



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

**Commercial – In – Confidence**

**Request to Transfer Sponsorship of  
ARTG Inclusions for Medical Devices – Accepting Company**

*Therapeutic Goods Act 1989*

**Accepting Sponsors Name**

**Client ID**

From

**Relinquishing Sponsors Name**

**Client ID**

**Relinquishing sponsor:**

The following steps must be completed in order to process a transfer of sponsorship of included medical devices:

- An authorised representative of the relinquishing company to complete the form “Request to Transfer the Sponsorship of an ARTG entry - Relinquishing Sponsor” available on the TGA website at <<http://www.tga.gov.au/meds/tsfrelinqco.htm>>.
- Ensures all annual charges have been paid before the entries can be transferred

**Accepting sponsor:**

- Establishes a Client ID and eBS account with TGA. Forms and guidance are available on the TGA’s eBS website <<https://www.ebs.tga.gov.au>>.
- Submits notification/s for new manufacturer’s evidence for the ARTG Inclusions to be transferred. Guidance on manufacturers’ evidence is available in *TGA Fact Sheet 17 Manufacturers Evidence* on the TGA website <[http://www.tga.gov.au/devices/fs\\_eccert.htm](http://www.tga.gov.au/devices/fs_eccert.htm)>.
- Once the new notifications for Manufacturers Evidence has been reviewed and “accepted” by the TGA an authorised person for the Accepting sponsor completes this form “***Request to Transfer Sponsorship of ARTG Inclusions for Medical Devices – Accepting Sponsor***” available on the TGA website at <<http://www.tga.gov.au/meds/tsfaceptco.htm>>.
- The accepting sponsor must submit this completed form to the TGA together with the applicable processing fees to enable the ARTG entries to be transferred.

The fee for a variation to an ARTG Inclusion that is incorrect or incomplete will apply for each ARTG inclusion to be transferred. A list of current fees and charges, and a Credit Card Authorisation form, is available on the TGA website <[www.tga.gov.au/docs/html/feesach.htm](http://www.tga.gov.au/docs/html/feesach.htm)>.

**Please Note:** When agreeing to accept an ARTG Inclusion, it is recommended that the accepting sponsor considers and completes the checklist on the next page.

## Accepting Sponsor Checklist

It is recommended the accepting sponsor completes the following checklist before requesting to transfer ARTG inclusions:

Y/N	Actions to complete	Rationale
	Do you have a Client ID number with TGA?	Required to conduct business with the TGA
	Do you have access to eBS?	eBS provides web access to submit applications to the TGA and/or view current ARTG entries
	Have you submitted and gained approval from the TGA for the manufacturer's evidence?	It is a condition of inclusion that the sponsor holds information to substantiate that the conformity assessment procedures have been applied.
	Do you have a contractual arrangement with the manufacturer of these devices?	It is a condition of inclusion that the sponsor has a contractual arrangement with the manufacturer and can obtain documentation required by the TGA in relation to the devices covered by the ARTG record.
	Does the scope of the manufacturers' certificate/s to be lodged as manufacturer's evidence cover the ARTG entries?	This is the sponsor's responsibility and will not be reviewed by the TGA as part of the transfer of sponsorship process.
	Is the manufacturer's name on the ARTG Inclusions to be transferred the same as the manufacturer's name on the new certifications and manufacturer's evidence to be submitted to TGA by the accepting sponsor?	This is the sponsor's responsibility and will not be reviewed by the TGA as part of the transfer of sponsorship process.
	Has the relinquishing sponsor provided copies of the distribution records for all the devices covered by the ARTG inclusions to be transferred?	It is a condition of inclusion that the sponsors holds these records
	Has the relinquishing sponsor verified there are no outstanding fees or charges?	The transfer of sponsorship cannot proceed if there are outstanding fees or charges
	Has the relinquishing sponsor verified whether there are any regulatory activities associated with devices covered by these ARTG inclusions (i.e. adverse events, product recalls, proposals to suspend or cancel)?	The accepting sponsor will be legally responsible for devices supplied under these ARTG records
	Check with the relinquishing sponsor to ensure that all matters certified by the applicant in the original device application/ s are true and correct?	The accepting sponsor assumes the legal responsibility for the certifications made by the original sponsor in the device applications
	Have you checked with the relinquishing sponsor to ensure the details on the ARTG record/s are correct?	The accepting sponsor assumes the responsibility for the details on the ARTG record
	Have you made arrangements to ensure the name and address of the accepting sponsor will be provided either on the device or on its label, packaging or instructions for use?	The accepting sponsor is responsible for ensuring the name and address of the accepting sponsor is provided with the device.

