

## 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 or modules	Annexes or articles of the directives
APRAGAZ A.S.B.L. Chaussée de Vilvorde 156 1120 BRUXELLES Belgium	0029	Active medical devices in Class I, IIa or IIb Non-active medical devices in Class I, IIa or IIb except Class IIb implantable 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 NORD CERT GmbH Langemarkstrasse 20 45141 ESSEN Germany	0044	Non-active medical devices Active medical devices, except - hyperthermy devices - hyperbaric therapy chambers - medical supply units - software	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 devices covered by directive 2003/32/EC	Full quality assurance system Production quality assurance	Annex II Annex V
National Standards Authority of Ireland (NSAI) 1 Swift Square, Northwood, Santry Dublin 9 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	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

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		<ul style="list-style-type: none"> <li>- ophtalmological devices</li> <li>- Non-implantable products for orthopaedics and rehabilitation</li> <li>orthopaedic implants</li> <li>- patient storage and transport equipment</li> <li>- soft tissue implants</li> <li>Surgical instruments</li> <li>Active medical devices               <ul style="list-style-type: none"> <li>- stimulation devices</li> </ul> </li> <li>Active surgical devices</li> <li>Monitoring devices for clinical use               <ul style="list-style-type: none"> <li>- oxygen therapy equipment (oxygen concentrator)</li> </ul> </li> <li>Medical devices incorporating stable derivatives of blood or human plasma, excluding@with ionizing radiation               <ul style="list-style-type: none"> <li>- radiotherapy devices</li> <li>- functional implants</li> </ul> </li> </ul>		
IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A. Via Quintiliano, 43 20138 - MILANO Italy	0051	Equipment for electrosurgery and accessories	Full quality assurance system	Annex II
		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	EC type-examination  EC verification  Production quality assurance  Product quality assurance	Annex III  Annex IV  Annex V  Annex VI

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		Dental equipment and accessories Ophthalmological equipment and accessories Equipment for aerosol therapy and accessories		
		Disposable syringes Urethral catheters, catheters for heart surgery and for the central circulatory system Bags for parenteral and enteral nutrition and accessories Auditory prostheses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Equipment and accessories for diagnosis and treatment using ultrasound Equipment and accessories for diagnostic imaging, using ionising and non-ionising radiation Equipment and accessories for treatment using ionising and non-ionising radiation	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
		Bone nails, screws and plates (including accessories) Contraceptive products Dressings Contact lenses and solutions for contact lenses Gloves for medical use dental implants and accessories	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		equipment for cryosurgery and accessories equipment for disinfection and sterilization equipment for orthopaedic rehabilitation and 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
IRCM ISTITUTO DI RICERCHE E COLLAUDI MASINI	0068	Equipment for aerosol therapy, humidification and	Full quality assurance system	Annex II

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S.R.L. Via Moscova, 11 20017 - Rho (MI) Italy		nebulisation Equipment for anaesthesia, assisted ventilation and support of vital functions - 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	EC type-examination EC verification Production quality assurance Product quality assurance	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 or modules	Annexes or articles of the directives
BSI PRODUCT SERVICES Maylands Avenue Hemel Hempstead Hertfordshire HP2 4SQ United Kingdom	0086	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
		All medical devices	EC verification Product quality assurance	Annex IV Annex VI
LLOYD'S REGISTER QUALITY ASSURANCE LTD (0088) Hiramford Middlemarch Office Village Siskin Drive Coventry CV3 4FJ United Kingdom	0088	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

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LANDESAMT FÜR MESS- UND EICHWESEN THÜRINGEN Unterpörlitzer Straße, 2 98693 ILMENAU Germany	0118	Non-active medical devices used for measurement - medical syringes - tonometers - Non-invasive sphygmomanometers - devices to ascertain vital functions - flow meters	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 used for measurement - medical weighing instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Active medical devices - hyperthermy devices except devices for laser surgical - 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 - medical thermometers	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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SGS UNITED KINGDOM LIMITED Worle Park, Weston-Super-Mare, Somerset, BS22 6WA United Kingdom	0120	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Male condoms - defibrillators Equipment and accessories for dialysis - Electrocardiographs Infusion / syringe pumps	EC type-examination	Annex III
		Male condoms - 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

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TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 MÜNCHEN Germany	0123	Active medical devices, except - hyperbaric therapy chambers - hyperthermy 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
		medical devices covered by directive 2000/70/EC medical devices covered by directive 2001/104/EC	Full quality assurance system Production quality assurance	Annex II Annex V
		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
		Medical devices covered by directive 2003/32/EC	Full quality assurance system Production quality assurance	Annex II Annex V

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Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures or modules	Annexes or articles of the directives
DEKRA Certification GmbH Handwerkstraße 15 70565 STUTTGART Germany	0124	Non-active medical devices	Full quality assurance system	Annex II
		Active medical devices	Production quality assurance Product quality assurance	Annex V Annex VI
		Male condoms	EC type-examination EC verification	Annex III Annex IV
		Medical devices covered by directive 2003/32/EC	Full quality assurance system Production quality assurance	Annex II Annex V
		non-active medical devices with already existing EC type examination certificate	EC type-examination	Annex III
		Active medical devices, except - disinfection and sterilization equipment - devices for extracorporal circulation, haemopheresis - devices for oxygen therapy and inhalation anaesthesia - devices for radiotherapy utilizing ionizing rays - ophthalmologic devices - rehabilitation devices and active protheses - respiratory devices	EC type-examination EC verification	Annex III Annex IV

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TÜV RHEINLAND PRODUCT SAFETY GMBH Am Grauen Stein 51105 Köln Germany	0197	Non-active medical devices Active medical devices, except - hyperthermy devices - hyperbaric therapy chambers - medical supply units - software	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 devices covered by directive 2003/32/EC	Full quality assurance system Production quality assurance	Annex II Annex V
DQS GmbH 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, except - hyperthermy devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Medical devices covered by directive 2003/32/EC	Full quality assurance system Production quality assurance	Annex II Annex V
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 Kettering, Northamptonshire, NN16 9JH United Kingdom	0321	Male condoms	EC verification	Annex IV
TNO CERTIFICATION BV Laan van Westenenk 501, Postbus 541	0336	All medical devices	Full quality assurance system EC type-examination	Annex II Annex III

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7300 AM APELDOORN Netherlands			EC verification Production quality assurance Product quality assurance	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, Leatherhead, Surrey, KT22 7SB United Kingdom	0359	Active medical devices but excluding - radiotherapy equipment - radionuclide and magnetic resonance imaging - blood gas analysers (in vivo) - anaesthesia machines - lung ventilators - respiratory therapy equipment - breathing systems attachments and components - extracorporeal blood treatment equipment - electrosurgical equipment - medical laser equipment - defibrillators	EC verification	Annex IV
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 - hyperthermy 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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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 (BS) 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
SP Sveriges Tekniska Forskningsinstitut AB 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	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 or modules	Annexes or articles of the directives
		reconstructions Diagnostic X-ray equipment Surgical instruments for single use Electromedical diagnostic equipment dental devices		
		All Class I sterile devices	Production quality assurance	Annex V
		Class I devices with a measuring function	Product quality assurance	Annex VI
TÜV AUSTRIA SERVICES GMBH Krugerstrasse 16 1015 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

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Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures or modules	Annexes or articles of the directives
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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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) - capnometers 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
		Blood pressure measurement devices - capnometers	EC type-examination EC verification	Annex III Annex IV

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ITALCERT SRL Viale Sarca, 336 20126 - MILANO Italy	0426	Devices for anaesthesia and ventilation - dental equipment (units, treatment chairs, etc.) Catheters and accessories Non-invasive devices in contact with damaged skin Devices for contact lens treatment Invasive devices for natural orifices Devices for the administration to or removal from the patient's body of medicines, body fluids or other substances Blood bags Apparatus and accessories for muscle stimulation Contraceptive products disinfectants and sterilizers for medical devices Functions relating to sterile / measuring Class I medical devices Products and accessories for surgical use Devices, materials and apparatus for dental treatment Elettrocardiographs Contact lenses and solutions for contact lenses skeleton implants Ultrasound equipment for diagnosis	Full quality assurance system Production quality assurance Product quality assurance Production quality assurance Product quality assurance Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI Annex V Annex VI 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

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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
Laboratoire national d'essais / G-MED 1, rue Gaston Boissier 75724 PARIS Cedex 15 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 Gaustadalleen 30 - PO Box 73 Blindern 0314 OSLO Norway	0470	Devices manufactured utilizing animal tissue covered by Directive 2003/32/EC are excluded:  All medical devices, except X-radiation and particle radiation equipment for diagnostic and therapeutic use	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
AMTAC CERTIFICATION SERVICES LTD Davy Avenue, Knowlhill Milton Keynes MK5 8NL United Kingdom	0473	Devices manufactured utilising animal tissue covered by Directive 2003/32/EC are included  All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

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CERMET S.c. a r.l. Via Cadriano, 23 40057 - Granarolo Emilia (BO) 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

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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 Devices for anaesthesia and ventilation Catheters, drains and probes Re-usable devices Devices for parenteral and enteral nutrition	EC type-examination EC verification	Annex III Annex IV
		All Class I sterile devices	Production quality assurance Product quality assurance	Annex V Annex VI

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ECM-ZERTIFIZIERUNGSGESELLSCHAFT FÜR MEDIZINPRODUKTE IN EUROPA MBH Eifelstraße 1c 52068 AACHEN Germany	0481	Non-active medical devices - bandages and dressings	EC type-examination EC verification	Annex III Annex IV
		Non-active medical devices - disposable medical devices - Devices for wound care - Implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Non-active medical devices - epidural catheters - implantable catheters	EC type-examination EC verification	Annex III Annex IV
		Non-active medical devices - non-implantable medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Non-active medical devices - spinal catheters	EC type-examination EC verification	Annex III Annex IV
		Medical devices covered by directive 2003/32/EC	Full quality assurance system Production quality assurance	Annex II Annex V
		Non-active medical devices - dental products - medical devices with special constituents/raw materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

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MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH Vorsetzen 35 20459 HAMBURG Germany	0482	Non-active medical devices Active medical devices, except - x-ray diagnostic devices for CT and angiographie; MR-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
		Medical devices covered by directive 2003/32/EC	Full quality assurance system Production quality assurance	Annex II Annex V

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MDC MEDICAL DEVICE CERTIFICATION GMBH Kriegerstrasse 6 70191 STUTTGART Germany	0483	non-active medical devices with already existing EC type examination certificate	EC type-examination	Annex III
		Non-active medical devices Active medical devices, except <ul style="list-style-type: none"> <li>- devices for inhalation anaesthesia</li> <li>- hyperthermy devices</li> <li>- devices for extracorporal circulation, haemopheresis</li> <li>- devices for hyperbaric therapy</li> </ul> Active medical devices <ul style="list-style-type: none"> <li>- radiotherapy devices               <ul style="list-style-type: none"> <li>- with ionizing radiation and with non-ionizing radiation</li> </ul> </li> <li>- ophtalmological devices</li> <li>- dental equipment</li> <li>- medical supply units</li> <li>- prostheses and rehabilitation devices</li> <li>- devices to monitor and determine vital signs</li> <li>- disinfection and sterilization equipment</li> <li>- infusion devices</li> <li>- imaging equipment</li> <li>- patient positioning and transport equipment</li> <li>- stimulators</li> <li>- surgical devices and aids</li> <li>- ventilators and oxygen therapy apparatus</li> <li>- software</li> </ul>	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

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		<ul style="list-style-type: none"> <li>- devices for imaging</li> <li>- with ionizing radiation</li> <li>- with non-ionizing radiation</li> </ul> Active medical devices, except <ul style="list-style-type: none"> <li>- external cardiac pacemakers and defibrillators</li> <li>- litholripter</li> </ul>		
SLG PRÜF UND ZERTIFIZIERUNGS GMBH Burgstädter Strasse 20 09232 Hartmannsdorf Germany	0494	Active medical devices, except <ul style="list-style-type: none"> <li>- hyperbaric therapy chambers</li> </ul>	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, 53 1749-004 LISBOA Portugal	0503	Non-active medical devices 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
Nordic Dental Certification P.O.Box 70 1303 HASLUM Norway	0510	Devices manufactured utilizing animal tissue covered by Directive 2003/32/EC are excluded: Medical devices for dentistry	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex II Annex III Annex IV Annex V

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			Product quality assurance	Annex VI
EUROCAT - INSTITUTE FOR CERTIFICATION AND TESTING GMBH Quarat Center, Wittichstrasse 2 64295 DARMSTADT Germany	0535	Non-active medical devices - Devices for wound care - Implants - instruments and equipment for dentistry - disposable medical devices - non-implantable 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
		Non-active medical devices - medical devices with special constituents/raw materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

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VTT (TECHNICAL RESEARCH CENTRE OF FINLAND) PL 1300 33101 Tampere 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 IIa and IIb devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II 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
DS Certificering A/S - Danish Medical Devices Certification Kollegievej, 6 DK-2920 Charlottenlund Denmark	0543	Infusion devices and accessories Wound care devices Drains, tubes, probes, catheters and suction devices Surgical devices and accessories Dental materials and implants Adhesives and sutures Contraceptives surgical implants (excluding orthopaedic implants and bone cement) Sterile and non-sterile single use products Cardio vascular implants Devices for assisted reproduction dental equipment and instruments electrocardiographs and electroencephalographs	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 or modules	Annexes or articles of the directives
		Devices for the sterilisation of medical devices Ultrasound equipment for diagnosis X-ray systems CT-scanners Patient monitoring devices Resuscitation equipment (includes defibrillators) Respiratory analysis equipment Electro surgical devices and assessories Heart Lung machines Treatment equipment using ionizing radiation, non-ionizing radiation and ultrasound Electro stimulation devices Contact lenses and contactlens solutions and accessories Neonatal devices Hearing aids and audiometres Disinfectants		
CERTIQUALITY S.R.L. - ISTITUTO DI CERTIFICAZIONE DELLA QUALITA' 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 Products and accessories for surgical use Products for endoscopy and laparoscopy Products for extracorporeal circulation and accessories, including active accessories Contraceptive products	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 or modules	Annexes or articles of the directives
		Products for disinfection of medical equipment and for the treatment of contact lenses Bendages, dressings, plasters, etc. Products for anaesthesia, reanimation and respiration Orthopaedic and rehabilitation products and materials and accessories, including powered accessories		
		All Class I sterile devices	Production quality assurance Product quality assurance	Annex V Annex VI
		Catheters and accessories Ophthalmic products non-active devices specifically intended for recording of X-ray diagnostic images	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 or modules	Annexes or articles of the directives
BERLIN CERT PRÜF- UND ZERTIFIZIERSTELLE FÜR MEDIZINPRODUKTE GMBH AN DER TECHNISCHEM UNIVERSITÄT BERLIN Dovesstraße 6 10587 BERLIN Germany	0633	Active medical devices, except - devices for hyperbaric therapy - devices for imaging and radiotherapy utilizing ionizing radiation - devices for laser surgery - devices for laser therapy - devices for magnetic resonance imaging - equipment and devices for hyperbaric therapy - lithotripter - software - ultrasonic equipment	EC type-examination EC verification	Annex III Annex IV
		devices for disinfection and sterilisation devices for stimulation rehabilitation devices and active protheses surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
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

**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 or modules	Annexes or articles of the directives
RESEARCH CENTER FOR BIOMATERIALS S.A. "EKEVYL S.A." Smyrnis 15 165 62 GLYFADA Greece	0653	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 Contact lenses and solutions for contact lenses Absorbable and non-absorbable surgical sutures - disinfectants and antiseptics 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
		All medical devices	Production quality assurance	Annex V
			Product quality assurance	Annex VI
		THERAPEUTIC GOODS ADMINISTRATION PO Box 100 ACT 2606 WODEN Australia	0805	All medical devices
			EC type-examination	Annex III
			EC verification	Annex IV
			Production quality assurance	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 or modules	Annexes or articles of the directives
UL INTERNATIONAL (UK) LTD Womersley House Building C The Guildway Old Portsmouth Road Guildford GU3 1LR United Kingdom	0843		Product quality assurance	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
		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
		Own Brand Labelling of all medical devices which have existing NB certification via their original manufacturer	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 III cardiac catheters	Full quality assurance system	Annex II
		All Dental Devices (Non Active)	Full quality assurance system Production quality assurance	Annex II Annex V
MAGYAR ELEKTROTECHNIKAI ELLENORZO INTÉZET KFT. Váci út 48/a-b 1132 Budapest	1007	Monitoring devices for clinical use Patient monitoring devices devices for extracorporeal circulation, infusions and	Full quality assurance system EC type-examination EC verification	Annex II 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 or modules	Annexes or articles of the directives
Hungary		haemopheresis respiratory devices, devices for for oxygen therapy and inhalation anaesthesia surgical devices Equipment and accessories for diagnostic imaging, using ionising and non-ionising radiation devices for stimulation Devices for patient positioning and transport electric power supply for active medical devices	Production quality assurance Product quality assurance	Annex V Annex VI
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	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 or modules	Annexes or articles of the directives
		<ul style="list-style-type: none"> <li>- sterile needles for syringes</li> <li>- insuline syringes/pen injectors</li> <li>- non-reusable medical gloves</li> <li>- condoms made from natural latex</li> <li>- Catheters</li> <li>- bandages and dressings</li> <li>- disposable products</li> <li>- disinfectants and antiseptics</li> <li>Active medical devices               <ul style="list-style-type: none"> <li>- anaesthesia workstations and their modules</li> <li>- ventilators (baby, adult), for intensive care, home use, emergency and transport</li> <li>- capnometers</li> <li>- oxygen monitors</li> <li>- Pulse oxymeters</li> <li>- oxygen therapy equipment (oxygen concentrator)</li> <li>- dental equipment (units, treatment chairs, etc.)</li> <li>- ergometers</li> <li>- spirographs</li> <li>- spirometers</li> <li>- infusion devices</li> <li>- electrocardiographs and electroencephalographs</li> <li>- hearing aids and audiometers</li> <li>- dialysis and urodynamic equipment</li> <li>- blood - and infusion - warming equipment</li> </ul> </li> </ul>		

### 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 or modules	Annexes or articles of the directives
		<ul style="list-style-type: none"> <li>- autotransfusion equipment, bloodcell-separators</li> <li>- baby incubator (clinical, intensive, transport)</li> <li>- non-invasive and invasive blood pressure measuring devices and blood pressure monitors</li> <li>- high frequency surgery equipment</li> <li>- short waves and devices for treatment using heat</li> <li>- medical laser equipment</li> <li>- Electrocardiographs</li> <li>- nerve and muscle stimulator</li> <li>- transcutane partial pressure measuring equipment</li> <li>- intensive care monitor equipment (incl. ECG-monitor)</li> <li>- external pacemakers</li> <li>- heart-defibrillator equipment</li> <li>- suction equipment</li> <li>- warming blankets, pads and mattresses for medical use</li> <li>- equipment for extracorporally induced lithotripsy</li> <li>- medical gas supply system and parts (units) thereof</li> <li>- medical equipment sterilizers</li> <li>- Equipment for endoscopy</li> <li>- operation microscopes</li> <li>- ophtalmological devices</li> <li>- operation and examination lamps</li> <li>- fever thermometers (active)</li> <li>- wheelchairs (electrically operated)</li> </ul>		

**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 or modules	Annexes or articles of the directives
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

**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 or modules	Annexes or articles of the directives
STROJIRENSKY ZKUSEBNI USTAV s.p. Hudcova 56B 621 00 BRNO Czech Republic	1015	Anaesthetic and respiratory equipment Electromedical apparatus for dentistry and stomatology Electromechanical medical devices 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)	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
		All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		medical devices in hospital hardware	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
TEXTILNÍ ZKUŠEBNÍ ÚSTAV s.p. Václavská 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	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 or modules	Annexes or articles of the directives
INSTITUT PRO TESTOVANI A CERTIFIKACI a.s. T. Bati 299 764 21 ZLIN - LOUKY Czech Republic	1023	usage) 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	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 - surgical equipment and ancillary surgical equipment - imaging equipment - with ionizing radiation and with non-ionizing radiation - ophthalmological devices - dental equipment - prostheses and rehabilitation devices - medical gas supply system and parts (units) thereof	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 or modules	Annexes or articles of the directives
		<ul style="list-style-type: none"> <li>- disinfection and sterilization equipment</li> <li>Non-active medical devices               <ul style="list-style-type: none"> <li>- soft tissue implants</li> <li>- functional implants</li> <li>- orthopaedic implants</li> </ul> </li> <li>Active medical devices               <ul style="list-style-type: none"> <li>- equipment for extracorporeal circuits, infusions and haemophoresis excluding heart-lung machines</li> </ul> </li> </ul>		
SGS INTERNATIONAL CERTIFICATION SERVICES AG Technopark, Technoparkstrasse 1 8005 ZÜRICH Switzerland	1251	Non-active medical devices <ul style="list-style-type: none"> <li>- functional implants</li> </ul> Sterile and non-sterile single use products <ul style="list-style-type: none"> <li>- Non-implantable products for orthopaedics and rehabilitation</li> <li>- reusable non-active medical instruments</li> <li>- bandages and dressings</li> <li>- suture material and clamps</li> <li>- dental equipment and instruments</li> <li>- dental materials</li> <li>- dental implants</li> <li>- disinfectants and antiseptics</li> </ul> Active medical devices <ul style="list-style-type: none"> <li>- devices to monitor and determine vital signs</li> <li>- devices for infusion, injection</li> <li>- imaging equipment               <ul style="list-style-type: none"> <li>- with non-ionizing radiation</li> </ul> </li> </ul>	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 or modules	Annexes or articles of the directives
		<ul style="list-style-type: none"> <li>- ophtalmological devices</li> <li>- disinfection and sterilization equipment</li> <li>- patient storage and transport equipment</li> </ul> Software for operating medical devices Measuring devices		
QS Schaffhausen AG Wiesengasse 20 CH-8222 Beringen Switzerland	1252	Non-active medical devices <ul style="list-style-type: none"> <li>- skeleton implants</li> <li>- functional implants</li> <li>- single use medical products</li> <li>- reusable non-active medical instruments</li> <li>- surgical instruments</li> <li>- wound dressings and bandages</li> <li>- sutures and surgical clips</li> <li>- instruments and equipment for dentistry</li> <li>- dental materials</li> </ul> Active medical devices <ul style="list-style-type: none"> <li>- patient storage and transport equipment</li> <li>- dental equipment</li> <li>- diagnostic devices without ionising radiation</li> <li>- measuring equipment as accessories to medical devices</li> <li>- prostheses and equipment for rehabilitation</li> </ul>	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
Swiss TS Technical Services AG Richtistrasse 15 CH-8304 Wallisellen Switzerland	1253	Active medical devices <ul style="list-style-type: none"> <li>- disinfection and sterilization equipment</li> <li>- dental equipment</li> </ul>	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 or modules	Annexes or articles of the directives
		<ul style="list-style-type: none"> <li>- prostheses and rehabilitation devices</li> <li>- surgical equipment and ancillary surgical equipment</li> <li>- patient storage and transport equipment</li> <li>Non-active medical devices</li> <li>Single-use products               <ul style="list-style-type: none"> <li>- reusable non-active medical instruments</li> </ul> </li> <li>Wound dressings and bandages</li> <li>Surgical instruments               <ul style="list-style-type: none"> <li>- suture material and surgical clamps and clips</li> <li>- dental equipment and instruments</li> <li>- dental materials</li> <li>- dental implants</li> <li>- non-energized medical instrumentation</li> <li>- contact lens care devices</li> <li>- disinfectants and antiseptics</li> </ul> </li> <li>Orthopaedic, prosthetic and rehabilitation products               <ul style="list-style-type: none"> <li>- ophthalmological products</li> <li>- products for anaesthesia and reanimation</li> </ul> </li> <li>Probes and catheters for urology, gastroenterology, respiratory tracts and surgical aspiration</li> <li>Catheters and accessories</li> <li>Devices for parenteral and enteral nutrition</li> </ul>		
QS Zürich AG Wehntalerstrasse Postfach 6335 CH-8050 Zürich Switzerland	1254	Non-active medical devices <ul style="list-style-type: none"> <li>- skeleton implants</li> <li>- functional implants</li> </ul>	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 or modules	Annexes or articles of the directives
		<ul style="list-style-type: none"> <li>- single use medical products</li> <li>- reusable non-active medical instruments</li> <li>- surgical instruments</li> <li>- wound dressings and bandages</li> <li>- sutures and surgical clips</li> <li>- instruments and equipment for dentistry</li> <li>- dental materials</li> <li>- dental implants</li> </ul> Active medical devices <ul style="list-style-type: none"> <li>- patient storage and transport equipment</li> <li>- dental equipment</li> <li>- diagnostic devices without ionising radiation</li> <li>- measuring equipment as accessories to medical devices</li> <li>- prostheses and equipment for rehabilitation</li> </ul>		
LGA INTERCERT ZERTIFIZIERUNGSGESELLSCHAFT MBH Tillystrasse, 2 90431 NÜRNBERG Germany	1275	Non-active medical devices Active medical devices, except <ul style="list-style-type: none"> <li>- hyperthermy devices</li> <li>- medical supply units</li> </ul>	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 devices covered by directive 2003/32/EC	Full quality assurance system Production quality assurance	Annex II Annex V
EVPU a.s. Trencianska 19 018 51 NOVA DUBNICA Slovakia	1293	All medical devices	Full quality assurance system EC type-examination EC verification	Annex II 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 or modules	Annexes or articles of the directives
			Production quality assurance Product quality assurance	Annex V Annex VI
VYSKUMNY USTAV ZVARACSKY - PRIEMYSELNY INSTITUT 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
Technicky skusobny ustav Piestany s.p. Krajinska cesta 2929/9 921 24 Piestany Slovakia	1299	Non-active class IIa and IIb devices  Non-active medical devices in Class III  Active medical devices and their accessories	EC type-examination EC verification Production quality assurance Product quality assurance  Full quality assurance system EC type-examination EC verification Production quality assurance  Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex III Annex IV Annex V Annex VI  Annex II Annex III Annex IV Annex V  Annex II Annex III Annex IV Annex V Annex VI
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	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 or modules	Annexes or articles of the directives
		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		
		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
SKLARSKY USTAV HRADEC KRALOVE, s.r.o Skroupova 957 501 01 HRADEC KRALOVE Czech Republic	1386	Hospital accessories (only glass transfusion bottles and glass bottles for blood)	Full quality assurance system EC verification	Annex II 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 or modules	Annexes or articles of the directives
POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. ul. Klobucka 23A 02-699 Warszawa Poland	1434	Medical gas pipeline systems	Full quality assurance system	Annex II
		active prosthesis and rehabilitation devices	Full quality assurance system	Annex II
		devices designed to image the function of the organs	EC type-examination	Annex III
		disinfectants and sterilizers for medical devices	EC verification	Annex IV
		electromedical apparatus for diagnosis and therapy	Production quality assurance	Annex V
		equipment for non-ionizing (laser, UV, temperature) and ionizing radiation therapy; software for therapy planning	Product quality assurance	Annex VI
		Gloves for medical use	Full quality assurance system	Annex II
		Catheters, drains and probes	EC type-examination	Annex III
		Probes and catheters for urology, gastroenterology, respiratory tracts, surgical aspiration and oxygen therapy	Production quality assurance	Annex V
		Syringes condoms and pessaries dental rotary instruments implants except orthopaedic implants and artificial heart valves multiple-use surgical instruments in Class IIa and above sterile medical devices except ophtalmic devices (Class IIa and above)	Product quality assurance	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 or modules	Annexes or articles of the directives
INSTYTUT WLOKIENICTWA ul. Brzezinska 5/15 92-103 Lodz Poland	1435	active therapeutic devices intended to administer or exchange energy - Class IIa  devices intended to be used for disinfection - Class IIa	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI
		invasive medical devices intended to administer and/or remove medicines, body liquids or other substances to or from the body - Class IIa, made of plastic  invasive, non-active implants - Class IIb, III, made of textiles	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 devices containing a medicinal product - Class III	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex II Annex III Annex IV Annex V
		medical devices used for contraception - Class IIb non-invasive medical devices intended for channelling or storing blood or body liquids - Class IIa and IIb, made of plastic primary wound dressing which come into contact with injured skin - Class I-sterile, IIa and IIb surgical threads - Class IIb and III, natural and synthetic	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 or modules	Annexes or articles of the directives
INSTYTUT NAFTY I GAZU 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
STOWARZYSZENIE ELEKTRYKOW POLSKICH - BIURO BADAWCZE DS. JAKOSCI ul. M. 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 LT-50131 KAUNAS Lithuania	1609	Medical electrical equipment, general requirements Non-invasive sphygmomanometers Medical electrical systems electroencephalographs Diagnostic and therapeutic laser equipment Nerve and muscle stimulators dental equipment and instruments	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 or modules	Annexes or articles of the directives
		Dental equipment and accessories		
SGS Belgium NV Noorderlaan 87 BE-2030 Antwerpen Belgium	1639	Non-active medical devices, except Class III devices 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
Oficiul Tehnic de Dispozitive Medicale-OTDM CERTIFICARE B-dul Nicolae Titulescu nr. 58, sector 1, cod postal 011144 Bucuresti Romania	1868	Active medical devices and their accessories 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

## 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 or modules	Annexes or articles of the directives
TUV Rheinland Italia SRL Via Mattei, 10 20010 - Pogliano Milanese (MI) Italy	1936	Equipment for measuring and/or monitoring and/or recording and/or analysing physiological parameters and vital functions Equipment for rehabilitation Equipment for aerosol therapy and accessories	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI
		Contraceptive products	Full quality assurance system	Annex II
		Medical weighing instruments	EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI
		Anaesthetic and respiratory equipment Infant radiant warmers dental equipment (except for: equipment for tartar ablation, equipment for dental diagnosis)	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI
		equipment for extracorporeal circulation (except for: equipment for haemodialysis, equipment for blood oxygenation in extracorporeal circulation)	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
		equipment for ionophoresis	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI
		equipment for medicinal gases administration	Full quality assurance system EC type-examination EC verification	Annex II 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 or modules	Annexes or articles of the directives
			Production quality assurance Product quality assurance	Annex V Annex VI
		equipment for radiology laser scalpel, ultrasound scalpel and electric scalpel optic devices/equipment echographers incubators blood heater heat exchanger for extracorporeal circulation electrically powered heat exchangers equipment for blood oxygenation in extracorporeal circulation suction pump, turbines and drills for chirurgical use	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI
		gloves for medical use, gauzes, syringes, needles and scalpels equipment for dental diagnosis therapeutic lasers	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		equipment for haemodialysis	EC type-examination EC verification	Annex III Annex IV
		equipment for peritoneal dialysis equipment for tartar ablation	EC verification	Annex IV
		cardiac stimulation equipment	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II 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 or modules	Annexes or articles of the directives
		equipment for diathermy (except for: blood heater, heat exchanger for extracorporeal circulation, infant radiant warmers, electrically powered heat exchangers)	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
muscular and neuromuscular electrostimulators endoscopes	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI		
SGS Hungária Minőségellenorzo, Kereskedelmi és Szolgáltató Kft. Sirály utca 4. H-1124 Budapest Hungary	1979	Active medical devices Non-active medical devices, except soft tissue implants, cardio vascular implants and 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 or modules	Annexes or articles of the directives
Bureau Veritas E & E Product Services GmbH Businesspark A96 86842 Türkheim Germany	2004	stimulators	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 extracorporeal circulation, infusions and haemopheresis respiratory devices, devices for for oxygen therapy and inhalation anaesthesia surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		electric power supply for active medical devices	EC type-examination EC verification	Annex III Annex IV
		equipment for measuring and/or recording and/or analysing vital functions software	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