

The following entities have been approved by the Secretary to be “approved Conformity Assessment Bodies” for the purposes of the EC-MRA

Country	ID No.	Body	Address	Contact Details	Has expertise to assess to Australia's requirements for
Germany	1275	LGA/InterCert Gmbh Zertifizierungsgesellschaft mbh Umweltgutachterorganisation  * Please Note the following CAB notified body (NB) no longer exists and has been taken over by the NB (1275) above: 0125 Landesgewerbeanstalt Bayern Prüfstelle für Gerätesicherheit(LGA). The TGA will continue to accept certificates from NB 0125 until they certificates expire.	Tillystraße, 2 D-90431 Nürnberg	Tel: +49 911 6555780 Fax: +49 911 6555777	Non-active medical devices Dental implants Active medical devices
Germany	0197	TÜV Rheinland Product Safety GmbH	Am Grauen Stein D-51105 Köln	Tel: +49 221 8061951 Fax: +49 221 8061309	Non-active medical devices Active medical devices
Germany	0123	TÜV Product Service GmbH Zertifizierstelle	Ridlerstrasse, 31 D-80339 München	Tel: +49 89 50084 0 Fax: +49 89 50084 230	Non-active medical devices  Active medical devices  Radiotherapy devices  Disinfectants & antiseptics
France	0459	GMED	1 Rue Gaston Boissier 75724 Paris Cedex 15 France	Tel: +33 1 40 95 63 54 Fax: +33 1 40 95 62 43	All medical devices
Italy	0373	ISTISAN	Viale Regina Elena 299 1- 00161 Roma	Tel: +39 6 4990 25 15 Fax: +39 6 4938 7079	All medical devices
United Kingdom	0086	British Standards Institution (BSI), Product Services	389 Chiswick High Road London W4 4AL	Tel: +44 161 928 8924 Fax: +44 161 927 7359	All medical devices
United Kingdom	0473	AMTAC Certification Services Ltd	Norman Road Broadheath Altrincham UK-Cheshire WA14 4EP	Tel: +44 161 928 8924 Fax: +44 161 927 7359	All medical devices except equipment emitting ionising radiation

The following entities have been approved by the Secretary to be “approved Conformity Assessment Bodies” for the purposes of the EC-MRA

Country	ID No.	Body	Address	Contact Details	Has expertise to assess to Australia’s requirements for
United Kingdom	0120	SGS Yarsley International Certification Services Ltd	Unit 202B Worle Parkway, Weston-Super-Mare GB-BS22 OWA North Somerset	Tel: +44 1934 522917 Fax: +44 1934 522137	All medical devices  Infusion/syringe pumps Electrocardiographs  Condoms & contraceptive pessaries  Equipment & accessories for dialysis  Blood pressure measurement devices  General electro/mechanical equipment  Electrical thermometers for clinical use
United Kingdom	0843	UL International (UK) Ltd	2 Station View Guildford Surrey GU1 4JY	Tel: +44 1483 302130 Fax: +44 1483 302230	Active medical devices and their accessories  Disinfectants and surgical instruments  Sterile single use medical devices excluding Class III devices, ophthalmic devices, (class IIa and above) and implants  Wound dressings (Class IIa and IIb)  Gloves for medical use Urethral Catheters
Denmark	0543	Danish Medical Devices Certification (DGM)	Kollegievej 6 DK-2920 Charlottenlund	Tel: +45 39 96 64 00 Fax: +45 39 96 64 01	<i>Non-active Medical Devices</i>  Infusion equipment

The following entities have been approved by the Secretary to be “approved Conformity Assessment Bodies” for the purposes of the EC-MRA

Country	ID No.	Body	Address	Contact Details	Has expertise to assess to Australia’s requirements for
Denmark cont.....	0543	Danish Medical Devices Certification (DGM)	Kollegievej 6 DK-2920 Charlottenlund	Tel: +45 39 96 64 00 Fax: +45 39 96 64 01	Bandage Drainage & suction equipment Surgical equipment Dental materials Dental implants Disinfectants Sutures & adhesives Contact lenses & fluids Condom & contraceptive pessaries Intra-uterine contraceptive devices Surgical implants (excluding orthopedical implants & bone cement) Disposables for heart machines Cardiovascular implants <i>Active Medical Devices</i> Suction equipment Dental equipment Hearing aids and audiometers Electrocardiographs & electroencephalographs Sterilizers for medical devices

The following entities have been approved by the Secretary to be “approved Conformity Assessment Bodies” for the purposes of the EC-MRA

Country	ID No.	Body	Address	Contact Details	Has expertise to assess to Australia’s requirements for
					Ultrasound equipment Patient monitoring equipment & equipment for the monitoring of life supporting functions Defibrillators Blood analyzers & anaesthetic gas monitors Electrosurgical equipment Surgical lasers Heart-lung machines Equipment for radiation therapy Software for planning radiation therapy Stimulation equipment Neonatal equipment

The following entities have been approved by the Secretary to be “approved Conformity Assessment Bodies” for the purposes of the EC-MRA

Country	ID No.	Body	Address	Contact Details	Has expertise to assess to Australia’s requirements for
Netherlands	0344	KEMA Quality B. V. (KEMA)	Utrechtseweg 310 6812 AR Arnhem, The Netherlands  PO Box 5185 6802 ED Arnhem The Netherlands	Tel: +31-26-356-2009 Fax: +31-26-352-5800 Email: <a href="mailto:kema.medical@kema.com">kema.medical@kema.com</a> <a href="http://www.kemamedical.com">www.kemamedical.com</a>	All medical devices as covered by the MRA (products specifically excluded in the scope of the medical devices sectoral annex as well as products covered in Section V of the sectoral annex are excluded).