PORTLAND ORTHOPAEDICS™

Portland Orthopaedics Limited
ABN 92 086 839 992

Unit 3, 44 McCauley Street
Matraville NSW 2036 Australia
Phone: +61 2 9666 8444
Fax: +61 2 9666 8544
Email: info@margron.com

30 a

21 September 2005

This letter added to the file at a later stage.
Rod Ferrari.

Rod Ferrari
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609
Australia

Dear Rod,

RE: CA & CE assessment reference number: DV-2005-4494

Please find included the documents required by the supplemental information form for Conformity Assessment and CE marking. The completed form appears in section 1 of folders 2 & 3. Please contact me should you require any further information or clarification.

The 3 folders contain the following information:

Folder 1: Quality Management System documents (1 copy)
Folder 2 & 3 : Technical Documentation (2 copies)

As a reminder, in our upcoming audit we wish to include the following certifications:

- Conformity Assessment
- CE marking
- Compliance with ISO 13485
- Approval for new product (Equator Plus Cup)

Yours Faithfully

David Sekel
CEO

Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

SUPPLEMENTAL INFORMATION REQUIRED FOR AN APPLICATION FOR A CONFORMITY ASSESSMENT CERTIFICATE AND AN EC CERTIFICATE OF CONFORMITY

26 May 2005

TGA Use only

Submission ID	

29

WHY DO I NEED TO COMPLETE THIS FORM?

This form seeks further information about the device, the manufacturer and the manufacturer's quality management system. This information will allow the TGA to undertake an appropriate assessment of the manufacturer's quality management system and claim of compliance to the Australian Essential Principles and European Essential Requirements (where CE Marking has been applied for). There is a special definition of who is a manufacturer in the *Therapeutic Goods Act, 1989*.

This form **must be completed by the *manufacturer*** applying for the Conformity Assessment Certificate (CA Certificate). This includes the Declaration (Section 6) and the Fit and Proper Person Certification (Sections 7 & 8). If the manufacturer is not Australian, then an Australian representative may liaise with the TGA on their behalf (see Section 10), but this form still needs to be completed and signed by the manufacturer.

Further assistance in applying for a Conformity Assessment Certificate and/or EC Certificate can be found in the accompanying document titled: *Guide for Applying for TGA CA & EC Certificates*.

1.0 MANUFACTURER CONTACT DETAILS

Manufacturer Name:	Portland Orthopaedics Limited
Contact Person:	Ronnie Eshel
Address: (including country if not Australia)	Unit 3 / 44 McCauley St Matraville, 2036 NSW
Telephone:	02-9666 8444
Facsimile:	02-9666 8544
Email:	info@portland-orthopaedics.com
ABN: (applicable only in Australia)	92 086 839 992
TGA Client ID Number	32827

2.0 CERTIFICATION SOUGHT

Is this application for a new CA/CE Certification or is it a change to an existing CA/CE Certificate? New ✓ Change ✓ (please quote existing certificate number below)

2.1 CONFORMITY ASSESSMENT CERTIFICATION

		Existing TGA Certificate Number
Schedule 3, Part 1 – Full Quality Assurance (excluding Part 1.6)	✔	Licence No 151126
Schedule 3, Part 1.6 – Examination of Design	☐	
Schedule 3, Part 2 – Type Examination	☐	
Schedule 3, Part 3 – Verification Procedure (non-sterile only)	☐	
Schedule 3, Part 4 – Production Quality Assurance	☐	
Schedule 3, Part 5 – Product Quality Assurance (non-sterile only)	☐	

Is the manufacturer ready for assessment and audit against the Australian Regulatory requirements of the *Therapeutic Goods Act, 1989* and the *Therapeutic Goods (Medical Devices) Regulations, 2002*?	Yes ✓ No ☐

2.2 CE CERTIFICATION

		Existing TGA Certificate Number
Annex II.4	☐	
Annex II (excluding Clause II.4)	✔	MRA Q00018/01
Annex III	☐	
Annex IV	☐	
Annex V	☐	
Annex VI	☐	

Is the manufacturer ready for assessment and audit against the European Regulatory requirements of the Medical Devices Directive (93/42/EEC)?	Yes ✓ No ☐

27

3.0 DEVICE DETAILS

NOTE: Photocopy this page, as required, if making an application for more than one device.

Device Name (please include *variant* details and model or catalogue numbers)	GMDN Code (for the GMDN 'preferred term')	Australian Classification	Schedule 2 Australian classification rule used
Margron Hip Replacement Catalogue numbers: 2-731-005, 2-731-006, 2-731-007 2-731-008 2-662-201,2-662-202, 2-731-017, 2-731-018, 2-662-203,2-662-204,,2-662-205,2-662-206, 2-662-207,2-662-208,2-662-209 1-726-000, 1-727-000, 1-647-000, 1-648-000, 1-649-000,1-650-000,1-651-000,1-652-000, 1-653-000,2-730-061,2-730-062,2-730-071, 2-730-072,2-662-011,2-662-012,2-662-021, 2-662-022,2-662-031,2-662-032,2-662-041, 2-662-042,2-662-051,2-662-052,2-662-061, 2-662-062,2-662-071,2-662-072 1-746-000,1-747-000 1-750-000,1-654-000,1-656-000,1-658-000, 1-686-000,1-687-000,1-688-000,1-689-000, 1-690-000, 1-685-000 2-730-061,2-730-062,2-730-963,2-730-964, 2-730-965,2-730-071,2-730-072, 2-730-973, 2-730-974, 2-730-975 2-662-011, 2-662-012, 2-662-913, 2-662-914, 2-662-915, 2-662-021, 2-662-022, 2-662-923, 2-662-924, 2-662-925, 2-662-031, 2-662-032, 2-662-933, 2-662-934, 2-662-935, 2-662-041, 2-662-,42,2-662-943, 2-662-944, 2-662-945, 2-662-051, 2-662-052, 2-662-953, 2-662-954, 2-662-955, 2-662-956, 2-662-061,2-662-062, 2-662-963, 2-662-964, 2-662-965, 2-662-966, 2-662-071,2-662-072	**GMDN 35-666**	Class IIb	4.3

Brief Description of the Device:
(this should include the physical size)

A component of a total hip joint prosthesis that is used to replace the femoral neck and stem. The device is made of metal and is modular. The Margron is designed to be used without bone cement.

Intended Purpose for the Device:

The Margron™ Hip Replacement System is intended for primary or revision reconstruction, without bone cement, of the femoral portion of a severely disabled and/or very painful hip joint, where radiographic evidence of sufficient sound bone is present.

For devices incorporating ancillary medicinal substances or potentially infective material, please complete the following:

Device:		If yes, please identify substance(s)
Does the device incorporate a medicinal substance that has an action that is ancillary to the device?	Yes ☐ No ✓	
Does the device incorporate an extract from human blood or human plasma that has an action that is ancillary to the device?	Yes ☐ No ✓	
Does the device incorporate material or substances of animal origin or, was manufactured using materials of animal origin?	Yes ☐ No ✓	
Does the device incorporate material or substances of microbial origin, or was manufactured using materials of microbial origin?	Yes ☐ No ✓	
Does the device incorporate material or substances produced using recombinant technology?	Yes ☐ No ✓	

15

DEVICE DETAILS

NOTE: Photocopy this page, as required, if making an application for more than one device.

Device Name (please include *variant* details and model or catalogue numbers)	GMDN Code (for the GMDN 'preferred term')	Australian Classification	Schedule 2 Australian classification rule used
Equator Plus Cup System Catalogue Numbers: 1-810-144 1-810-146 1-810-148 1-810-150 1-810-152 1-810-154 1-810-156 1-810-158 1-810-160 1-810-162 1-810-164 1-810-166 1-810-168 1-810-170 1-810-244 1-810-246 1-810-248 1-810-250 1-810-252 1-810-254 1-810-256 1-810-258 1-810-260 1-810-262 1-810-264 1-810-266 1-810-268 1-810-270 1-804-133 1-804-134 1-804-135 1-804-136 1-804-137 1-804-155 1-804-156 1-804-157 1-804-176 1-804-177 1-804-233 1-804-234 1-804-235 1-804-236 1-804-237 1-804-255 1-804-256 1-804-257 1-804-276 1-804-277 1-806-132 1-806-133 1-806-134 1-806-135 1-806-136 1-806-137 1-806-154 1-806-154 1-806-155 1-806-156 1-806-157 1-806-177 1-806-177 1-812-115 1-812-120 1-812-125 1-812-130 1-812-135 1-812-140 1-812-145 1-812-150 1-813-110 1-813-265	35-661	Class IIb	4.3

Brief Description of the Device:
(this should include the physical size)

The Equator Plus™ Acetabular Cup System is to be used as part of a modular total hip replacement system. The Equator Plus™ Acetabular Cup System is comprised of these units: the first is a porous coated outer shell manufactured from titanium alloy (Ti-6Al-4V); the second unit is either a ultra high molecular weight polyethylene (UHMWPE) liner force fitted into an outer cobalt chrome metal dome casing (provided as a single pre-assembled component) or an alumina ceramic surrounded by a cobalt chrome ring (and is provided as a single pre-assembled component). Bone screws may be used to assist in fixation

Intended Purpose for the Device:

The Equator Plus Hip Acetabular Cup System is intended for primary reconstruction of the acetabular portion of a severely disabled and/or very painful hip joint, where radiographic evidence of sufficient sound bone is present.

For devices incorporating ancillary medicinal substances or potentially infective material, please complete the following:

Device:

		If yes, please identify substance(s)
Does the device incorporate a medicinal substance that has an action that is ancillary to the device?	Yes ☐ No ✓	
Does the device incorporate an extract from human blood or human plasma that has an action that is ancillary to the device?	Yes ☐ No ✓	
Does the device incorporate material or substances of animal origin or, was manufactured using materials of animal origin?	Yes ☐ No ✓	

Does the device incorporate material or substances of microbial origin, or was manufactured using materials of microbial origin?	Yes ☐ No ✓	
Does the device incorporate material or substances produced using recombinant technology?	Yes ☐ No ✓	

23

4.0 MANUFACTURER AND SUPPLIER DETAILS

4.1 Manufacturer's Facility

Manufacturer's Facility Name:	Portland Orthopaedics Limited
Facility Address:	Unit 3 / 44 McCauley St Matraville, 2036 NSW
Management Representative: (name & position)	David Sekel CEO
N° of employees at this facility:	12
Hours of operation:	7am – 10pm
Volume of product supplied by manufacturer (per annum):	35-666 1000 units 35-661 1000 units
TGA Client ID:	32827

Does the manufacturer's facility have any existing Regulatory Certification ***other than*** a TGA issued Conformity Assessment Certificate? Yes ☐ No ☑

(Note: certificate must be issued to the manufacturer identified with the same name and address as above)

If yes, please provide the following details:

TGA Licence or GMP Certificate of Manufacturers Facility:

Licence Number	Scope of Licence	Date of last audit
151126	Manufacture of a single therapeutic good for human use	20/2/2002

CE (Europe) & CMDCAS (Canada) Certification:

Certificate N°	Cert Type (eg: MDD Annex N° or QMS Standard used)	Scope of Certificate	Issuing Body	Date of last audit
MRA Q00018/01	MDD annex II section 3 with exemption of section 4	Design, manufacture and final control of GMDN 35-66	TGA (0805)	20/2/2002

Does the manufacturer have any existing voluntary Quality System Certification? Yes ☐ No ☑
(Note: certificate must be issued to the manufacturer identified with the same name and address as above)

If yes, please provide the following details:

Certificate N°	Cert. Type (standard issued against)	Scope of Certificate	Issuing Body	Date of last audit

4.2 Key Facilities & Suppliers

Please indicate, by completing the table provided on the next page, whether the critical steps in the manufacturing stages listed below are undertaken by the manufacturer or are subcontracted to key suppliers. Furthermore, if the manufacturer has multiple manufacturing sites, please indicate the facility where the manufacturing step is carried out.

- **Design**

  Indicate which design activities are undertaken by the manufacturer and which activities are subcontracted to key suppliers. Such activities include identifying design inputs; developing the design; reviewing the design or verifying & validating that design meets specified inputs. **NB: if this application is for a Part 1 *Full Quality Assurance* certificate this stage must be addressed in the table.**

- **Production**

  Indicate which steps of the product realisation process, including testing and inspection, are carried out by the manufacturer and which steps are subcontracted to key suppliers.

- **Sterilisation**

  Indicate which steps of the sterilisation process, including process planning and validating, are carried out by the manufacturer and which steps are subcontracted to key suppliers. **NB: if the device is to be supplied sterile this stage must be addressed in the table.**

- **Packaging**

  Indicate whether the manufacturer or a key supplier packages the device(s) into its final packaging, that is, the packaging it is presented to the manufacturer's customer in.

- **Labelling**

  Indicate whether the manufacturer or a key supplier labels the device with the manufacturer's details.

- **Final Release**

  Indicate whether the manufacturer or a key supplier releases the device(s) for supply.

- **Warehousing & dispatch**

  Indicate whether the manufacturer or a key supplier stores the device(s) prior to, and dispatches the device(s) for supply.

Where the steps involved with a particular manufacturing stage are carried out by a number of key suppliers, or by the manufacturer and a number of key suppliers then provide a brief description of the step(s) undertaken by each entity. **NB:** Key suppliers act under the direction of the manufacturer.

If all steps for a particular manufacturing stage are undertaken by the manufacturer at a single facility, or by a single key supplier, it is sufficient to identify the manufacturer's facility, or the key supplier, and indicate that 'all steps' of the manufacturing stage are undertaken at this facility, or by this key supplier; it is not necessary to further identify all the steps.

Please address all applicable manufacturing stages listed above.

21

(Photocopy this page as required)

Manufacturing Stage (design, production, sterility, packaging, labelling, final release and warehousing & dispatch)	**Manufacturer's Facility or Key Supplier Involved**	**Brief Description of Step**
Design, prototype, production, packaging, marking labelling, final release, warehousing and dispatch	Portland Orthopaedics Limited	All manufacture is conducted within ISO13485
Production Crack Testing	HVT Inspection Service	Crack testing of machined parts
Production Hydroxy-Apatite coating	United Surface Technologies	Application of Hydroxy-Apatite coating on Margron Femoral Stem & Modular Extension Components
Production Hydroxy-Apatite testing	Molten Splat Pty. Ltd	Chemical & Physical testing of Hydroxy-Apatite
Production Plasma Porous Coating	Engelhard	Plasma spray porous coating on Equator Plus exterior shell
Production Ceramic Liners	CeramTec AG	Produce ceramic liners
Production Polyethylene inserts	MediTECH -	Produce Polyethylene inserts
Production & Packaging Bone Screw	Australian Surgical Design & Manufacture (ASDM)	Produce Bone Screws
Sterilisation	Steritech Limited	Gammar Irradiation and Ethylene Oxide of single use implants are processed at this facility. Dosimeter reading (Wetherill Park)
Sterilisation Biological Testing	ams Laboratories	Micro - Biological Testing

4.3 Details of Key Suppliers

(Photocopy this page as required)

Details of Key Suppliers

(Photocopy this page as required)

Supplier's Name:	HVT
Address:	Unit 3 9-11 Cullen Place Smithfield NSW 2164
Management Representative: (name & position title)	Jim Lloyd QA
N° of employees at this address:	15
Hours of operation:	7am - 4pm
Volume of work performed for manufacturer (per annum):	10 batches per annum approximately 100 units per batch
TGA Client ID (if available):	

If applicable, please provide details of the supplier's existing regulatory and quality system certification as taken into account by the manufacturer during an evaluation of the supplier. Such certification could include a TGA licence, a GMP Certificate of Manufacturer's Facility issued by the TGA, an EC or CMDCAS certificate or voluntary quality system certificates issued by an accredited third party organisation.

NAT certificate #2282 for ISO17025(1999)

19

Details of Key Suppliers

(Photocopy this page as required)

Supplier's Name:	United Surface Technologies
Address:	26-32 Aberdeen Rd Altona Vic 3018
Management Representative: (name & position title)	Richard Moore General Manager
N° of employees at this address:	30
Hours of operation:	7am – 5pm
Volume of work performed for manufacturer (per annum):	4 batches per annum approximately 100 units per batch
TGA Client ID (if available):	22922

If applicable, please provide details of the supplier's existing regulatory and quality system certification as taken into account by the manufacturer during an evaluation of the supplier. Such certification could include a TGA licence, a GMP Certificate of Manufacturer's Facility issued by the TGA, an EC or CMDCAS certificate or voluntary quality system certificates issued by an accredited third party organisation.

ISO9002:1994 from Quality Assurance Services

Details of Key Suppliers

(Photocopy this page as required)

Supplier's Name:	Molten Splat
Address:	55 Gissing St Blackburn South ViC 3130
Management Representative: (name & position title)	Karlis Gross Managing Director
N° of employees at this address:	1
Hours of operation:	9am-5pm
Volume of work performed for manufacturer (per annum):	10 batches per annum
TGA Client ID (if available):	

If applicable, please provide details of the supplier's existing regulatory and quality system certification as taken into account by the manufacturer during an evaluation of the supplier. Such certification could include a TGA licence, a GMP Certificate of Manufacturer's Facility issued by the TGA, an EC or CMDCAS certificate or voluntary quality system certificates issued by an accredited third party organisation.

[x]

Details of Key Suppliers

(Photocopy this page as required)

Supplier's Name:	Engelhard Corporation Inc
Address:	12 Thompson Road East Windsor Connecticut Phone #: ++ 1 860 6239901
Management Representative: (name & position title)	Marc Froning Engineering Manager
N° of employees at this address:	1000
Hours of operation:	6am – 7pm
Volume of work performed for manufacturer (per annum):	3 batches per annum
TGA Client ID (if available):	

If applicable, please provide details of the supplier's existing regulatory and quality system certification as taken into account by the manufacturer during an evaluation of the supplier. Such certification could include a TGA licence, a GMP Certificate of Manufacturer's Facility issued by the TGA, an EC or CMDCAS certificate or voluntary quality system certificates issued by an accredited third party organisation.

ISO 9001:2000
AS9100:2004 Rev b
Issued by LRQA

Details of Key Suppliers

(Photocopy this page as required)

Supplier's Name:	CeramTec AG
Address:	Fabrikstrasse 23 - 29 D-73207 Plochingen Tel.: +49 (0)7153 / 6 11-0 Fax: +49 (0)7153 / 2 54 21
Management Representative: (name & position title)	Paul Silberer Business Manager Export
N° of employees at this address:	600
Hours of operation:	8am – 5:30pm
Volume of work performed for manufacturer (per annum):	
TGA Client ID (if available):	28492

If applicable, please provide details of the supplier's existing regulatory and quality system certification as taken into account by the manufacturer during an evaluation of the supplier. Such certification could include a TGA licence, a GMP Certificate of Manufacturer's Facility issued by the TGA, an EC or CMDCAS certificate or voluntary quality system certificates issued by an accredited third party organisation.

15

Details of Key Suppliers

(Photocopy this page as required)

Supplier's Name:	MediTECH
Address:	2710 American Way Fort Wayne, Indiana 46809 U.S.A. Phone: 260-479-4387 Fax: 260-478-1074
Management Representative: (name & position title)	Lou Matrisciano Development Manager
N° of employees at this address:	300
Hours of operation:	6:30 am – 4pm
Volume of work performed for manufacturer (per annum):	3 batches per annum
TGA Client ID (if available):	

If applicable, please provide details of the supplier's existing regulatory and quality system certification as taken into account by the manufacturer during an evaluation of the supplier. Such certification could include a TGA licence, a GMP Certificate of Manufacturer's Facility issued by the TGA, an EC or CMDCAS certificate or voluntary quality system certificates issued by an accredited third party organisation.

MediTECH is are the largest UHMWPE supplier to the orthopaedic industry, supply product used by all 5 of the top Implant manufacturers (Zimmer, Stryker, DePuy, Biomet, S&N). They have provided us a copy of their Quality Manual and are in the process of applying for accreditation of their quality systems.

Details of Key Suppliers

(Photocopy this page as required)

Supplier's Name:	Australian Surgical Design & Manufacture (ASDM)
Address:	PO Box 72 St Leonards NSW 2065 Tel: (02) 9522 2300
Management Representative: (name & position title)	Graham Blucher QA Manger
N° of employees at this address:	60
Hours of operation:	6:30am – 5:30 pm
Volume of work performed for manufacturer (per annum):	1 batch per annum
TGA Client ID (if available):	23077

If applicable, please provide details of the supplier's existing regulatory and quality system certification as taken into account by the manufacturer during an evaluation of the supplier. Such certification could include a TGA licence, a GMP Certificate of Manufacturer's Facility issued by the TGA, an EC or CMDCAS certificate or voluntary quality system certificates issued by an accredited third party organisation.

13

Supplier's Name:	Steritech Limited
Address:	5 Widemere Road Wetherill Park NSW 2164 Phone #: 02 9609 5566
Management Representative: (name & position title)	Jeremy Piggott Regulatory Affairs Manager
N° of employees at this address:	50
Hours of operation:	24 hours
Volume of work performed for manufacturer (per annum):	2000 units
TGA Client ID (if available):	12892

If applicable, please provide details of the supplier's existing regulatory and quality system certification as taken into account by the manufacturer during an evaluation of the supplier. Such certification could include a TGA licence, a GMP Certificate of Manufacturer's Facility issued by the TGA, an EC or CMDCAS certificate or voluntary quality system certificates issued by an accredited third party organisation.

TGA licence for sterilisation licence number: 80

Details of Key Suppliers

Supplier's Name:	ams Laboratories
Address:	118 Hattersley Street Rockdale NSW 2216
Management Representative: (name & position title)	Paul Priscot Managing Director
N° of employees at this address:	5
Hours of operation:	8am - 5pm
Volume of work performed for manufacturer (per annum):	100 units
TGA Client ID (if available):	26145

If applicable, please provide details of the supplier's existing regulatory and quality system certification as taken into account by the manufacturer during an evaluation of the supplier. Such certification could include a TGA licence, a GMP Certificate of Manufacturer's Facility issued by the TGA, an EC or CMDCAS certificate or voluntary quality system certificates issued by an accredited third party organisation.

TGA licence: 11808

5.0 SUPPORTING DATA CHECKLIST

or the quality management system (all device classes):	**Supplied**	**Location in Supporting Data**
1. Latest version of the Quality Manual (ISO 13485:2003, clause 4.2.2) **Note:** this must include at least a reference to documented procedures.	✓	(Folder 1) Section 1 MANL-001
2. Organisational Chart	✓	(Folder 1) Section 2 Org Chart
3. Quality planning documentation (ISO 13485:2003, clauses 5.4.2, 4.2.1 & 7.1 note 1)	✓	(Folder 1) Section 3 PROC-010, PROC-011, PROC-015
4. Product requirements (specifications) for the product	✓	(Folder 1) Section 4 SGHP-001, SGHP-002, SGHP-003, SGHP-004 SGHP-005, SGHP-006, SGHP-007, SGHP-008
5. Purchasing procedures and records of supplier evaluation for critical suppliers (ISO 13485:2003 Clause 7.4.1)	✓	(Folder 1) Section 5 PROC-009, PROC-018
6. Plan of facilities	✓	(Folder 1) Section 6
7. Reports of critical processes that are required to be validated (ISO 13485:2003, clause 7.5.2.1)	✓	(Folder 1) Section 7 Various
8. Procedure for a feedback system (ISO 13485:2003 Clause 8.2.1, Regulations for post-marketing requirements)	✓	(Folder 1) Section 8 PROC-001, PROC-003
9. Procedure for the issue and implementation of advisory notices & notification of adverse events (ISO 13485 Clause 8.5.1, Uniform recall procedure for therapeutic goods)	✓	(Folder 1) Section 9 PROC-004, PROC-003 (See Section 8)

***And** For Class IIb, IIa, Is and Im devices:*

10. Completed essential principles checklist (Australian Medical Devices Guidance Doc. 22) **Note:** include a separate Essential Requirements checklist (for either the AIMDD or MDD) if EC Certification is required.	✓	Folder 2 & 3 Section 2 EP for RF-012 Equator Plus Cup STED 050819
11. Risk management report (ISO 14971:2000, clause 8)	✓	Folder 2 & 3 Section 3 RSK-003-03 Risk Analysis for Margron Acetabular Cups .pdf
12. Clinical evidence (EP14, Reg 3.1, Sch3 Prt8, Australian Medical Devices Guidance Doc. 4)	x	Not yet available
13. Labelling, instructions for use & advertising material	✓	Folder 2 & 3 Section 4 Labels

***Or** for Class III or AIMD devices:*

14. Compilation of Quality Management System Design and Development records showing conformity to essential principles (Clause 7.3 – ISO 13485: 2003 - Design Dossier)	☐	N/A

***AND** for all device classes:*

15. Fit and proper person certification (see sections 7 & 8 of this form) signed and completed.	✓	Folder 2 & 3 Section 1

		Supplemental Information Form for CA & CE

***AND** for all devices containing medicinal substance(s):*

16. A statement which indicates whether the medicinal substance(s) have been previously used in therapeutic goods supplied in Australia and whether Drug Master File(s) have been submitted to the TGA	☐	N/A
17. If Drug Master File(s) have been submitted to the TGA, then you will need to include a letter from the Drug supplier which gives the TGA authorisation to use the Drug Master File for the purpose of assessing your application.	☐	N/A

***AND** for all devices containing material of animal origin:*

18. Quality system records of the assessment, evaluation and control of the subcontractors which source you with materials of animal origin	☐	N/A
19. Copies of quality system procedures to show that the principles laid in Conformity Assessment Standard Order No 2 have been put in place in your manufacturing operation	☐	N/A
20. Samples of quality system records to demonstrate that the principles in Conformity Assessment Standard Order No 2 are applied and are relevant to the suppliers of materials of animal origin	☐	N/A
21. If the source suppliers of materials of animal origin hold current certifications by pertinent national authorities, copies of such certification	☐	N/A

***AND** for sterile manufacture:*

22. If reference is to be made to a sterilisation masterfile, the TGA reference for the assessment of the masterfile	☐	N/A
23. Sterilisation validation reports (ISO 13485:2003, clause 7.5.2.2)	✓	Folder 2 & 3 Section 5

6.0 APPLICATION DECLARATION

All manufacturers to sign.

I declare that the information given in this form is current and correct and I acknowledge the following (extracted from Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*):

I acknowledge the need to:

- Apply the Australian classification rules for medical devices and apply an appropriate Australian Conformity Assessment procedure based on the class of the products to be manufactured
- keep the following records in relation to the system and the kind of device:
  - the documentation which includes:
    - manufacturer's quality objectives
    - the organisation of the manufacturer's business
    - the design of the kind of medical device
    - for a device that is intended by the manufacturer to be connected to another device – evidence that the device will comply with the applicable provisions of the essential principles when it is connected to the other device and both devices are used for their intended purposes
    - a statement indicating whether or not the device incorporates a substance mentioned in Clause 7.4 of the essential principles (medicinal substance)
    - a statement indicating whether or not the device contains tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin
    - a copy of the clinical evidence
    - a copy of the information to be provided with the kind of device
  - details of any changes made to the quality system and to the information and documentation which includes:
    - name and address of the manufacturer
    - details of each manufacturing site where the system is to be applied
    - all relevant information about the kind of medical devices to which the system is to be applied
    - the documentation in relation to the system
    - an undertaking by the manufacturer to continue to comply with the requirements of the system after assessment
    - an undertaking by the manufacturer to ensure that the system is at all times adequate and efficacious
    - an undertaking by the manufacturer to notify the Secretary, or the person in relation to whom the kind of device is included in the Register of the following information:
      - any malfunction or deterioration in the characteristics or performance of the device; or
      - any inadequacy in the design, production, labelling or instructions for use of the kind of device, or in the advertising material for the kind of device; or
      - any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

      that might lead, or might have led, to the death of a patient or user of the device, or to a serious deterioration in his or her state of health; and
      - information relating to any technical or medical reason for a malfunction or deterioration in the characteristics or performance of the device that has led

the manufacturer to take steps to recover devices of that kind that have been distributed

- if the device is a Class AIMD medical device or Class III medical device, the following information in writing:
  - the design
  - the production processes
  - the intended performance
- details of any changes made to the kind of medical device and to the following documentation in relation to the design of the device:
  - the manufacturer's quality objectives
  - the organisation of the manufacturer's business
  - the design of the kind of medical device
  - for a device that is intended by the manufacturer to be connected to another device – evidence that the device will comply with the applicable provisions of the essential principles when it is connected to the other device and both devices are used for their intended purposes
  - a statement indicating whether or not the device incorporates a substance mentioned in Clause 7.4 of the essential principles
  - a statement indicating whether or not the device contains tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin
  - a copy of the clinical evidence
  - a copy of the information to be provided with the kind of device
  - **the Australian declaration of conformity (showing the UPI, Class and GMDNS code)**
  - details of the systematic review carried out, post- production, in relation to medical devices of that kind any notice, report, certificate or other document in relation to the system issued to the manufacturer by the Secretary.
  - notify the Secretary of any substantial change to the quality system, or to the kinds of devices to which the quality system is to be applied; and
  - arrange for assessment of any such change by the Secretary; and
  - to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.
  - Keep the records for at least 5 years after the manufacture of the last medical device to which the quality management system was applied
  - On request from the Secretary, make the records available to the Secretary

Authorised Signature:	
Name (please print):	David Sabel
Date:	21/9/05

7

7.0 FIT AND PROPER PERSON UNDER SECTIONS 41EC AND 41ET OF THE *THERAPEUTIC GOODS ACT 1989*

Section 41EC of the *Therapeutic Goods Act 1989 (the Act)* was amended in 2003 to provide that, in addition to the existing requirements, the Secretary must consider whether the applicant for a conformity assessment certificate is a fit and proper person. Further, the Secretary must consider whether all persons who participate in or are likely to participate in managing the affairs of an applicant for a conformity assessment certificate, or otherwise have effective control, or are likely to have effective control, over the applicant, are fit and proper persons.

Section 41ET of the Act was also amended to expand the circumstances for suspending or revoking a conformity assessment certificate. A conformity assessment certificate can be suspended or revoked if the holder of the certificate, or any of the persons who participate in or are likely to participate in managing the affairs of, or otherwise has, or is likely to have, effective control over the holder of the certificate, ceases to be a fit and proper person.

Manufacturers applying for conformity assessment certificates are therefore required to complete the certification titled (Section 8.0 of this form):

CERTIFICATION IN RELATION TO THE MANUFACTURER AND OTHER PERSONS INVOLVED WITH THE APPLICATION FOR A CONFORMITY ASSESSMENT CERTIFICATE

FIT & PROPER PERSON CERTIFICATION
SENT TO F & PP UNIT ON 25 Oct. 05.

25/10/05