assurance procedures) + Part 2 (Type examination procedures)	Annex V + Annex III	Schedule 3, Part 4, clause 4.7

Class of medical device	Conformity assessment procedure required under Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)	Directive 93/42/EEC on Medical Devices - European Union equivalent	Declaration of conformity required under Schedule 3 of the Regulations
Class III (sterile)	Part 1 (Full quality assurance procedures) + clause 1.6 (Examination of design) OR	Annex II.3 + Annex II.4 OR	Schedule 3, Part 1, clause 1.8 OR
	Part 4 (Production quality assurance procedures) + Part 2 (Type examination procedures)	Annex V + Annex III	Schedule 3, Part 4, clause 4.7
AIMD	Part 1 (Full quality assurance procedures) + clause 1.6 (Examination of design) OR	Annex 2.3 + Annex 2.4 OR	Schedule 3, Part 1, clause 1.8 OR
	Part 3 (Verification procedures) + Part 2 (Type examination procedures) OR	Annex 4 + Annex 3 OR	Schedule 3, Part 3, clause 3.5 OR

Class of medical device	Conformity assessment procedure required under Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)	Directive 93/42/EEC on Medical Devices - European Union equivalent	Declaration of conformity required under Schedule 3 of the Regulations
	Part 4 (Production quality assurance procedures) + Part 2 (Type examination procedures)	Annex 5 + Annex 3	Schedule 3, Part 4, clause 4.7
System or Procedure Packs	Part 7 (Procedures for medical devices used for a special purpose)	Annex VIII & Article 12	Schedule 3, Part 7, clause 7.5

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

Schedule 3, Part 1 clause 1.8

Template: Manufacturer's declaration of conformity - full quality assurance procedure (rtf,57kb) (//www.tga.gov.au/sites/default/files/devices-forms-declaration-conformity-fullqa-130205.rtf)

Declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002

Schedule 3, Part 3, clause 3.5

Template: Manufacturer's declaration of conformity - verification (rtf,54kb) (//www.tga.gov.au/sites/default/files/devices-forms-declaration-conformity-verification-130205.rtf)

Declaration made in accordance with the requirements of Clause 3.5 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002

Schedule 3, Part 6, clause 6.6

Template: Manufacturer's declaration of conformity - Clause 6.6 (rtf,61kb) (//www.tga.gov.au/sites/default/files/devices-forms-declaration-conformity-130205.rtf)
Declaration made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002

Schedule 3, Part 4, clause 4.7

Template: Manufacturer's declaration of conformity - production quality management system (rtf,59kb) (//www.tga.gov.au/sites/default/files/devices-forms-declaration-conformity-productionqms-130205.rtf)
Declaration made in accordance with the requirements of Clause 4.7 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002

Schedule 3, Part 5, clause 5.7

Template: Manufacturer's declaration of conformity - product quality management system (rtf,57kb) (//www.tga.gov.au/sites/default/files/devices-forms-declaration-conformity-productqms-130205.rtf)
Declaration made in accordance with the requirements of Clause 5.7 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002

Schedule 3, Part 7, clause 7.5

Template: Manufacturer's declaration of conformity - procedure pack or system (rtf,55kb) (//www.tga.gov.au/sites/default/files/devices-forms-declaration-conformity-procedurepack-130205.rtf)
Declaration made under Clause 7.5 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002

Category: Manufacturing, Medical devices/IVDs
Tags: forms, conformity assessment
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