**Declaration of conformity templates (medical devices)**

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](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause66) |
| 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](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause18)  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](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause66) |
| 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](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause18)  OR |
| Part 6 (Declaration of conformity procedures) + Part 4 (Production quality assurance procedures) | Nil + Annex V | [Schedule 3, Part 6, clause 6.6](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause66) |
| Class IIa | Part 1 excluding clause 1.6 (Full Quality Assurance Procedures)  OR | Annex II.3  OR | [Schedule 3, Part 1, clause 1.8](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause18)  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](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause66) |
| 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](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause18)  OR |
| Part 4 (Production quality assurance procedures) (excluding clause 4.7) | Annex V | [Schedule 3, Part 6, clause 6.6](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause66) |
| Class IIb | Part 1 excluding clause 1.6 (Full quality assurance procedures)  OR | Annex II.3  OR | [Schedule 3, Part 1, clause 1.8](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause18)  OR |
| Part 3 (Verification procedures) + Part 2 (Type examination procedures)  OR | Annex IV + Annex III  OR | [Schedule 3, Part 3, clause 3.5](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause35)  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](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause47)  OR |
| Part 5 (Product quality assurance procedures) + Part 2 (Type examination procedures) | Annex VI + Annex III | [Schedule 3, Part 5, clause 5.7](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause57) |
| 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](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause18)  OR |
| Part 4 (Production quality assurance procedures) + Part 2 (Type examination procedures) | Annex V + Annex III | [Schedule 3, Part 4, clause 4.7](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause47) |
| 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](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause18)  OR |
| Part 3 (Verification procedures) + Part 2 (Type examination procedures)  OR | Annex IV + Annex III  OR | [Schedule 3, Part 3, clause 3.5](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause35)  OR |
| Part 4 (Production quality assurance procedures) + Part 2 (Type examination procedures) | Annex V + Annex III | [Schedule 3, Part 4, clause 4.7](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause47) |
| 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](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause18)  OR |
| Part 4 (Production quality assurance procedures) + Part 2 (Type examination procedures) | Annex V + Annex III | [Schedule 3, Part 4, clause 4.7](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause47) |
| 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](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause18)  OR |
| Part 3 (Verification procedures) + Part 2 (Type examination procedures)  OR | Annex 4 + Annex 3  OR | [Schedule 3, Part 3, clause 3.5](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause35)  OR |
| Part 4 (Production quality assurance procedures) + Part 2 (Type examination procedures) | Annex 5 + Annex 3 | [Schedule 3, Part 4, clause 4.7](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause47) |
| 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](http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm#clause75) |