

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 90/385/EEC Active implantable medical devices

Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures / modules	Annexes / articles of the directives
RWTÜV SYSTEMS GMBH Langemarkstrasse, 20 45141 ESSEN Germany	0044	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5
NATIONAL STANDARDS AUTHORITY OF IRELAND (NSAI) Glasnevin 9 DUBLIN Ireland	0050	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5
BSI PRODUCT SERVICES Maylands Avenue HP2 4SQ HEMEL HEMPSTEAD United Kingdom	0086	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 5
TÜV PRODUCT SERVICE GMBH Ridlerstraße 65 80339 MÜNCHEN Germany	0123	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5
TÜV RHEINLAND PRODUCT SAFETY GMBH Am Grauen Stein 51105 Köln Germany	0197	All active implantable medical devices	EC declaration of conformity (complete quality assurance system)	Annex 2
DEUTSCHE GESELLSCHAFT ZUR ZERTIFIZIERUNG VON MANAGEMENTSYSTEMEN MBH August-Schanz Straße, 21 60433 FRANKFURT AM-MAIN Germany	0297	Active implantable medical devices (pacemakers, biostimulators, nerve stimulators, muscle stimulators, bladder stimulators, sphincter stimulators, diaphragm stimulator and ear stimulators)	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5
TÜV-ZERTIFIZIERUNGSGEMEINSCHAFT e.V. TÜV CERT Reuterstraße, 161 53113 BONN Germany	0298	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5
BUREAU VERITAS QUALITY INTERNATIONAL (BVQI)	0301	All active implantable medical devices	EC declaration of conformity (complete quality	Annex 2

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 90/385/EEC Active implantable medical devices

Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures / modules	Annexes / articles of the directives
2nd Floor, Tower Bridge Road, 224-226 SE1 2TX LONDON United Kingdom			assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 5
AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS MINISTERIO DE SANIDAD Y CONSUMO Paseo del Prado, 18-20 28014 MADRID Spain	0318	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5
KEMA QUALITY B.V. Utrechtseweg 310 (Postbus 9035) 6800 ET ARNHEM Netherlands	0344	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 5
CENTRUM VOOR MEDISCHE TECHNOLOGIE VAN HET INSTITUUT VOOR VEROUDERINGS- EN VAATZIEKTEN ONDERZOEK TNO Zernikedreef, 9 2333 CK LEIDEN Netherlands	0345	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5
ISTITUTO SUPERIORE DI SANITA Viale Regina Elena, 299 00161 ROMA Italy	0373	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5
TÜV- ÖSTERREICH Krugerstrasse 16 1010 WIEN Austria	0408	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5
G-MED GROUPEMENT POUR L'ÉVALUATION DES DISPOSITIFS MÉDICAUX 33, avenue du Général Leclerc 92260 FONTENAY-AUX-ROSES France	0459	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 90/385/EEC Active implantable medical devices

Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures / modules	Annexes / articles of the directives
MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH Vorsetzen 35 20459 HAMBURG Germany	0482	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5
PRÜFANSTALT FÜR MEDIZINISCHE GERÄTE- UND MEDIZINISCHE UNIVERSITÄT GRAZ Inffeldgasse, 18 8010 GRAZ Austria	0636	Active implantable medicinal devices and their accessories	EC Type-examination EC verification	Annex 3 Annex 4
LABORATÓRIO DE ENSAIOS E METROLOGIA DA SAÚDE - LEMES Av. Padre Cruz, Complexo Inst. Ricardo J 1699 Lisboa Codex Portugal	0932	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5
ORVOS- ÉS KÓRHÁZTECHNIKAI INTÉZET (ORKI) (INSTIT. FOR MEDICAL AND HOSPITAL ENGIN.) Diós Árok 3 1125 Budapest Hungary	1011	Implantable heart pacemakers	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5
ELEKTROTECHNICKÝ ZKUSEBNÍ ÚSTAV S.P. Pod Lisem 129 171 02 PRAHA 71 - Troja Czech Republic	1014	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5
INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI A.S. T. Bati 299 764 21 ZLÍN Czech Republic	1023	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5
SCHWEIZERISCHE VEREINIGUNG FÜR QUALITÄTS- UND MANagementsYSTEME (SQS) Bernstrasse, 103 3052 ZOLLIKOFEN	1250	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 90/385/EEC Active implantable medical devices

Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures / modules	Annexes / articles of the directives
Switzerland				
LGA INTERCERT ZERTIFIZIERUNGSGESELLSCHAFT MBH Tillystrasse, 2 90431 NÜRNBERG Germany	1275	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5
EVPU, A. S. Trencianska 19 018 51 NOVA DUBNICA Slovakia	1293	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5
POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. (PCBC) ul. Klobucka 23A 02 699 Warszawa Poland	1434	All active implantable medical devices	EC declaration of conformity (complete quality assurance system) EC Type-examination EC verification EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 3 Annex 4 Annex 5