

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 93/42/EEC 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
APRAGAZ A.S.B.L. Chaussée de Vilvorde 156 1120 BRUXELLES Belgium	0029	Class IIa non-invasive devices for gas storage, distribution or administration	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI
		Class IIb active devices for administering gas and/or extracting medicines/substances	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
TÜV NORD CERT GMBH & CO. KG Am TÜV 1 30519 HANNOVER Germany	0032	Non-active medical devices : - bandages and dressings - suture material and clamps Single-use medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Active medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
RWTÜV SYSTEMS GMBH Langemarkstrasse, 20 45141 ESSEN Germany	0044	Active medical devices Non-active medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
NATIONAL STANDARDS AUTHORITY OF IRELAND (NSAI) Glasnevin 9 DUBLIN Ireland	0050	Anaesthetic and life support equipment - cardiovascular implants Contraceptives Devices, materials and apparatus for dental treatment - Cleaning, disinfecting and sterilizing devices Devices containing medicinal substances - imaging equipment : - with non-ionizing radiation - devices for infusion, injection Devices for wound care - disposable products Non-active class I devices with a measuring function - ophthalmological devices - Non-implantable products for orthopaedics and rehabilitation Orthopaedic implants - patient storage and transport equipment	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

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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
		- soft tissue implants Surgical instruments Active medical devices : - stimulation devices Active surgical devices Monitoring devices for clinical use - oxygen therapy equipment (oxygen concentrator) Medical devices incorporating stable derivatives of blood or human plasma, excluding: - imaging equipment : . with ionizing radiation - radiotherapy devices : - functional implants		
IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A. Via Quintiliano, 43 20138 MILANO Italy	0051	Eye examination equipment Equipment for electrosurgery and accessories Anaesthetics equipment, incubators, ventilators, oxygen therapy equipment and accessories Equipment for extracorporeal circulation, infusion, transfusion, haemophoresis and accessories Equipment for dialysis and accessories Equipment for checking and recording vital functions and accessories Cardiac and muscular stimulation equipment and accessories Dental equipment and accessories Ophtalmological equipment and accessories Disinfection and sterilization equipment Equipment for aerosol therapy and accessories Clinical imaging equipment using ionizing radiation, non-ionizing radiation and ultrasound Treatment equipment using ionizing radiation, non-ionizing radiation and ultrasound	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		Disposable syringes Urethral catheters, catheters for heart surgery and for the central circulatory system Bags for parenteral and enteral nutrition and accessories Contact lenses Solutions for contact lenses Auditory prostheses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
IRCM ISTITUTO DI RICERCHE E COLLAUDI MASINI S.R.L. Via Moscova 11	0068	Equipment for aerosol therapy, humidification and nebulisation Equipment for anaesthesia, assisted ventilation and support of vital functions	Full quality assurance system EC Type-examination EC verification	Annex II Annex III Annex IV

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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
20017 RHO Italy		- surgical equipment and ancillary surgical equipment Equipment for electrosurgery Equipment for peritoneal dialysis and hemodialysis - Equipment for endoscopy Equipment for infusion, transfusion, extracorporeal circulation, plasmapheresis and blood collection Equipment for the production, visualisation and processing of images using non-ionising radiation or ultrasound Equipment for measuring and/or monitoring and/or recording and/or analysing physiological parameters and vital functions Dental instruments (non sterile) equipment Equipment for rehabilitation Equipment for nerve, heart or muscle stimulation or electrotherapy Equipment for treatment using non-ionising radiation or ultrasound Incubators and equipment for neonatal pathology Non-active devices for anaesthesia and assisted ventilation Non-active devices for surgery and endoscopy Non-active devices for measuring physiological parameters	Production quality assurance Product quality assurance	Annex V Annex VI
BSI PRODUCT SERVICES Maylands Avenue HP2 4SQ HEMEL HEMPSTEAD United Kingdom	0086	All medical devices	EC verification Product quality assurance	Annex IV Annex VI
		All medical devices including medical devices incorporating human blood derivatives	Full quality assurance system EC Type-examination Production quality assurance	Annex II Annex III Annex V
LLOYD'S REGISTER QUALITY ASSURANCE (LRQA) LTD EUROPEAN DIRECTIVE SERVICES Middlemarch Office Village - Siskin Driv CV3 4FJ Hiramford - Coventry United Kingdom	0088	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
LANDESAMT FÜR MEß- UND EICHWESEN THÜRINGEN Unterpörlitzer Straße, 2 98693 ILMENAU Germany	0118	Active medical devices : - tonometers - devices to monitor and determine vital signs - imaging equipment : . with non-ionizing radiation - radiotherapy equipment with non-ionizing radiation - stimulation devices Medical weighing instruments Non-active medical devices used for measurement : - clinical mercury-in-glass, maximum reading thermometers - medical syringes - tonometers	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI

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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
		- non-invasive sphygmomanometers - devices to ascertain vital functions - flow meters Medical weighing instruments		
SGS UNITED KINGDOM LIMITED Worle Park, Weston-Super-Mare BS22 OWA SOMERSET United Kingdom	0120	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Male condoms	EC Type-examination EC verification	Annex III Annex IV
		- defibrillators Equipment and accessories for dialysis - Electrocardiographs Infusion / syringe pumps	EC Type-examination	Annex III
		- fever thermometers (active) - fever thermometers (non-active) Active medical devices [class I (measuring) and IIA only] which require compliance with EN 60601-1 and measurements of voltage, current, temperature, pressure, weight and time	EC verification	Annex IV
TÜV PRODUCT SERVICE GMBH Ridlerstraße 65 80339 MÜNCHEN Germany	0123	Non-active medical devices Active medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
DEKRA INTERTEK CERTIFICATION GMBH Handwerkstraße 15 70565 STUTTGART Germany	0124	Non-active medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Male condoms	EC Type-examination EC verification	Annex III Annex IV
		Active medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
TÜV RHEINLAND PRODUCT SAFETY GMBH Am Grauen Stein	0197	Active medical devices Non-active medical devices	Full quality assurance system EC Type-examination	Annex II Annex III

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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
51105 Köln Germany			EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI
DEUTSCHE GESELLSCHAFT ZUR ZERTIFIZIERUNG VON MANagementsYSTEMEN MBH August-Schanz Straße, 21 60433 FRANKFURT AM-MAIN Germany	0297	Non-active medical devices	Full quality assurance system Production quality assurance	Annex II Annex V
		Active medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS MINISTERIO DE SANIDAD Y CONSUMO Paseo del Prado, 18-20 28014 MADRID Spain	0318	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
SATRA TECHNOLOGY CENTRE Satra House - Rockingham Road NN16 9JH KETTERING United Kingdom	0321	Male condoms	EC verification	Annex IV
TNO CERTIFICATION Laan van Westenenk 501, Postbus 541 7300 AM APELDOORN Netherlands	0336	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
KEMA QUALITY B.V. Utrechtseweg 310, Postbus 5185 6802 ED ARNHEM Netherlands	0344	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
INTERTEK TESTING & CERTIFICATION LTD Intertek House, Cleeve Road KT22 7SB Leatherhead United Kingdom	0359	Active medical devices but excluding : - blood gas analysers (invivo) - anaesthesia machines - lung ventilators - respiratory therapy equipment - breathing systems attachments and components - extracorporeal blood treatment equipment - electrosurgical equipment - medical laser equipment	EC Type-examination EC verification	Annex III Annex IV

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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
		<ul style="list-style-type: none"> - defibrillators - radiotherapy equipment - radionuclide and magnetic resonance imaging 		
VDE - VERBAND DER ELEKTROTECHNIK ELEKTRONIK INFORMATIONSTECHNIK E.V. - VDE PRÜF-UND ZERTIFIZIERUNGSSTELLE Merianstraße, 28 63069 OFFENBACH (AM MAIN) Germany	0366	Active medical devices, except : - disinfection and sterilization equipment	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
ISTITUTO SUPERIORE DI SANITA Viale Regina Elena, 299 00161 ROMA Italy	0373	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
CPM - ISTITUTO RICERCHE PROVE ED ANALISI SRL Via Artigiani, 63 25040 BIENNO Italy	0398	Single-use products	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Equipment for electrosurgery Apparatus and accessories for muscle stimulation Equipment and accessories for infusion, perfusion and transfusion Equipment and accessories for diagnosis and treatment using ultrasound Equipment and accessories for dialysis Equipment and accessories for diagnostic imaging, using ionising and non-ionising radiation Equipment and accessories for treatment using ionising and non-ionising radiation - patient-monitoring equipment and equipment for recording vital functions - disinfection and sterilization equipment	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI

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SP - SWEDISH NATIONAL TESTING AND RESEARCH INSTITUTE LTD Box 857 501 15 BORAS Sweden	0402	Non active devices specifically intended for recording of X-ray diagnostic images. (Annex IX, 4.4. Rule 16) Equipment for anaesthesia and intensive care Bone anchored implants for dental and craniofacial reconstructions Diagnostic X-ray equipment Surgical instruments for single use Electromedical diagnostic equipment Dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		All Class I sterile devices Class I devices with a measuring function	Production quality assurance Product quality assurance	Annex V Annex VI
TÜV- ÖSTERREICH Krugerstrasse 16 1010 WIEN Austria	0408	All medical devices including their accessories except: - soft tissue implants - neurosurgical and neurological implants - cardiovascular implants	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
INTERTEK SEMKO AB PO Box 1103 164 22 KISTA Sweden	0413	Active therapeutic devices Active devices intended for diagnosis Devices for the administration to or removal from the patient's body of medicines, body fluids or other substances Re-usable devices Disposables Wound dressings Passive implants Dental devices Functional implants Devices with a measuring function Sterile devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Electrical devices intended to administer and/or remove medicines or products, body liquids or other substances to or from the body Electrical therapeutic devices Electrical devices intended for diagnosis	EC Type-examination EC verification	Annex III Annex IV
		Class I devices with a measuring function	EC verification	Annex IV

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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
ICIM - ISTITUTO DI CERTIFICAZIONE INDUSTRIALE PER LA MECCANICA S.P.A. Piazza A. Diaz 2 20123 MILANO Italy	0425	Medical gas pipeline systems - disinfection and sterilization equipment	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		Operating theatre equipment Single Usage Device (?) Dressings Non-active class I devices with a measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Blood pressure measurement devices - fever thermometers (active)	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		Non active devices specifically intended for recording of X-ray diagnostic images. (Annex IX, 4.4. Rule 16)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		- capnometers	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		Devices, materials and apparatus for dental treatment	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Products and accessories for surgical use, such as suture needles, syringes, surgical gloves - contact lenses - Pulse oxymeters	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		Devices for anaesthesia and ventilation - dental equipment (units, treatment chairs, etc.) Catheters and accessories	EC Type-examination EC verification	Annex III Annex IV

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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
ITALCERT Viale Sarca, 336 20216 MILANO Italy	0426	Devices in sterile packs	Production quality assurance Product quality assurance	Annex V Annex VI
		Measuring devices Single-use products - dental materials - dental equipment - ultrasound equipment - electrocardiographs and electroencephalographs - contact lenses Non-invasive devices in contact with damaged skin Orthopaedic implants Devices for contact lens treatment Devices for the sterilisation of medical devices Invasive devices for natural orifices Invasive devices for surgical use Probes and catheters for urology, gastroenterology, respiratory tracts, surgical aspiration and oxygen therapy Devices for the administration to or removal from the patient's body of medicines, body fluids or other substances Contraceptives Blood bags Products and accessories for surgical use, such as suture needles, syringes, surgical gloves Apparatus and accessories for muscle stimulation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
MATERIALPRÜFUNGSAMT NORDRHEIN-WESTFALEN (MPA NRW) Marsbruchstraße 186 D-44287 DORTMUND Germany	0432	Active medical devices : - hearing aids and audiometers	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
DET NORSKE VERITAS CERTIFICATION AS Veritasveien 1 1322 HOVIK Norway	0434	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
G-MED GROUPEMENT POUR L'ÉVALUATION DES DISPOSITIFS MÉDICAUX 33, avenue du Général Leclerc 92260 FONTENAY-AUX-ROSES France	0459	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
NEMKO AS	0470	All medical devices, except X-radiation and particle radiation	Full quality assurance system	Annex II

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Gautstadalleen 30 - PO Box 73 Blindern 0314 OSLO Norway		equipment for diagnostic and therapeutic use	EC Type-examination EC verification Production quality assurance Product quality assurance	Annex III Annex IV Annex V Annex VI
AMTAC CERTIFICATION SERVICES LTD Regus Bus. C. Threapwood Road M22 0RR Manchester United Kingdom	0473	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
CERMET Via Aldo Moro, 22 40068 S. LAZZARO DI SAVENA Italy	0476	Electromedical apparatus for physiotherapy and rehabilitation Electromedical apparatus for cardiology Electromedical apparatus for anaesthesia and cardiac surgery Electromedical apparatus for dentistry and stomatology Electromedical apparatus for nephrology and dialysis Electromedical apparatus for pediatrics and neonatal care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Prostheses Dental prostheses Orthopaedic prostheses Infusion and withdrawal needles Cannulas, probes and tubes Catheters and accessories Tubular devices of synthetic material for administration and withdrawals Filters for blood or solutions; other filters Syringes Circuits and accessories for anaesthesia and resuscitation Equipment and accessories for dialysis Products for dental treatment	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
BIOLAB SPA - CENTRO DI ANALISI E RICERCHE BIOLOGICHE Via Bruno Buozzi, 2 20090 VIMODROME Italy	0477	Non-resorbable surgical implants Devices for infusion, transfusion, injection, withdrawal, extracorporeal circuits - ophthalmological devices - disinfectants and antiseptics Contact lenses maintenance products Non-resorbable suture materials and clamps Single-use products Dressings Devices, materials and apparatus for dental treatment Surgical instruments Gloves for medical use Contraceptives	EC Type-examination EC verification	Annex III Annex IV

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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
		Devices for anaesthesia and ventilation Catheters, drains and probes Re-usable devices Devices for parenteral and enteral nutrition		
		All Class I sterile devices	Production quality assurance Product quality assurance	Annex V Annex VI
ECM-ZERTIFIZIERUNGSGESELLSCHAFT FÜR MEDIZINPRODUKTE IN EUROPA MBH Eifelstraße, 1c 52068 AACHEN Germany	0481	Non-active medical devices: . infusion / transfusion sets . catheters / catheter sets . drainage devices . tubing for extracorporeal circulation - OP products - bandages and dressings	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		- ophthalmological products - disinfection means	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH Vorsetzen 35 20459 HAMBURG Germany	0482	Non-active medical devices Active medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI

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MDC MEDICAL DEVICE CERTIFICATION GMBH Kriegerstrasse 6 70191 STUTTGART Germany	0483	Non-active medical devices	Full quality assurance system EC Type-examination Production quality assurance Product quality assurance	Annex II Annex III Annex V Annex VI
		Active medical devices :	EC Type-examination Production quality assurance Product quality assurance	Annex III Annex V Annex VI
		- devices to monitor and determine vital signs	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		- infusion devices - ventilators and oxygen therapy apparatus, except for devices for hyperbaric therapy - imaging equipment : - surgical devices and aids, except for lithotripsy devices - with ionizing radiation - with non-ionizing radiation - stimulators, except external pacemakers and defibrillators - radiotherapy devices : - with ionizing radiation and with non-ionizing radiation - ophthalmological devices - dental equipment - patient storage and transport equipment - medical supply units - prostheses and rehabilitation devices	EC Type-examination Production quality assurance Product quality assurance	Annex III Annex V Annex VI
SLG PRÜF UND ZERTIFIZIERUNGS GMBH Burgstädedter Strasse 20 09232 Hartmannsdorf Germany	0494	All active medical devices (except for devices for hyperbaric therapy)	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
SOCIETE NATIONALE DE CERTIFICATION ET D'HOMOLOGATION S.À.R.L. (SNCH) 11, Route de Sandweiler 5230 SANDWEILER Luxembourg	0499	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
INSTITUTO NACIONAL DA FARMACIA E DO MEDICAMENTO Parque da Saúde de Lisboa -Av. do Brasil	0503	Non-active medical devices	Full quality assurance system EC Type-examination EC verification	Annex II Annex III Annex IV

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1700 LISBOA Portugal			Production quality assurance Product quality assurance	Annex V Annex VI
NIOM CERTIFICATION P.O.Box 70 1344 HASLUM Norway	0510	Medical devices for dentistry	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
EUROCAT - INSTITUTE FOR CERTIFICATION AND TESTING GMBH Quarat Center, Wittichstrasse 2 64295 DARMSTADT Germany	0535	Non-active medical devices, except Class III devices: - reusable non-active medical instruments - bandages and dressings - dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		All active medical devices (except for devices for hyperbaric therapy)	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
VTT INDUSTRIAL SYSTEMS (VTT TUOTTEET JA TUOTANTO) P.O. Box 1700 02044 VTT Finland	0537	Active medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		Non-active class I devices placed on the market in a sterile state Non-active class I devices with a measuring function	EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI
		Non-active class IIa and IIb devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
DANSK STANDARD - DANSK GODKENDELSE AF MEDICINSK UDSTYR Kollegievej, 6 2920 CHARLOTTENLUND Denmark	0543	Non-active medical devices : - infusion devices - dental materials - bandages and dressings - dental implants - disinfection means - surgical articles - contact lenses - contact lens fluids - sutures and adhesives	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI

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		<ul style="list-style-type: none"> - condoms and contraceptive pessaries - intrauterine contraceptives - drains, probes and suction devices - surgical implants (non-orthopaedic implants and bone cement) - single use products for heart-lung machines - cardiovascular implants Active medical devices : - radiotherapy equipment - radiotherapy planning software - stimulation equipment - heart-lung machines - neonatal equipment - dental devices - hearing aids and audiometers - medical equipment sterilizers - electrocardiographs and electroencephalographs - equipment for measuring blood and anaesthetic gas - defibrillators - surgical lasers - ultrasound equipment - patient-monitoring equipment and equipment for recording vital functions - electrosurgical equipment - suction equipment Diagnostic X-ray equipment CT-scanner 		
ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ Via G. Giardino, 4 20123 MILANO Italy	0546	Medical and measuring equipment with independent power supply or non-powered Dental products and materials and accessories, including powered accessories Ophthalmic products, e.g. spectacles and intraocular lenses Products and accessories for surgical use Products for endoscopy and laparoscopy Sensitive materials for medical use Products for extracorporeal circulation and accessories, including active accessories Catheters and non-disposable accessories Contraceptive products Artificial skin, etc. Products for disinfection of medical equipment and for the treatment of contact lenses Bendages, dressings, plasters, etc. Materials for sutures	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

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		Disposable products Products for anaesthesia, reanimation and respiration Orthopaedic and rehabilitation products and materials and accessories, including powered accessories		
NATIONAL QUALITY ASSURANCE LTD Gainsborough House - Houghton Hall Park W5 5XZ Houghton Regis, Dunstable United Kingdom	0577	Devices for the administration to or removal from the patient's body of medicines, body fluids or other substances - ultrasound equipment Electromedical equipment	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Anaesthetic and life support equipment	Full quality assurance system	Annex II
		Drainage and suction devices (non-powered) Surgical dressings (class IIa) Measuring and monitoring equipment Operating theatre equipment Diagnostic X-ray equipment Anaesthetic and respiratory equipment Blood contact devices Functions relating to sterile / measuring Class I medical devices	Production quality assurance Product quality assurance	Annex V Annex VI
BERLIN-CERT-PRÜF- UND ZERTIFIZIERSTELLE FÜR MEDIZINPRODUKTE GMBH AN DER TECHNISCHEM UNIVERSITÄT BERLIN Dovestrasse, 6 10587 BERLIN Germany	0633	All active medical devices (except for devices for hyperbaric therapy)	EC Type-examination EC verification	Annex III Annex IV
PRÜFANSTALT FÜR MEDIZINISCHE GERÄTE-TECHNISCHE UNIVERSITÄT GRAZ Inffeldgasse, 18 8010 GRAZ Austria	0636	Active medical devices and their accessories	EC Type-examination EC verification	Annex III Annex IV

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RESEARCH CENTER FOR BIOMATERIALS S.A. "EKEVYL S.A." Smyrnis 15 165 62 GLYFADA Greece	0653	All medical devices	Production quality assurance Product quality assurance	Annex V Annex VI
		All medical devices	Full quality assurance system	Annex II
		Implantable and non-implantable orthopaedic materials and devices Other implantable devices Artificial limbs and related components for disabled Bandages, surgical dressings, medical grade cotton and other relevant products Dental devices Disinfectants and antiseptics Disinfectants and antiseptics Contact lenses and solutions for contact lenses Absorbable and non-absorbable surgical sutures - disinfectants and antiseptics Absorbable and non-absorbable surgical sutures Sterile and non-sterile single use products Contraceptives Contact lenses maintenance products Absorbable and non-absorbable surgical sutures Sterile and non-sterile single use products Contraceptives	EC Type-examination	Annex III
		Only devices mentioned in § B	EC verification	Annex IV
PRÜF UND FORSCHUNGSINSTITUT E.V. Marie-Curie Str. 19 66955 PIRMASENS Germany	0713	Non-active, non-sterile medical devices for orthopaedic treatment and the rehabilitation of the foot and leg (Category IIa)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
THERAPEUTIC GOODS ADMINISTRATION PO Box 100 ACT 2606 WODEN Australia	0805	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI

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UL INTERNATIONAL (UK) LTD Womersley House Building C, Old Portsm. R. GU3 1LR GUILDFORD United Kingdom	0843	Active medical devices and their accessories	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		Disinfectants and surgical instruments Sterile single use medical devices excluding Class III devices, ophthalmic devices, (class IIa and above) and implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Wound dressings (Class IIa and IIb)	EC Type-examination EC verification	Annex III Annex IV
		Gloves for medical use Urethral catheters	EC verification	Annex IV
LABORATÓRIO DE ENSAIOS E METROLOGIA DA SAÚDE - LEMES Av. Padre Cruz, Complexo Inst. Ricardo J 1699 Lisboa Codex Portugal	0932	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
MAGYAR ELEKTROTECHNIKAI ELLENORZO INTÉZET KFT. Váci út 48/a-b 1132 Budapest Hungary	1007	Medical electrical equipment, general requirements Electromedical equipment Programmable electronic systems - high frequency surgery equipment - short waves and devices for treatment using heat - defibrillators - ultrasound equipment Microwave therapy equipment High-voltage generators for diagnostic X-ray generators - nerve and muscle stimulator Electroconvulsive therapy equipment - baby incubator (clinical, intensive, transport) Infant radiant warmers - medical laser equipment - transcutane partial pressure measuring equipment - infusion devices - electrocardiographs and electroencephalographs Electrocardiographic monitoring equipment Blood pressure measurement devices Associate equipment of X-ray equipment Electrically operated hospital beds Electromyographs	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 93/42/EEC 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
		Operating tables Electrical equipment for measurement, control and laboratory use - Pulse oxymeters - capnometers - oxygen therapy equipment (oxygen concentrator) - suction equipment - oxygen monitors - hearing aids and audiometers - wheelchairs (electrically operated)		
ORVOS- ÉS KÓRHÁZTECHNIKAI INTÉZET (ORKI) (INSTIT. FOR MEDICAL AND HOSPITAL ENGIN.) Diós Árok 3 1125 Budapest Hungary	1011	Non-active medical devices : - non-active accessories of anaesthesia and respiration - dental devices - dental materials - dental implants - suture material and clamps - non-active surgical implants (bone-prostheses and implantation tools) - intrauterine devices - artificial heart valves - vessel prostheses and stents - contact lenses - contact lens fluids - intraocular lenses and materials for intraocular use - fever thermometers (non-active) - sterile syringes - sterile needles for syringes - insuline syringes/pen injectors - non-reusable medical gloves - condoms made from natural latex - Catheters - bandages and dressings - disposable products - disinfectants and antiseptics Active medical devices : - anaesthesia workstations and their modules - ventilators (baby, adult), for intensive care, home use, emergency and transport - capnometers - oxygen monitors - Pulse oxymeters - oxygen therapy equipment (oxygen concentrator) - dental equipment (units, treatment chairs, etc.) - ergometers	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 93/42/EEC 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
		<ul style="list-style-type: none"> - spirographs - spirometers - infusion devices - electrocardiographs and electroencephalographs - hearing aids and audiometers - dialysis and urodynamic equipment - blood - and infusion - warming equipment - autotransfusion equipment, bloodcell-separators - baby incubator (clinical, intensive, transport) - non-invasive and invasive blood pressure measuring devices and blood pressure monitors - high frequency surgery equipment - short waves and devices for treatment using heat - medical laser equipment - Electrocardiographs - nerve and muscle stimulator - transcutane partial pressure measuring equipment - intensive care monitor equipment (incl. ECG-monitor) - external pacemakers - heart-defibrillator equipment - suction equipment - warming blankets, pads and mattresses for medical use - equipment for extracorporally induced lithotripsy - medical gas supply system and parts (units) thereof - medical equipment sterilizers - Equipment for endoscopy - operation microscopes - ophthalmological devices - operation and examination lamps - fever thermometers (active) - wheelchairs (electrically operated) 		
ELEKTROTECHNICKY ZKUSEBNI USTAV S.P. Pod Lisem 129 171 02 PRAHA 71 - Troja Czech Republic	1014	Active medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		Non-active medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
STROJIRENSKY ZKUSEBNI USTAV S.P. Hudcova 56B	1015	Anaesthetic and respiratory equipment Electromedical apparatus for dentistry and stomatology	Full quality assurance system EC Type-examination	Annex II Annex III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 93/42/EEC 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
621 00 BRNO Czech Republic		Electromechanical medical devices Hospital equipment (equipment for sterilization, disinfection, transport of patients and also transportable incubators) Non-active implantable medical devices (except devices manufactured from plastic and ceramic materials) Ophthalmic and optic medical devices (only active electrical devices) Re-usable devices Disposable syringes and needles Technical aids for handicapped people - wheelchairs and lifting devices Medical devices for actinopraxis (for diagnosis and therapy)	EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI
TEXTILNI ZKUSEBNI USTAV S.P. Vaclavska 6 658 41 BRNO Czech Republic	1021	Non-active implantable medical devices (only from textile or composed devices based on textile) Disposable medical devices (only manufactured from textile or composed devices based on textile or manufactured from plastic materials with just the same usage)	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
INSTITUT PRO TESTOVANI A CERTIFIKACI A.S. T. Bati 299 764 21 ZLIN Czech Republic	1023	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
SCHWEIZERISCHE VEREINIGUNG FÜR QUALITÄTS- UND MANAGEMENTSYSTEME (SQS) Bernstrasse, 103 3052 ZOLLIKOFEN Switzerland	1250	Non-active medical devices : - orthopaedic implants - soft tissue implants - functional implants Single-use products - anaesthetic, orthopaedic and rehabilitation devices - non-energized medical instrumentation - reusable non-active medical instruments - bandages and dressings - suture material and clamps - dental equipment and instruments - dental materials - dental implants - disinfectants and antiseptics Active medical devices: - equipment for extracorporeal circuits, infusions and haemophoresis - surgical equipment and ancillary surgical equipment - imaging equipment :	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 93/42/EEC 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
		<ul style="list-style-type: none"> . with ionizing radiation and with non-ionizing radiation - ophthalmological devices - dental equipment - prostheses and rehabilitation devices - medical gas supply system and parts (units) thereof - disinfection and sterilization equipment 		
SGS INTERNATIONAL CERTIFICATION SERVICES AG Technopark, Technoparkstr. 1 8005 ZÜRICH Switzerland	1251	Non-active medical devices : - functional implants Sterile and non-sterile single use products - Non-implantable products for orthopaedics and rehabilitation - reusable non-active medical instruments - bandages and dressings - suture material and clamps - dental equipment and instruments - dental materials - dental implants - disinfectants and antiseptics Active medical devices : - devices to monitor and determine vital signs - devices for infusion, injection - imaging equipment : . with non-ionizing radiation - ophthalmological devices - disinfection and sterilization equipment - patient storage and transport equipment Software for operating medical devices Measuring devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
QS SCHAFFHAUSEN AG Wiesengasse, 20 8222 BERINGEN Switzerland	1252	Non-active medical devices : Single-use products - reusable non-active medical instruments Surgical instruments - bandages and dressings - suture material and clamps - dental equipment and instruments - dental materials - dental implants Active medical devices : - patient storage and transport equipment - dental equipment Active devices intended for diagnosis . with non-ionizing radiation Measuring devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 93/42/EEC 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
		- prostheses and rehabilitation devices skeleton implants Functional implants		
SWISS TS TECHNICAL SERVICES AG Allmendstrasse 86 3602 THUN Switzerland	1253	Non-active medical devices : Single-use products - reusable non-active medical instruments Surgical instruments - bandages and dressings - suture material and clamps - dental equipment and instruments - dental materials - dental implants -contact lens care devices - disinfectants and antiseptics - non-energized medical instrumentation Orthopaedic prostheses Equipment for rehabilitation - ophthalmological products - products for anaesthesia and reanimation Probes and catheters for urology, gastroenterology, respiratory tracts, surgical aspiration and oxygen therapy Catheters and accessories Devices for parenteral and enteral nutrition Infusion and withdrawal needles Cannulas, probes and tubes Tubular devices of synthetic material for administration and withdrawals Filters for blood or solutions; other filters Active medical devices : - disinfection and sterilization equipment - dental equipment - prostheses and rehabilitation devices - surgical equipment and ancillary surgical equipment - patient storage and transport equipment	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
QS ZÜRICH AG Wehntalerstrasse, Postfach 211 8057 ZÜRICH Switzerland	1254	Non-active medical devices : Single-use products - reusable non-active medical instruments Surgical instruments - bandages and dressings - suture material and clamps - dental equipment and instruments - dental materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 93/42/EEC 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
		- dental implants Active medical devices : - patient storage and transport equipment - dental equipment Active devices intended for diagnosis . with non-ionizing radiation Measuring devices - prostheses and rehabilitation devices skeleton implants Functional implants		
LGA INTERCERT ZERTIFIZIERUNGSGESELLSCHAFT MBH Tillystrasse, 2 90431 NÜRNBERG Germany	1275	Active medical devices Non-active medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
EVPU, A. S. Trencianska 19 018 51 NOVA DUBNICA Slovakia	1293	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
VYSKUMNY USTAV TEXTILNEJ CHÉMIE (VUTCH - CHEMITEX), S. R. O. Jana Milca 8 011 68 ZILINA Slovakia	1296	Non-active medical devices : Bandages, surgical dressings, medical grade cotton and other relevant products Plasters	EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI
VYSKUMNY USTAV ZVARAČSKÝ - PRIEMYSELNÝ INŠTITUT SLOVENSKEJ REPUBLIKY Racianska 71 832 59 BRATISLAVA Slovakia	1297	Transportable gas cylinders for use with medical gases Pressure regulators for use with medical gases Medical gas pipeline systems Quick-action couplings with shut-of valves	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
CEROT, S.R.O. Jozefa Haragu 4-9 831 51 BRATISLAVA Slovakia	1298	Testing optical devices and equipment photometric measurement, climatic and resistance testing	EC Type-examination EC verification	Annex III Annex IV

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 93/42/EEC 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
SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ Trzaska cesta 2 1000 LJUBLJANA Slovenia	1304	Active medical devices: - patient-monitoring equipment and equipment for recording vital functions - stimulation devices - medical supply units Equipment for treatment using non-ionising radiation or ultrasound Equipment for the production, visualisation and processing of images using non-ionising radiation or ultrasound Blood pressure measurement devices Electrical thermometers for clinical use - medical laser equipment Class I devices with a measuring function	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		Non-active medical devices : - disinfection and sterilization equipment - orthopaedic implants - dental equipment and instruments - dental materials - dental implants Cannulas, probes and tubes Catheters and accessories Equipment and accessories for dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
VSEOBECNA FAKULTNI NEMOCNICE V PRAZE U nemocnice 2 126 08 PRAHA 2 Czech Republic	1385	Dental devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
SKLARSKY USTAV HRADEC KRALOVE S.R.O Skroupova 957 501 01 HRADEC KRALOVE Czech Republic	1386	Hospital accessories (only glass transfusion bottles and bottles for blood)	Full quality assurance system Product quality assurance	Annex II Annex VI
POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. (PCBC) ul. Klobucka 23A 02 699 Warszawa Poland	1434	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
INSTYTUT TECHNIK I TECHNOLOGII DZIEWIARSKICH (TRICOTEXTIL) ul. Piotrkowska 270 90 361 Lodz	1435	Non-invasive medical devices falling within Classes I, IIa or IIb limited to: Wound dressings (Class IIa and IIb) Active therapeutic devices	Full quality assurance system EC Type-examination EC verification Production quality assurance	Annex II Annex III Annex IV Annex V

LIST OF BODIES NOTIFIED UNDER DIRECTIVE 93/42/EEC 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
Poland		- non-active surgical implants	Product quality assurance	Annex VI
INSTYTUT NAFTY I GAZU (ING) ul. Lubicz 25A 31 503 KRAKOW Poland	1450	Class IIa non-invasive devices for gas storage, distribution or administration	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		Medical gas pipeline systems	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
OSRODEK BADAWCZO-ROZWOJOWY PREDOM - OBR ul. Krakowiakow 53 02 255 WARSZAWA Poland	1451	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
ELTEST M. JEWTUCH SPOLKA JAWNA ul. Ratuszowa 11 00 450 WARSZAWA Poland	1465	Active medical devices in Class I, IIa or IIb	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
BIURO BADAWCZE DS. JAKOSCI STOWARZYSZENIA ELEKTRYKOW POLSKICH (BBJ-SEP) Pozaryskiego 28 04-703 WARSZAWA Poland	1509	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
SERTIKA - CERTIFICATION CENTRE FOR ELECTRONIC EQUIPMENT COMPANY LTD Savanoriu av. 271-253 50131 KAUNAS Lithuania	1609	Medical electrical equipment, general requirements - nerve and muscle stimulator - electrocardiographs and electroencephalographs - dental equipment Non-invasive sphygmomanometers	EC Type-examination EC verification	Annex III Annex IV
SGS SYSTEMS & SERVICES CERTIFICATION EESV Noorderlaan 87 2030 Antwerpen Belgium	1639	Active medical devices in Class I, IIa or IIb - devices emitting ionising radiation and devices intended to image in vivo distribution of radiopharmaceuticals Non-active medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI