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 <http://www.tga.gov.au/about/tga-information-to.htm>.

Attachment 3: Recertification checklist

Complete this attachment when applying for recertification of *existing* conformity assessment certificates of any kind.

You are required to provide the data location details (i.e. where the document is located within the supplied data package) when a section is checked as 'Applicable Y þ '.

Quality management system CA certificates (TGA, Schedule 3, Parts 1, 4, and 5)

Applicable ☐ Y ☐ N

Material	Location of data in supplied supporting documentation
Certificate to be recertified (Provide a copy of the certificate)	
Confirm certificate details (i.e., Manufacturer's name, address, facilities, suppliers, scope, conditions)	
Surveillance Inspection reports with non-conformity close-out since certification.	

Design/Type exam certificates (TGA, Schedule 3, Part 1 clause 1.6, and Part 2)

Applicable ☐ Y ☐ N

Material	Location of data in supplied supporting documentation
Certificate to be recertified (Provide a copy of the certificate)	

Material	Location of data in supplied supporting documentation
Confirm certificate details (i.e., Manufacturer's name, address, facilities, scope, devices, conditions) (Note: Indicate any devices not to be recertified)	
Post-market data Details of any reportable adverse events, recalls or notices from within or outside Australia since certification including device ARTG numbers.	
Updated risk management report demonstrating continual compliance with the Essential Principles/Requirements; taking into consideration: · experience gained post market · additional information on existing and new hazards with regard to the 'state of the art' (e.g., standards) and updated clinical data · new regulatory developments	