AUSTRALIAN MEDICAL DEVICES
GUIDANCE DOCUMENT NUMBER 5

The Declaration of Conformity

30 October 2003
DISCLAIMER
This document is provided for guidance only. It should not be relied upon to address every aspect of relevant legislation. Please refer to the Therapeutic Goods Act, 1989 and the Therapeutic Goods (Medical Devices) Regulations, 2002 for legislative requirements.

FURTHER INFORMATION
The Medical Devices Information Unit of the Office of Devices, Blood and Tissues of the Therapeutic Goods Administration (TGA) can be contacted by:

Telephone: 1800 141 144
Facsimile: (02) 6232 8299
Email: cab.medical.device.information@health.gov.au
Website: www.tga.gov.au/devices/devices.htm
Mail: PO Box 100
       Woden
       ACT  2606

© Commonwealth of Australia 2003
<table>
<thead>
<tr>
<th>Version Number</th>
<th>Date of Amendment</th>
<th>Summary of Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.6</td>
<td>30 October 2003</td>
<td>Cover page modified watermarks removed from the Attachment 1.</td>
</tr>
</tbody>
</table>
CONTENTS

Disclaimer ..............................................................................................................................................2
Further information.................................................................................................................................2
Amendment schedule ............................................................................................................................3
Introduction ............................................................................................................................................5
What is a declaration of conformity? ....................................................................................................5
Who is responsible for the conformity assessment of a medical device and the declaration of conformity? ........................................................................................................................................6
Choice of conformity assessment procedure and relevant declaration of conformity ..................7
Attachment 1 ..........................................................................................................................................9
INTRODUCTION

This guidance document is one of a series that has been produced to help explain the new regulatory system for medical devices in Australia that commenced on 4 October 2002. The new system has been established by the Therapeutic Goods Act, 1989 as amended by the Therapeutic Goods Amendment (Medical Devices) Bill, 2002 and the Therapeutic Goods (Medical Devices) Regulations, 2002.

Many other guidance documents are available in this series. The series was developed to assist a wide-ranging audience and additional documents can be included if there is enough demand. A separate guidance document is available describing the series.

Although each guidance document has been developed to provide information about particular aspects of the new medical devices regulatory system in Australia, it is expected that a certain amount of cross-referencing to other documents in the series will be inevitable.

WHAT IS A DECLARATION OF CONFORMITY?

As part of the conformity assessment procedures, the manufacturer of a medical device will be required to make a declaration of conformity which, in most cases, declares that the medical device complies with:

- the applicable provisions of the essential principles;
- the classification rules; and
- the conformity assessment procedures;

before being supplied in Australia.

The declaration also requires the manufacturer to provide:

- their name and address;
- details of the:
  - scope of the declaration (including product identification information);
  - certification;
  - classification;
  - nomenclature code;
  - conformity assessment standards (quality management standards); and
  - medical device standards (product standards);

relevant to the conformity assessment procedure and the manufacture of the medical device covered by the declaration.

The essential principles of safety and performance, which apply to all medical devices, are detailed in Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002. There are two main categories. The general principles apply to all devices. The applicability of the principles dealing with design and construction will depend on the intended purpose and properties of the medical device. The essential principles include:
● General Principles
  ○ the use of a medical device must not compromise health and safety
  ○ the design and construction of a medical device has to conform with safety principles
  ○ medical devices are to be suitable for the intended purpose
  ○ long term safety
  ○ medical devices are not adversely affected by transport or storage
  ○ the benefits of medical devices are to outweigh any side effects

● Principles about Design and Construction
  ○ chemical, physical and biological properties
  ○ infection and microbial contamination
  ○ construction and environmental properties
  ○ medical devices with a measuring function
  ○ protection against radiation
  ○ medical devices connected to or equipped with an energy source
  ○ information to be provided with medical devices
  ○ clinical evidence

WHO IS RESPONSIBLE FOR THE CONFORMITY ASSESSMENT OF A MEDICAL DEVICE AND THE DECLARATION OF CONFORMITY?

The responsibility for the classification and the conformity assessment of a medical device rests with the manufacturer of the medical device. The choice of an appropriate conformity assessment procedure, which will be governed by the class of the medical device, is left to the manufacturer. The role of the TGA, or an overseas conformity assessment body, is to issue certification after it has been confirmed that the conformity assessment procedures are appropriate and have been applied. This assessment will vary according to the class of the device.

More information about these requirements can be found in the guidance document titled “Conformity Assessment Procedures”.

Assessment by the TGA is also required for Australian manufacturers of medical devices intended for supply in Australia. In addition, the TGA will undertake assessments of overseas manufacturers when requested by sponsors of imported devices.

The wording of the declaration of conformity will depend on the conformity assessment procedure chosen by the manufacturer.

Templates for each of the six possible types of declarations of conformity have been included as attachments to this guidance document. The italicised comments in the templates enclosed in the brackets “< >” are not template fields but rather provide some indication of the possible options that should appear in the corresponding part of the declaration form.

The manufacturer of the medical device can sign the declaration of conformity or a person authorised by the manufacturer. Evidence of the authorisation may be required for the declaration to be valid.
CHOICE OF CONFORMITY ASSESSMENT PROCEDURE AND RELEVANT DECLARATION OF CONFORMITY

The table below summarises the options available to manufacturers when deciding which conformity assessment procedure and which declaration of conformity is appropriate for each class of medical device. The conformity assessment procedures and declarations of conformity are detailed in the parts and clauses of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Comparisons of Alternatives for Conformity Assessment Procedures and the Required Declarations of Conformity under Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*, for each Class of Medical Device

<table>
<thead>
<tr>
<th>Class or Category of Medical Device</th>
<th>Minimum Conformity Assessment Procedures Alternatives</th>
<th>Declaration of Conformity Required under Schedule 3 of <em>Therapeutic Goods (Medical Devices) Regulations 2002</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Class AIMD</td>
<td>Part 1 (Full Quality Assurance Procedures)</td>
<td>Clause 1.8</td>
</tr>
<tr>
<td></td>
<td>Part 2 (Type Examination Procedures) + Part 3 (Verification Procedures)</td>
<td>Clause 3.5</td>
</tr>
<tr>
<td></td>
<td>Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)</td>
<td>Clause 4.7</td>
</tr>
<tr>
<td>Class III</td>
<td>Part 1 (Full Quality Assurance Procedures)</td>
<td>Clause 1.8</td>
</tr>
<tr>
<td></td>
<td>Part 2 (Type Examination Procedures) + Part 3 (Verification Procedures)</td>
<td>Clause 3.5</td>
</tr>
<tr>
<td></td>
<td>Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)</td>
<td>Clause 4.7</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Part 1 excluding Clause 1.6 (Full Quality Assurance Procedures)</td>
<td>Clause 1.8</td>
</tr>
<tr>
<td></td>
<td>Part 2 (Type Examination Procedures) + Part 3 (Verification Procedures)</td>
<td>Clause 3.5</td>
</tr>
<tr>
<td></td>
<td>Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)</td>
<td>Clause 4.7</td>
</tr>
<tr>
<td></td>
<td>Part 2 (Type Examination Procedures) + Part 5 (Product Quality Assurance Procedures)</td>
<td>Clause 5.7</td>
</tr>
<tr>
<td>Class IIb (sterile)</td>
<td>Part 1 excluding Clause 1.6 (Full Quality Assurance Procedures)</td>
<td>Clause 1.8</td>
</tr>
<tr>
<td></td>
<td>Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)</td>
<td>Clause 4.7</td>
</tr>
</tbody>
</table>
Comparisons of Alternatives for Conformity Assessment Procedures and the Required Declarations of Conformity under Schedule 3 of the Therapeutic Goods (medical Devices) Regulations 2002, for each Class of Medical Device (continued)

<table>
<thead>
<tr>
<th>Class or Category of Medical Device</th>
<th>Minimum Conformity Assessment Procedures Alternatives</th>
<th>Declaration of Conformity Required under Schedule 3 of Therapeutic Goods (Medical Devices) Regulations 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class IIa</td>
<td>Part 1 excluding Clause 1.6 (Full Quality Assurance Procedures) + Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 3 (Verification Procedures) + Part 4 (Production Quality Assurance Procedures) + Part 5 (Product Quality Assurance Procedures)</td>
<td>Clause 1.8 + Clause 6.6 + Clause 6.6 + Clause 6.6 + Clause 6.6</td>
</tr>
<tr>
<td>Class IIa (sterile)</td>
<td>Part 1 excluding Clause 1.6 (Full Quality Assurance Procedures) + Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures)</td>
<td>Clause 1.8 + Clause 6.6</td>
</tr>
<tr>
<td>Class I</td>
<td>Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 3 (Verification Procedures) + Part 4 (Production Quality Assurance Procedures) + Part 5 (Product Quality Assurance Procedures)</td>
<td>Clause 6.6</td>
</tr>
<tr>
<td>Class I (sterile)</td>
<td>Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures) + Part 5 (Product Quality Assurance Procedures)</td>
<td>Clause 6.6</td>
</tr>
<tr>
<td>System or Procedure Packs</td>
<td>Part 7 (Procedures for Medical Devices Used for a Special Purpose)</td>
<td>Clause 7.5</td>
</tr>
</tbody>
</table>
ATTACHMENT 1

Templates for Declarations of Conformity under Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 for:

Clause 1.8
Clause 3.5
Clause 4.7
Clause 5.7
Clause 6.6
Clause 7.5
MANUFACTURER’S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
FULL QUALITY ASSURANCE PROCEDURE

This is a declaration made in accordance with the requirements of Clause 1.8 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>

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:

Medical Device(s): < Unique Product Identifier (eg product name or model number)>
< OR See Attached Schedule for multiple products >

Classification: < Class of Device covered by this Declaration (AIMD, III, IIb, IIa) >
< OR See Attached Schedule for the class of multiple products >

GMDN Code and Term: < Code and Preferred Term >
< OR See Attached Schedule for the GMDN code and term of multiple products >

Scope of Application: < All OR specific or ranges of batches, lots or serial numbers, OR times of manufacture OR See Attached Schedule for multiple batches, lots or serial numbers … to which the approved Full Quality Assurance Procedures have been applied>

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Full Quality Management System Certificate:
< Assessment Body and Certificate Number:
TGA issued:
Conformity Assessment Certificate(s) - Full Quality Management System; OR
Equivalent Overseas Certification:
MRA Conformity Assessment Body Certificate(s); OR
European Medical Devices Directive Annex II without Clause 4 Certificate(s); OR
European Active Implantable Medical Devices Directive Annex II Certificate(s); OR
See Attached Schedule for multiple certificates >

Design Examination Certificate:
< Assessment Body and Certificate Number:
TGA issued:
Conformity Assessment Certificate(s) - Design Examination; OR
Equivalent Overseas Certification:
MRA Conformity Assessment Body Certificate(s); OR
European Medical Devices Directive Annex II Clause 4 Certificate(s); OR
See Attached Schedule for multiple certificates >

Standards Applied: < A standard referenced in a Medical Device Standard Order or a Conformity Assessment Standard Order; OR
European Harmonised Standard; OR
See Attached Schedule for multiple standards >

Authorised Signatory:

_________________________________________________________ ______________________
Name, Position Date
MANUFACTURER’S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

VERIFICATION

This is a declaration made in accordance with the requirements of Clause 3.5 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>

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:

Medical Device(s): < Unique Product Identifier >
< OR See Attached Schedule for multiple products >

Classification: < Class of Device covered by this Declaration (AIMD, III, IIb) >
< OR See Attached Schedule for the class of multiple products>

GMDN Code and Term: < Code and Preferred Term; OR >
< See Attached Schedule for the GMDN Codes and Terms for multiple products >

Scope of Application: < All OR specific or ranges of batches, lots or serial numbers, OR times of manufacture OR See Attached Schedule for multiple batches, lots or serial numbers … to which the verification procedures have been applied>

Each kind of medical device <or batch of devices> to which the Verification Procedures have been applied conforms to an approved Type and complies with the applicable provisions of the essential principles and the classification rules before being supplied. This declaration is being made on the basis of the following certificates:

Type Examination Certificate:
<Assessment Body and Certificate Number:
TGA issued:
Conformity Assessment Certificate(s) - Type Examination; OR
Equivalent Overseas Certification:
MRA Conformity Assessment Body Certificate(s); OR
European Medical Devices Directive Annex III Certificate(s); OR
European Active Implantable Medical Devices Directive Annex III Certificate(s); OR
See Attached Schedule for multiple certificates >

Verification Certificate:
< Assessment Body and Certificate Number:
TGA issued:
Conformity Assessment Certificate(s) - Verification; OR
Equivalent Overseas Certification:
MRA Conformity Assessment Body Certificate(s); OR
European Medical Devices Directive Annex IV Certificate(s); OR
See Attached Schedule for multiple certificates >

Standards Applied: < A standard referenced in a Medical Device Standard Order or a Conformity Assessment Standard Order; OR
European Harmonised Standard; OR
See Attached Schedule for multiple standards >

Authorised Signatory:

------------------------------------------------------------------------------------------------
Name, Position ______________________________ Date ____________________________
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.

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:

Classification: < Class of Device covered by this Declaration (AIMD, III, IIb) >
< OR See Attached Schedule for the class if multiple classes>

GMDN Code and Term: < Code and Preferred Term >
< OR See Attached Schedule for the GMDN Codes and Terms if multiple classes >

Scope of Application: < All OR specific or ranges of batches, lots or serial numbers, OR kinds of medical devices OR times of manufacture OR See Attached Schedule for multiple batches, lots or serial no.s for which the production quality assurance procedures have been applied>

For each kind of 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 provisions of the essential principles and the classification rules before being supplied. This declaration is being made on the basis of the following certificates:

Type Examination Certificate: <Assessment Body and Certificate Number: TGA issued: Conformity Assessment Certificate(s) - Type Examination; OR Equivalent Overseas Certification: MRA Conformity Assessment Body Certificate(s); OR European Medical Devices Directive Annex III Certificate(s); OR European Active Implantable Medical Devices Directive Annex III Certificate(s); OR See Attached Schedule for multiple certificates>

Production Quality Management System Certificate:
< Assessment Body and Certificate Number: TGA issued: Conformity Assessment Certificate(s) - Production Quality Management System; OR Equivalent Overseas Certification: MRA Conformity Assessment Body Certificate(s); OR European 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 European Harmonised Standard; OR Other Quality Management System or process Standard; OR See Attached Schedule if multiple standards have been applied>

Authorised Signatory:

Name, Position Date
MANUFACTURER’S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
PRODUCT QUALITY MANAGEMENT SYSTEM

This is a declaration made in accordance with the requirements of Clause 5.7 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>

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:

Medical Device(s): < Unique Product Identifier >
< OR See Attached Schedule for multiple products >

Classification: Class IIb

GMDN Code and Term: < Preferred Term and Code >
< OR See Attached Schedule for the GMDN Codes and Terms for multiple products >

Scope of Application: < All OR specific or ranges of batches, lots or serial numbers, OR times of manufacture OR See Attached Schedule for multiple batches, lots or serial numbers … to which the product quality assurance procedures have been applied>

For each kind of medical device to which the Product Quality Assurance Procedures has 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 provisions of the essential principles and the classification rules before being supplied. This declaration is being made on the basis of the following certificates.

Type Examination Certificate:
<TGA issued:
Conformity Assessment Certificate(s) - Type Examination; OR
Equivalent Overseas Certification:
MRA Conformity Assessment Body Certificate(s); OR
European Medical Devices Directive Annex III Certificate(s); OR
European Active Implantable Medical Devices Directive Annex III Certificate(s); OR
See Attached Schedule for multiple certificates >

Product Quality Management System Certificate:
<TGA issued:
Conformity Assessment Certificate(s) - Product Quality Management System; OR
Equivalent Overseas Certification:
MRA Conformity Assessment Body Certificate(s); OR
European Medical Devices Directive Annex VI Certificate(s); OR
See Attached Schedule for multiple certificates >

Conformity Assessment Standards Applied:
< A standard referenced in a Conformity Assessment Standard Order; OR
European Harmonised Standard; OR
Other Quality Management System or process Standard >
See Attached Schedule if multiple standards have been applied >

Authorised Signatory:

Name, Position ______________________ Date ______________________
MANUFACTURER’S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

This is a declaration made in accordance with the requirements of Clause 6.6 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.

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:

Medical Device(s): <Unique Product Identifier> <OR See Attached Schedule for multiple products>

Classification: <Class I OR Class I supplied sterile OR Class I with a measuring function OR Class IIa> <OR See Attached Schedule for the class if multiple products>

GMDN Code and Term: <Code and Template Term for Class I, where available> <Code and Preferred Term for Class IIa or where a template term is not available for a Class I product> <OR See Attached Schedule for the GMDN code and term if multiple products>

Scope of Application: <All OR specific or ranges of batches, lots or serial numbers, OR times of manufacture OR See Attached Schedule for multiple batches, lots or serial numbers … to which the Declaration of Conformity (not requiring assessment by the Secretary) Procedure has been applied>

<For Class IIa sterile or Class I sterile>
For each kind of medical device that is supplied sterile and to which the Conformity Assessment Procedures (not requiring assessment by Secretary) have been applied the Production Quality Assurance Procedures have also been applied. Each kind of medical device complies with the applicable provisions of the essential principles and the classification rules before being supplied.

<For Class IIa non-sterile or Class I non-sterile with a measuring function:>
For each kind of medical device to which the Declaration of Conformity (not requiring assessment by Secretary) procedures have been applied the select one: the verification procedures, the production quality assurance procedures; the product quality assurance procedures have also been applied. Each kind of medical device complies with the applicable provisions of the essential principles, the classification rules before being supplied.

<For Class IIa sterile or Class I sterile or Class I with a measuring function:>
<Verification Certificate OR Production / Product Quality Management System Certificate:>

<Assessment Body and Certificate Number:>
eg TGA issued Conformity Assessment Certificate(s)
Verification
Production Quality Management System; OR
Product Quality Management System
Equivalent Overseas Certification:
MRA Conformity Assessment Body Certificate(s); OR
European Medical Devices Directive Annex IV Certificate(s); OR
European Medical Devices Directive Annex V Certificate(s); OR
European Medical Devices Directive Annex VI Certificate(s); OR
See Attached Schedule for multiple certificates>

Standards Applied: <A standard referenced in a Medical Device Standard Order or a Conformity Assessment Standard Order; OR
European Harmonised Standard; OR
See Attached Schedule for multiple standards>

Authorised Signatory:

Name, Position Date
MANUFACTURER’S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
<SYSTEM OR PROCEDURE PACK>

This is a declaration made in accordance with the requirements of Clause 7.5 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated <system or procedure pack or the systems or procedure packs stated in the attached Schedule>.

Reference: <If a schedule is attached, a reference to this declaration must be included in the Schedule>

Manufacturer’s Name: <Person responsible for packaging and labelling>

Business Address:

SYSTEM OR PROCEDURE PACK:
Identification and Contents / Components of each system or procedure pack and each item in the system or procedure pack
< OR See Attached Schedule >

Classification: <Class of System(s) or Class of Procedure Pack(s) covered by this Declaration>
< OR See Attached Schedule >

GMDNS Code and Term: <Template Term and Code for Class I, where available>
< Preferred Term and Code in all other case>
< OR See Attached Schedule for the code and term if multiple products >

Scope of Application: <All OR specific or ranges of batches, lots or serial numbers, OR kinds of medical devices OR times of manufacture OR See Attached Schedule >

Medicine Registration or Listing: <AUSTR or AUSTL numbers for each medicine included in the system or procedure pack>

Other Registration of Listing: <AUSTR or AUSTL numbers for any other therapeutic good included in the system or procedure pack>

Each kind of medical device included the above <system(s) OR procedure pack(s)> have been subject to the relevant conformity assessment procedures by the manufacturer of the medical device and each medical device included in the <system(s) OR procedure pack(s)> has been shown by its manufacturer to comply with the applicable provisions of the essential principles.

Each medical device in the <system(s) OR procedure pack(s)> is intended to be used for its original intended purpose and each medicine or other therapeutic goods in the package is intended to be used within the approved indications for use specified by the manufacturer of those items.

The mutual compatibility of each medical device, medicine or other therapeutic goods, and any other goods, in the package has been verified in accordance with any instructions for use provided by the manufacturer of each item or the approved indications for use of each item.

Where applicable, the system or procedure pack has been manufactured in accordance with the original manufacturer’s instructions (if any) or indications.

The information supplied with the system or procedure pack for the use of the system or procedure pack includes instructions for use provided by the manufacturer of each item in the package.

The process of manufacturing the system or procedure pack, and the verification and packaging of the system or procedure pack, has been subjected to a documented method of internal control and inspection that ensures the safety, quality, performance and effectiveness of each item in the package.

<For a system(s) or a procedure pack(s) that contains items that are sterilised by the manufacturer of the system or procedure pack>

For each kind of medical device that is sterilised by the manufacturer of the system or procedure pack the production quality assurance procedures (other than Schedule 3 Clause 4.7) have been applied to the system or procedure pack in accordance with the manufacturer’s instructions for use, or the approved indications for use, of each item in the package.
Production Quality Management System Certificate:
< Assessment Body and Certificate Number:
TGA issued:
Conformity Assessment Certificate(s) - Production Quality Management System; OR
Equivalent Overseas Certification:
MRA Conformity Assessment Body Certificate(s); OR
European 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
European Harmonised Standard; OR
Other Quality Management System or process Standard >
See Attached Schedule if multiple standards have been applied >

Authorised Signatory:

Name, Position --------------------------------- Date ---------------------------------