AGREEMENT
SECTORAL ANNEX ON MEDICAL DEVICES TO THE EUROPEAN COMMUNITY-AUSTRALIA
AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT,
CERTIFICATES AND MARKINGS

SCOPE AND COVERAGE

The provisions of this Sectoral Annex shall apply to the following products:

Products for export to the European Community	Products for export to Australia
All medical devices[1] subject to third party conformity assessment procedures, both product related and quality system related, provided for in Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, However, products indicated in *Appendix 1*- are excluded.	All medical devices subject under the Australian Therapeutic Goods Act 1989 and Therapeutic Goods Regulationssubject to TGA conformity assessment procedures, both product related and quality systems related. However, products indicated in *Appendix 1*are excluded.

SECTION I
LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community with which Australian designated conformity assessment bodies shall assess compliance	The legislative, regulatory and administrative requirements of Australia with which European Community designated conformity assessment bodies shall assess compliance
— Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended and complemented — Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended and complemented — and any legislation adopted on the basis of these Directives.	— Therapeutic Goods Act 1989, as amended — Therapeutic Goods Regulations 1990, as amended — Therapeutic Goods (Medical Devices) Regulations 2002, as amended — and any subordinate legislation referred to in the above Acts or Regulations, as amended[2]

[1] Accessories to be used together with medical devices fall in the scope of Directive 93/42/EEC and are treated as medical devices in their own right. Such accessories therefore fall in the scope of products for export to the European Community.
[2] General reference to Australia's subordinate legislation referred to in the Therapeutic Goods Act & Regulations and to anticipate any legislative changes.

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The conformity assessment bodies designated by Australia to assess products against the European Community's legislative, regulatory and administrative requirements	The conformity assessment bodies designated by the European Community to assess products against Australia's legislative, regulatory and administrative requirements
The designated conformity assessment bodies are listed *in Appendix II.*	The designated conformity assessment bodies are listed *in Appendix II.*

SECTION III

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES FOR THE PURPOSES OF THIS AGREEMENT

For the conformity assessment bodies designated by Australia	For the conformity assessment bodies designated by the Member States of ***the European Community***
— Department of Health and Ageing for the Therapeutic Goods Administration	— *Belgium* Ministère de la santé publique, de l'environnement et de l'intégration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie — *Denmark* Sundhedsministeriet — *Germany* Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten — *Greece* Ministry of Health — *Spain* Ministerio de Sanidad y Consumo — *France* Agence française de sécurité sanitaire des produits de santé (AFSSAPS). — *Ireland* Department of Health — *Italy* Istituto superiore di sanita. — *Luxembourg* Ministère de la santé — *Netherlands* Staat der Nederlanden — *Austria* Bundesministerium für Arbeit, Gesundheit und Soziales — *Portugal* Ministério de saúde — *Finland* Sosiaali- ja terveysministeriö/ Social- och hälsovårdsministeriet — *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *United Kingdom* Medicines and Healthcare Products Regulatory Agency (MHRA) - *Czech Republic* Czech Office for Standards, Metrology and

	Testing

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating conformity assessment bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating conformity assessment bodies to assess products against Australia's requirements
The Therapeutic Goods Administration of the Department of Health and Ageing must meet the requirements of the Directives listed in Section I, taking into account Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives and be designated for specific categories or classes of devices and conformity assessment procedures. For product covered by Section V, designation will occur on the basis of a confidence building program as mentioned in article 1.2 of Section V.[3]	Conformity assessment bodies must meet the requirements as mentioned in the Directives listed in Section I, taking into account Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives and be designated for specific ***categories or classes of*** devices and conformity assessment procedures. For product covered by Section V, designation will occur on the basis of a confidence building program as mentioned in article 1.2 of Section V.[4]

SECTION V

ADDITIONAL PROVISIONS

1. Confidence building with respect to high-risk devices

1.1. A confidence building process for the purpose of strengthening confidence in the designating systems of each of the Parties, will apply for the following Medical Devices:

— active implantable devices as defined in the legislation referred to in Section I,

— devices that are classified as class III devices under the legislation referred to in Section I

— *Deleted*: ~~A medical device that is an implantable contraceptive device~~.

— a medical device that is an implantable intra-ocular lens,

— a medical device that is an intra-ocular visco elastic fluid,

—

— a medical device that is a barrier indicated for contraception or prevention of the sexual transmission of disease,

1.2. The Parties will establish a detailed programme to this effect involving the Therapeutic Goods

[3] Presumption of competence is following successful completion of confidence building for Section V devices.

[4] Presumption of competence is following ***successful completion of*** confidence building ***for Section V devices***.

Administration and the European Community's competent authorities.

1.3 The confidence building period will be reviewed after 2 years commencing from the date the sectoral annex, as amended, becomes effective.

2. Registration, listing and inclusion procedures for the Australian Register of Therapeutic Goods (ARTG)

2.1. The Parties recognise that Australian procedures under the Therapeutic Goods Act 1989 for the registration, listing or inclusion of products for market surveillance purposes, and corresponding European Community procedures, are unaffected by this Agreement.

2.2. Within the framework of this Agreement, the Australian Regulatory Authority will without delay (5) enter a product on the ARTG from the European Community without further assessment of the product. This is contingent upon receipt of a ***product*** application accompanied by the prescribed fee and conformity assessment body's certification to Australia's requirements**.**, ***The application must be an*** effective application ***submitted and*** received under the Australian Device Electronic Application Lodgement System (DEAL).[5]

2.3. Any fees attached to ***registration*** by either Party will be related only to the costs of the medical device registration, enforcement and post-market surveillance activities of the Parties in this sector.

3. Exchange of information

The Parties agree to inform each other *of:*

- certificates, withdrawn, suspended, restricted ***or*** ***, revoked*** ~~***or no longer in effect***~~***;***
- adverse events in the context of the GHTF medical device vigilance procedure***;*** ~~***and***~~
- matters concerning product safety ***; and***
- any legislation or amendment to existing legislation adopted on the basis of the legal texts listed in section I.

The Parties shall establish contact points for ***each of these*** purposes.

The Parties will consider the consequences of the establishment of Eudamed.
In addition, the Therapeutic Goods Administration will advise of any certificates issued.

4. New legislation

The Parties note that Australia is to introduce new legislation concerning in vitro diagnostics and new legislation reflecting an Australia - New Zealand joint regulatory agency, and that any new arrangements will respect the principles on which the Mutual Recognition Agreement is based, notably Article 2 of the Agreement.
The Parties declare their intention to extend the scope of the MRA to IVDs as soon as the Australian legislation on IVDs is in place.

5. Measures to protect public health and safety

Implementation of this MRA does not constrain a Party from taking measures necessary to protect public health and safety, in accordance with the regulation referred to in Section 1. Each Party will duly inform the other Party of such measures.

[5] Administrative requirements required under the Therapeutic Goods Act 1989.

APPENDIX 1

AUSTRALIA - EUROPEAN COMMUNITY MUTUAL RECOGNITION AGREEMENT

SECTORAL ANNEX –ON MEDICAL DEVICES

SCOPE AND COVERAGE

The provisions of this Sectoral Annex shall **not** apply to the following devices:

-: medical devices that contain or are manufactured using cells, tissues or tissue derivatives of animal origin that have been rendered non-viable, where the safety with regard to viruses or other transferable agents requires validated methods for elimination or viral inactivation in the course of the manufacturing process,

Mis en forme : Non Surlignage

- medical devices that contain tissues, cells or substances of microbial, bacterial or recombinant origin and are intended for use in or on the human body,
- medical devices incorporating tissues or tissue derivatives of human origin
- medical devices incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device,
- medical devices that incorporate, or intend to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device,
- a medical device that is intended by the manufacturer specifically to be used for disinfecting another medical device,[6]

Both Parties may, however, decide by common agreement, to extend the application of this Annex to the aforementioned medical devices.

[6] Wording is reflective of terms used in Australia's legislation.

APPENDIX 2

AUSTRALIA - EUROPEAN COMMUNITY MUTUAL RECOGNITION AGREEMENT

SECTORAL ANNEX –ON MEDICAL DEVICES

DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by *Australia* to assess products against *the European Community's* legislative, regulatory and administrative requirements	**The Conformity Assessment Bodies designated by the European Community to assess products against Australia's legislative, regulatory and administrative requirements**
The Therapeutic Goods Administration of the Department of Health and Ageing, in respect of the conformity assessment procedures required under the community legislation cited in Section I, for all medical devices and for all modules for the various phases of the conformity assessment procedures applicable for such devices	The designated conformity assessment bodies are : **Danish Medical Devices Certification (DGM)** Kollegievej 6 DK-2920 Charlottenlund **LNE / G-MED** 1, rue Gaston Boissier 75724 PARIS Cedex 15 **LGA InterCert Zertifizierungsgesellschaft mbH** Tillystrasse 2 D-90431 Nürnberg **RWTÜV Systems GmbH** Langemarckstr. 20 D-45141Essen

APPENDIX 2 cont'd.

The Conformity Assessment Bodies designated by the European Community to assess products against Australia's legislative, regulatory and administrative requirements	**The Conformity Assessment Bodies designated by the European Community to assess products against Australia's legislative, regulatory and administrative requirements**
The Therapeutic Goods Administration of the Department of Health and Ageing, in respect of the conformity assessment procedures required under the community legislation cited in Section I, for all medical devices and for all modules for the various phases of the conformity assessment procedures applicable for such devices	**TÜV Rheinland Product Safety GmbH** Am Grauen Stein D-51105 Köln **TÜV Product Service GmbH** Ridlerstrasse 65D-80339 München **ISTISAN** Viale Regina Margherita, 299 I-00161 Roma **BSI Product Services** 389, Chiswick High Rd London W4 4AL **AMTAC Certification Services** Norman Rd Broadheath Altringham Cheshire WA14 4EP **SGS Yarsley Intl. Certification Services** Unit 202B Worle Parkway Weston-super-Mare BS22 0WA UL International (UK) Ltd