Appendix 2: Proposed amendments summarised

The current and proposed changes to the minimal applicable conformity assessment procedure pathways in the Therapeutic Goods (Medical Devices) Regulations 2002 are.

Device class	Current options for conformity assessment	Proposed options for conformity assessment
Class I	• Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary)	Part 6 (Declaration of Conformity Procedures)
Class I with measuring function and/or sterile	• Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 3 (Verification Procedures other than clause 3.5) OR • Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures other than clause 4.7) • Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 (Examination of Design) with limited assessment • Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 5 (Product Quality Procedures other than clause 5.7)	• Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 (Examination of Design) with limited assessment, OR • Proposed MDSAP procedure
Class IIa,	• Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 (Examination of Design) OR • Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 3 (Verification Procedures other than clause 3.5) OR • Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures other than clause 4.7) OR • Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 5 (Product Quality Procedures other than clause 5.7)	**Include reusable surgical instruments** • Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 (Examination of Design), OR • Proposed MDSAP procedure

Class IIb implantable	• Part 1 (Full Quality Assurance Procedures) OR • Part 2 (Type Examination Procedures) + Part 3 (Verification Procedures) OR • Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures) • Part 2 (Type Examination Procedures) + Part 5 (Product Quality Procedures)	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design), OR • Proposed MDSAP procedure + Examination of Design
Class IIb non-implantable	• Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 OR • Part 2 (Type Examination Procedures) + Part 3 (Verification Procedures) OR • Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures) • Part 2 (Type Examination Procedures) + Part 5 (Product Quality Procedures)	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design) for representative device, OR • Proposed MDSAP procedure + Examination of Design for representative device
Class III	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design) OR • Part 2 (Type Examination Procedures) + Part 3 (Verification Procedures) OR • Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design), OR • Proposed MDSAP procedure + Examination of Design
System or Procedure Packs or custom made medical device	• Part 7 (Procedures for Medical Devices Used for a Special Purpose)	To note: Part 1 would be the only option for sterile devices if Part 4 is removed
Class 1 IVD	• Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary)	• Part 6 (Declaration of Conformity Procedures)
Class 2 IVD	• Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 (Examination of Design) for representative device OR • Part 4 (Production Quality Assurance Procedures other than clause 4.7) + Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary)	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design) for representative device, OR • Proposed MDSAP procedure + Examination of Design for representative device

Class 3 IVD	• Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 OR • Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design) for representative device, OR • Proposed MDSAP procedure + Examination of Design for representative device
Class 4 IVD	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design) OR • Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design), OR • Proposed MDSAP procedure + Examination of Design