TGA Therapeutic Goods Administration

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Commonwealth Department of
Health and
Family Services

Dr Ronald Sekel
Portland Square Pty Ltd
St George Private Hospital Medical Centre
Suite 3, Level 5
1 South Street
Kogarah NSW 2217

Dear Dr. Sekel

RE: Request for information on Conformity Assessment for CE Marking of Medical Devices

Under the recently signed Mutual Recognition Agreement (MRA)[1], the TGA has the authority to undertake conformity assessment against the requirements of the European Medical Device Directives or Active Implantable Medical Device Directive as required. An Australian or New Zealand manufacturer may make a "Declaration of Conformity" and legally affix the CE mark when the TGA has issued the required certifications for the product.

Before making a request for an estimate, if you have not already carried out these steps, I would make the following suggestions, for example, for any device that falls under the definition of a 'medical device' as given in the European Directive 93/42/EEC:

1. Obtain a copy of the Medical Devices Directive (93/42/EEC) from -

Hunter Publications	Hunter Publications
58A Gipps Street	PO Box 404
Collingwood VIC 3066	Abbotsford VIC 3064
Tel: +61 3 9417 5361	Fax: +61 3 9419 7154

2. Identify the products that you wish to CE Mark and prepare a statement of intended use for each.
3. Ensure that the products meet the definition of a medical device as defined in Article 1(2) of the Directive.
4. Familiarise yourself with the classification rules of Annex IX and classify the products that you have chosen.
5. Based on the classification, select a route to conformity from Article 11 of the Directive.
6. Refer to the appropriate Annex and follow the defined procedure. A conformity assessment body (TGA) will need to be involved in the certification under any of the Annexes II to VI. Please note that non-sterile, non-measuring function Class I devices are outside the scope of the MRA.

[1] Mutual Recognition Agreement in relation to Conformity Assessment, Certificates and Marking between the European Community and Australia.

A technical file must be prepared for a medical device before the device can be assessed and certification given to allow a CE mark to be affixed. Manufacturers must also implement quality systems control over their manufacturing activities. Instructions for the preparation of a technical file and quality system requirements are described in the relevant Annexes of the Directive.

Once a device has been classified, a route to conformity may be chosen. Each route requires a technical file to be prepared and may require a quality system to be established. A pre-assessment application may be made when all of these elements have been finalised. As there is no application form at this stage, a pre-assessment application will be accepted if the following is provided in writing:

1. Name, address and contact details of the Australian/New Zealand manufacturer who will be placing the device on the European market.

2. A brief description of the device including:
   - Intended use and how it is achieved;
   - All accessory or system components and their interaction. (Indicate if any of the system components have a CE mark or is the subject of an active application for conformity assessment with a notified body);
   - The device technologies used (materials, components etc).
   - The manufacturing technologies used (sterilisation, injection moulding etc);
   - Location and main activities undertaken at the manufacturing site(s);

3. A declaration that the product or quality systems to be assessed is not the subject of a current application for conformity assessment with a notified body.

4. Device classification.

5. Annexes chosen by the manufacturer for the conformity assessment procedures (ie Annexes II-VI of the MDD)

6. Complete the attached Essential Requirements Checklist indicating:

   - the MDD Annex I or AIMDD Annex 1 essential requirements that have or have not been applied and the reason why they have been applied.
   - the MDD article 5 Standards, AIMDD Article 5 Standards, European Norms, International Standards, European National Standards, and third country Standards or Manufacturers procedures that have been applied.

There is no pre-assessment fee. On review of the above information TGA will provide an estimate calculated from our current scale of fees and charges for technical documentation review and quality system audit. A copy of TGA's standard contract for conformity assessment services and details of the format for a formal application will accompany the estimate. A technical meeting may be required to complete the pre-assessment.

Please contact me if you require any further clarification.

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Fx: (02) 62328785
E-mail: Keith.m.smith@health.gov.au

Yours sincerely,

Keith M Smith
Manager, Conformity Assessment Services
Device Registration and Assessment Section
Conformity Assessment Branch

27 January, 1999