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|  | **TGA USE ONLY** |

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 <<https://www.tga.gov.au/treatment-information-provided-tga>>.

# MANUFACTURER’S DECLARATION OF CONFORMITY

AUSTRALIAN *THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002*

### Production Quality Management System

This is a declaration made in accordance with the requirements of Clause 4.7 of Schedule 3 of the Australian *Therapeutic Goods (Medical Devices) Regulations 2002*relating to the *<stated devices OR the devices stated in the attached Schedule>*

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| **Reference:** | *< If a schedule is attached, a reference to this declaration must be included in the Schedule>* |
| **Manufacturer's Name:** | *< Person responsible for design production packaging and labelling>* |
| **Business Address:** | *<Address of the manufacturer>* |
| **IVD Medical Device(s):** | *<Unique Product Identifier (UPI)>**<OR See Attached Schedule for multiple products>* |
| **Classification:** | *< Class of Device covered by this Declaration (Class 3, 4 IVD or Class 4 in-house IVD) >* *< OR See Attached Schedule for the class of multiple products >* |
| **GMDN Code and Term:** | *< GMDN Preferred term name and code (Class 4 non-IHR); OR* *GMDN Collective term name and code (Class 4 IHR, Class 3 IVD);>**<OR See Attached Schedule for the GMDN term name and code of multiple products>* |
| **Scope of Application:** | *< All OR specific batches, lots or serial numbers, OR times of manufacture OR See Attached Schedule for multiple batches, lots or serial numbers …for which the production quality assurance procedures have been applied>* |

For each kind of IVD medical device to which the Production Quality Assurance procedures have been applied the Type Examination procedures have also been applied. The kind of device has been shown to conform to an approved Type and to the applicable classification rules and essential principles before being supplied.

This declaration is being made on the basis of the following certificates:

**Production Quality Assurance Certificate:**

< Assessment Body and Certificate Number:

TGA issued:

Conformity Assessment Certificate(s) - Production Quality Management System; OR

Overseas Certification:

European In Vitro Diagnostic Medical Devices Directive Annex VII certificate(s); OR

ISO 13485:2003 certificate(s); OR

See Attached Schedule for multiple certificates >

**Type Examination Certificate:**

< Assessment Body and Certificate Number:

TGA issued:

Conformity Assessment Certificate(s) – Type Examination; OR

Overseas Certification:

European In Vitro Diagnostic Medical Devices Directive Annex V certificate(s): OR

See Attached Schedule for multiple certificates >

**Conformity Assessment Standards Applied:**

< A standard referenced in a Conformity Assessment Standard Order; OR
TGA-recognised Standard; OR

Other Quality Management System or process Standard; OR
See Attached Schedule if multiple standards have been applied >

#### Authorised signatory:

|  |  |
| --- | --- |
| Name, Position  |  |
| Signature |  | Date |  |