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	29	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 Ilb 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	32	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 ANLAGENTECHNIK GMBH UNTERNEHMENSGRUPPE TÜV RHEINLAND/BERLIN-BRANDENBURG Am Grauen Stein D-51105 Köln Germany	35	Active medical devices :	EC Type-examination EC verification	Annex III Annex IV
		- equipment for infusions		
		- anaesthesia devices, respirators and oxygen therapy equipment		
		- vital-parameter monitoring and plotting devices		
		- surgical equipment and ancillary surgical equipment		
		- stimulation devices		
		- ophtalmological devices		
		- dental equipment		
		- prostheses and rehabilitation devices		
		- disinfection and sterilization equipment		
		- radiotherapy equipment with non-ionizing radiation		
		- medical supply units		
		- patient storage and transport equipment		
		- imaging equipment :		
		. with ionizing radiation		
		. with non-ionizing radiation		
RWTÜV ANLAGENTECHNIK GMBH Langemarkstrasse, 20 45138 ESSEN Germany	44	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
		- orthopaedic implants		
		- soft tissue implants		

Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures / modules	Annexes / articles of the directives
RWTÜV ANLAGENTECHNIK GMBH Langemarkstrasse, 20 45138 ESSEN Germany	44	- function 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
		- disposable medical devices		
		- anaesthetic, orthopaedic and rehabilitation products		
		- non-energized medical instrumentation		
		- reusable non-active medical instruments		
		- bandages and dressings		
		- suture material and clamps		
		- dental equipment and instruments		
		- dental materials		
		- dental implants		
		Active medical devices :		
		- devices to ascertain vital functions		
		- equipment for extracorporeal circuits, infusions and haemophoresis		
		- anaesthesia devices, incubators, respirators and oxygen therapy equipment		
		- surgical equipment and ancillary surgical equipment		
		- stimulation devices		
		- ophtalmological devices		
		- dental equipment		
		- prostheses and rehabilitation devices		
		- disinfection and sterilization equipment		
		- radiotherapy devices :		
		. with ionizing radiation and with non-ionizing radiation		
		. with non-ionizing radiation		
		- imaging equipment :		
		. with ionizing radiation		
		. with non-ionizing radiation		
NATIONAL STANDARDS AUTHORITY OF IRELAND (NSAI) Glasnevin 9 DUBLIN Ireland	50	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

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
ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ (IMQ S.P.A.) Via Quintiliano, 43 20138 MILANO Italy	51	Eye examination equiment	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 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		
		Disposable syringes	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Urethral catheters, catheters for heart surgery and for the central cirulatory system		
		Bags for parenteral and enteral nutrition and accessories		
		Contact lenses		
		Solutions for contact lenses		
		Auditory prostheses		
ISTITUTO DI RICERCHE E COLLAUDI M. MASINI SRL Via Moscova 11 20017 RHO Italy	68	Equipment for aerosol therapy, humidification and nebulisation	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 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		

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
ISTITUTO DI RICERCHE E COLLAUDI M. MASINI SRL Via Moscova 11 20017 RHO Italy	68	Equipment for infusion, transfusion, extracorporeal circulation, plasmapheresis and blood collection	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 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		
BSI 389 Chiswick High Road W4 4AL LONDON United Kingdom	86	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	88	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
BAYERISCHES LANDESAMT FÜR MAß UND GEWICHT Franz-Schrank Straße, 9 80638 MÜNCHEN Germany	104	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
		- measuring devices to determine body temperature		
		- tonometers		
		- non-invasive sphygmomanometers		
		- audiometers		
		- therapy dosimeters		
		- diagnostic dosimeters		

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
LANDESAMT FÜR MEß- UND EICHWESEN DES LANDES BRANDENBURG Stahnsdorfer Damm, 81 14532 KLEINMACHNOW Germany	106	Electrical thermometers for clinical use Non-invasive sphygmomanometers	EC verification	Annex IV
LANDESAMT FÜR MEß- UND EICHWESEN THÜRINGEN Unterpörlitzer Straße, 2 98693 ILMENAU Germany	118	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
		- measuring devices to determine body temperature		
		- tonometers		
		- non-invasive sphygmomanometers		
		- flow meters		
		- 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		
		- non-invasive sphygmomanometers		
		- devices to ascertain vital functions		
		- flow meters		
SGS UNITED KINGDOM LIMITED Worle Park, Weston-Super-Mare BS22 OWA SOMERSET United Kingdom	120	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Infusion / syringe pumps	EC Type-examination	Annex III
		General electro / mechanical equipment - stimulation devices	EC verification	Annex IV
		- defibrillators	EC Type-examination	Annex III
		- condoms and contraceptive pessaries	EC Type-examination EC verification	Annex III Annex IV
		Equipment and accessories for dialysis	EC Type-examination	Annex III
		- Electrocardiographs		

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
SGS UNITED KINGDOM LIMITED Worle Park, Weston-Super-Mare BS22 OWA SOMERSET United Kingdom	120	Blood pressure measurement devices Electrical thermometers for clinical use	EC verification	Annex IV
TÜV PRODUCT SERVICE GMBH Ridlerstraße, 65 80339 MÜNCHEN Germany	123	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
		- orthopaedic implants		
		- soft tissue implants		
		- function implants		
		- disposable medical devices		
		- anaesthetic, orthopaedic and rehabilitation products		
		- non-energized medical instrumentation		
		- reusable non-active medical instruments		
		- bandages and dressings		
		- suture material and clamps		
		- dental equipment and instruments		
		- dental materials		
		- dental implants		
		Active medical devices :		
		- devices to ascertain vital functions		
		- equipment for extracorporeal circuits, infusions and haemophoresis		
		- anaesthesia devices, incubators, respirators and oxygen therapy equipment		
		- surgical equipment and ancillary surgical equipment		
		- stimulation devices		
		- ophtalmological devices		
		- dental equipment		
		- prostheses and rehabilitation devices		
		- disinfection and sterilization equipment		
		- disinfectants and antiseptics		
		- radiotherapy devices :		
		. with ionizing radiation and with non-ionizing radiation		
		. with non-ionizing radiation		
		- imaging equipment :		
		. with ionizing radiation		

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
TÜV PRODUCT SERVICE GMBH Ridlerstraße, 65 80339 MÜNCHEN Germany	123	. with non-ionizing 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
DEKRA CERTIFICATION SERVICES (DCS) GMBH Handwerkstraße 15 70565 STUTTGART Germany	124	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
		- orthopaedic implants		
		- soft-tissue implants		
		- function implants		
		- disposable medical devices		
		- anaesthetic, orthopaedic and rehabilitation products		
		- non-energized medical instrumentation		
		- reusable non-active medical instruments		
		- bandages and dressings		
		- suture material and clamps		
		- dental equipment and instruments		
		- dental materials		
		- dental implants		
		Active medical devices :		
		- devices to ascertain vital functions		
		- equipment for extracorporeal circuits, infusions and haemophoresis		
		- anaesthesia devices, incubators, respirators and oxygen therapy equipment		
		- surgical equipment and ancillary surgical equipment		
		- stimulation devices		
		- ophtalmological devices		
		- dental equipment		
		- prostheses and rehabilitation devices		
		- disinfection and sterilization equipment		
		- radiotherapy devices :		
		. with ionizing radiation and with non-ionizing radiation		
		. with non-ionizing radiation		
		- imaging equipment :		
		. with ionizing radiation		
		. with non-ionizing radiation		

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
DEKRA CERTIFICATION SERVICES (DCS) GMBH Handwerkstraße 15			Full quality assurance system EC Type-examination EC verification	Annex II Annex III Annex IV
LGA - LANDESGEWERBEANSTALT BAYERN Tillystraße, 2 90431 Nürnberg Germany	125	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
		- orthopaedic implants		
		- soft tissue implants		
		- funtion implants		
		- disposable medical devices		
		- anaethestic, orhtopaedic and rehabilitation products		
		- non-energized medical instrumentation		
		- reusable non-active medical instruments		
		- bandages and dressings		
		- suture material and clamps		
		- dental equipment and instruments		
		- dental implants		
		Active medical devices :		
		- devices to ascertain vital functions		
		- equipment for extracorporeal circuits, infusions and haemophoresis		
		- anaesthesia devices, incubators, respirators and oxygen therapy equipment		
		- surgical equipment and ancillary surgical equipment		
		- stimulation devices		
		- ophtalmological devices		
		- dental equipment		
		- prostheses and rehabilitation devices		
		- disinfection and sterilization equipment		
		- radiotherapy devices :		
		. with ionizing radiation and with non-ionizing radiation		
		. with non-ionizing radiation		
		- imaging equipment :		
		. with ionizing radiation		
		. with non-ionizing radiation		

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
TÜV RHEINLAND PRODUCT SAFETY GMBH Am Grauen Stein 51105 Köln Germany	197	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
		- devices to ascertain vital functions		
		- stimulation equipment		
		- anaesthesia devices, incubators, respirators and oxygen therapy equipment		
		- equipment for extracorporeal circuits, infusions and haemophoresis		
		- ophtalmological devices		
		- surgical equipment and ancillary surgical equipment		
		- dental equipment		
		- prostheses and rehabilitation devices		
		- disinfection and sterilization equipment		
		- radiotherapy devices :		
		. with non-ionizing radiation		
		. with ionizing radiation and with non-ionizing radiation		
		- imaging equipment :		
		. with ionizing radiation		
		. with non-ionizing radiation		
		Non-active medical devices : - orthopaedic implants - soft tissue implants - function implants - suture material and clamps - anaesthetic, orthopaedic and rehabilitation devices - non-energized medical instrumentation - reusable non-active medical instruments - bandages and dressings - dental equipment and instruments - dental materials - dental implants	Full quality assurance system EC Type-examination Production quality assurance Product quality assurance	Annex II Annex III Annex V Annex VI
DEUTSCHE GESELLSCHAFT ZUR ZERTIFIZIERUNG VON MANAGEMENTSYSTEMEN MBH - QUALITÄTS- UND UMWELTGUTACHTER August-Schanz Straße, 21 60433 FRANKFURT AM-MAIN Germany	297	Non-active medical devices:  - soft tissue implants - function implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

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
DEUTSCHE GESELLSCHAFT ZUR ZERTIFIZIERUNG VON MANAGEMENTSYSTEMEN MBH - QUALITÄTS- UND UMWELTGUTACHTER August-Schanz Straße, 21 60433 FRANKFURT AM-MAIN Germany	297	- disposable medical products  - anaesthetic, orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		- orthopaedic implants		
		- non-energized medical instrumentation		
		- bandages and dressings		
		- reusable non-active medical instruments		
		- suture material and clamps		
		- dental equipment and instruments		
		- dental materials		
		- dental implants		
		Active medical devices :		
		- devices to ascertain vital functions		
		- equipment for extracorporeal circuits, infusions and haemophoresis excluding heart-lung machines		
		- anaesthesia devices, incubators, respirators and oxygen therapy equipment		
		- surgical equipment and ancillary surgical equipment		
		- stimulation devices		
		- ophtalmological devices		
		- dental equipment		
		- prostheses and rehabilitation devices		
		- disinfection and sterilization equipment		
		- radiotherapy equipment with non-ionizing radiation		
		- imaging equipment: . with ionizing radiation . with non-ionizing radiation		
TÜV- ZERTIFIZIERUNGSGEMEINSCHAFT e.V. TÜV CERT Reuterstraße, 161 53113 BONN Germany	298	Active medical devices :	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
•		- devices to ascertain vital functions		
		- equipment for extracorporeal circuits, infusions and haemoforesis		

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
TÜV- ZERTIFIZIERUNGSGEMEINSCHAFT e.V. TÜV CERT Reuterstraße, 161 53113 BONN Germany	298	- anaesthesia devices, incubators, respirators and oxygen therapy equipment	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		- surgical equipment and ancillary surgical equipment		
		- stimulation devices		
		- ophtalmological devices		
		- dental equipment		
		- prostheses and rehabilitation devices		
		- disinfection and sterilization equipment		
		- radiotherapy devices :		
		. with ionizing radiation and with non-ionizing radiation		
		. with non-ionizing radiation		
		- imaging equipment :		
		. with ionizing radiation		
		. with non-ionizing radiation		
DIRECCION GENERAL DE FARMACIA Y PRODUCTOS SANITARIOSMINISTERIO DE SANIDAD Y CONSUMO PO. del Prado, 18-20 28014 MADRID Spain	318	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
TNO CERTIFICATION B.V. Laan Westenenk 501,Postbus 541 7300 AM APELDOORN Netherlands	336	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 9035) 6800 ET ARNHEM Netherlands	344	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
ITS TESTING AND CERTIFICATION LTD ITS House, Cleeve Road KT22 7SB Leatherhead United Kingdom	359	Active medical devices but excluding :	EC Type-examination EC verification	Annex III Annex IV
		- blood gas analysers (invivo)		
		- anaesthesia machines		
		- lung ventilators		
		- respiratory therapy equipment		

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
ITS TESTING AND CERTIFICATION LTD ITS House, Cleeve Road KT22 7SB Leatherhead United Kingdom	359	- breathing systems attachments and components	EC Type-examination EC verification	Annex III Annex IV
		- extracoporeal blood treatment equipment		
		- electrosurgical equipment		
		- medical laser equipment		
		- 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	366	Active medical devices, except :	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
		- disinfection and sterilization equipment		
ISTITUTO SUPERIORE DI SANITA Viale Regina Elena, 299 00161 ROMA Italy	373	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
ISTITUTO DI RICERCHE, PROVE E ANALISI SRL Via Artigiani, 63 25040 BIENNO Italy	398	Single-use products	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Equipment for electrosurgery	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
		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		

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
ISTITUTO DI RICERCHE, PROVE E ANALISI SRL Via Artigiani, 63 25040 BIENNO Italy	398	- 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
TÜV- ÖSTERREICH Krugerstrasse 16 1015 Wien Austria	408	Active medical devices(including 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
		Non-active medicinal devices (including accessories)		
		Bone nails, screws and plates (including accessories)		
		- disposable products		
		- For preserving/conducting blood, other body fluids and tissue,		
		liquids and gases		
		- For contraception		
		- Dressings		
		- Dental products excluding dental materials		
		- Cleaning, disinfecting and sterilizing devices		
		- Products for endoscopy and endoscopic surgery		
		- Non-implantable products for orthopaedics and rehabilitation		
		All Class I sterile devices	Production quality assurance	Annex V
SEMKO AB Torshamnsgatan, 43 164 22 KISTA Sweden	413	Active therapeutic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		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		
		Electrical devices intended to administer and/or remove medicines or products, body liquids or other substances to or from the body	EC Type-examination EC verification	Annex III Annex IV
		Electrical therapeutic 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
SEMKO AB Torshamnsgatan, 43 164 22 KISTA Sweden	413	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
ITALCERT Viale Sarca, 336 20126 MILANO Italy	426	Devices in sterile packs	Production quality assurance Product quality assurance	Annex V Annex VI
		Measuring devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		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		
MATERIALPRÜFUNGSAMT NORDRHEIN-WESTFALEN (MPA NRW) Marsbruchstraße 186 D-44287 DORTMUND Germany	432	Active medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		- radiotherapy equipment with non-ionizing radiation		
		- hearing aids and audiometers		
		- ultrasound equipment		

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
MATERIALPRÜFUNGSAMT NORDRHEIN-WESTFALEN (MPA NRW) Marsbruchstraße 186 D-44287 DORTMUND Germany	432	- imaging equipment :	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		. with ionizing radiation		
		. with non-ionizing radiation		
DET NORSKE VERITAS REGION NORGE AS (DNV RN) Veritasveien 1 1322 HOVIK Norway	434	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 BP n° 8 92260 FONTENAY-AUX-ROSES France	459	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	470	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 Norman Road - Broadheath WA14 4EP ALTRINCHAM United Kingdom	473	All medical devices except equipment emitting ionising radiation	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	476	Electromedical apparatus for physiotherapy and rehabilitation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		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		
		Prostheses	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
		Dental prostheses		
		Orthopaedic prostheses		
		Infusion and withdrawal needles		

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
CERMET Via Aldo Moro, 22 40068 S. LAZZARO DI SAVENA Italy	476	Cannulas, probes and tubes	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
		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		
BIOLAB SPA - CENTRO DI ANALISI E RICERCHE BIOLOGICHE Via Bruno Buozzi, 2 20090 VIMODROME Italy	477	Non-resorbable surgical implants	EC Type-examination EC verification	Annex III Annex IV
		Devices for infusion, transfusion, injection, withdrawal, extracorporeal circuits		
		- ophtalmological 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		
		All Class I sterile devices	Production quality assurance Product quality assurance	Annex V Annex VI

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
ECM- ZERTIFIZIERUNGSGESELLSCHAFT FÜR MEDIZINPRODUKTE IN EUROPA MBH Eifelstraße, 1C 52068 AACHEN Germany	481	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
		- disposable medical products :		
		. infusion / transfusion sets		
		. catheters / catheter sets		
		. drainage devices		
		. tubing for extracorporeal circulation		
		- OP products		
		- bandages and dressings		
		- soft tissue implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		- disinfection means		
		- orthopaedic implants		
		- contact lenses		
		- contact lens care products		
MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSHAFT FÜR DIE MEDIZIN GMBH Vorsetzen 32 20459 HAMBURG Germany	482	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
		- orthopaedic implants		
		- soft tissue implants		
		- disposable medical products		
		- function implants		
		- non-energized medical instrumentation		
		- anaesthetic, orthopaedic and rehabilitation products		
		- reusable non-active medical instruments		
		- bandages and dressings		
		- suture material and clamps		
		- dental equipment and instruments		
		- dental materials		
		- dental implants		
		Active medical devices :		

Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures / modules	Annexes / articles of the directives
MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSHAFT FÜR DIE MEDIZIN GMBH Vorsetzen 32 20459 HAMBURG Germany	482	- patient storage and transport 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
		- imaging equipment using non-ionizing radiation, with the exception of MR		
		- X-ray equipment apart from CT and angiography		
		- surgical equipment and accessories, including lithotriptors; Hf, Laser and ultra-sound surgery; endoscopes		
		- vital-parameter monitoring and plotting devices		
		- breathing apparatus and oxygen-therapy equipment including hyperbaric therapy chambers		
		- equipment for extracorporeal circuits, infusions and haemophoresis		
		- inhalation anaesthesizing equipment		
		- stimulation devices		
		- ophtalmological devices		
		- dental equipment		
		- prostheses and rehabilitation devices		
		- disinfection and sterilization equipment		
		- radiotherapy equipment with non-ionizing radiation		
		- medical supply units		
MDC MEDICAL DEVICE CERTIFICATION GMBH Heilbronner Strasse 43 70191 STUTTGART Germany	483	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
		Active medical devices:     - devices to ascertain vital functions     - infusion devices     - ventilators and oxygen therapy apparatus, except for devices for hyperbaric therapy     - surgical devices and aids, except for lithotripsy devices     - imaging equipment:     . with ionizing radiation     . with non-ionizing radiation     - stimulators, except external pacemakers and defibrillators     - radiotherapy devices:     . with ionizing radiation and with non-ionizing radiation     - ophtalmological devices     - dental equipment     - rehabilitation devices and active prostheses     - patient storage and transport equipment     - medical supply units	EC Type-examination Production quality assurance Product quality assurance	Annex III Annex V Annex VI

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
SLG PRÜF UND ZERTIFIZIERUNGS GMBH Burgstädedter Strasse 20 09232 Hartmannsdorf Germany	494	- Narcosis devices, incubators, ventilators and oxygen therapy apparatus, 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
		- surgical equipment and ancillary surgical equipment		
		- ophtalmological devices		
		- dental equipment		
		- disinfection and sterilization equipment		
		- radiotherapy equipment with non-ionizing radiation		
		- medical supply units		
		- patient storage and transport equipment		
		Equipment for measuring and/or monitoring and/or recording and/or analysing physiological parameters and vital functions		
		Equipment for rehabilitation		
		Auditory prostheses		
		Software for operating medical devices		
		- Devices for imaging processes with non-ionizing radiation, except for nuclear spin tomography devices		
		- Radiation therapy devices using non-ionizing radiation, except for laser therapy devices		
		- stimulators - dental treatment devices - rehabilitation devices and active prostheses - patient storage and transport equipment - devices for medical care	Full quality assurance system EC Type-examination EC verification Product quality assurance	Annex II Annex III Annex IV Annex VI
SOCIETE NATIONALE DE CERTIFICATION ET D'HOMOLOGATION S.À.R.L. (SNCH) 11, Route de Sandweiler 5230 SANDWEILER Luxembourg	499	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 1700 LISBOA Portugal	503	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
NORDISK INSTITUTE FOR ODONTOLOGISK MATERIALPRØVNING (SCANDINAVIAN INSTITUTE OF DENTAL MATERIALS) P.O.Box 70 1344 HASLUM Norway	510	Medical devices for dentistery	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

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
SIRA CERTIFICATION SERVICESIRA TEST & CERTIFICATION LIMITED South Hill BR7 5EH Chislehurst - Kent United Kingdom	518	All active medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI
EUROCAT - INSTITUTE FOR CERTIFICATION AND TESTING GMBH Wittichstrasse, 2 64295 DARMSTADT Germany	535	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
		- software for the operation of medical products		
		- medical supply units		
		- patient storage and transport equipment, excluding incubators		
		- surgical aids		
		Active medical devices:		
		- stimulation devices		
		- disinfection and sterilization equipment		
		- prostheses and rehabilitation devices		
		- surgical equipment and ancillary surgical equipment		
		- equipment for extracorporeal circuits, infusions and haemophoresis		
		- ophtalmological devices		
		- dental equipment		
		- Narcosis devices, incubators, ventilators and oxygen therapy apparatus, except for devices for hyperbaric therapy		
		- devices to monitor and determine vital signs		
		- devices for extracorporal circulation, infusions and haemopheresis		
		- radiotherapy devices :		
		. with ionizing radiation and with non-ionizing radiation		
		. with non-ionizing radiation		
		- imaging equipment :		
		. with ionizing radiation		
		. with non-ionizing radiation		
VTT INDUSTRIAL SYSTEMS (VTT TUOTTEET JA TUOTANTO) P.O. Box 13001 33101 Tampere Finland	537	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

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
VTT INDUSTRIAL SYSTEMS (VTT TUOTTEET JA TUOTANTO) P.O. Box 13001 33101 Tampere Finland	537	Non-active class IIa and IIb devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
ZDH-ZERT [RECHTSNACHFOLGER IS DIE MDC MEDICAL DEVICE CERTIFICATION GMBH, KENN-NR 0483, STUTTGART] Heilbronner Strasse, 43 70191 STUTTGART Germany	538	Non-active medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		- orthopaedic implants		
		- reusable non-active medical instruments		
		- dental equipment and instruments		
		- disposable products		
		Active medical devices :		
		- high frequency surgery equipment		
		- dental equipment		
		- hearing aids and audiometers		
		- devices to monitor and determine vital signs		
		- ventilators and oxygen therapy apparatus, except for devices for hyperbaric therapy		
		- surgical devices and aids, except for lithotripsy devices		
		- electrical stimulation and acupuncture devices, hydro electric bath		
		- short waves and devices for treatment using heat		
		- rehabilitation devices and active prostheses		
		- patient storage and transport equipment		
DANSK STANDARD - DANSK GODKENDELSE AF MEDICINSK UDSTYR Kollegievej, 6 2920 CHARLOTTENLUND Denmark	543	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
		- infusion devices		
		- dental materials		
		- bandages and dressings		
		- dental implants		
		- disinfection means		
		- surgical articles		
		- contact lenses		

	Identification number	Responsible for the following products	Responsible for the following procedures / modules	Annexes / articles of the directives
DANSK STANDARD - DANSK GODKENDELSE AF MEDICINSK UDSTYR Kollegievej, 6 2920 CHARLOTTENLUND Denmark	543	- contact lens fluids	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
		- sutures and adhesives		
		- condoms and contraceptive pessaries		
		- intrauterine contraceptives		
		- drains, probes and suction devices		
		- surgical implants (non-orthopaedic implants and bone cement)		
		Active medical devices :		
		- radiotherapy equipment		
		- radiotherapy planning software		
		- stimulation equipment		
		- heart-lung machines		
		- neonatal equipment		
		- dental devices		
		- hearing aids and audiometers		
		- electrocardiographs and electroencephalographs		
		- medical equipment sterilizers		
		- defibrillators		
		- equipment for measuring blood and anaesthesic gas		
		- surgical lasers		
		- ultrasound equipment		
		- patient-monitoring equipment and equipment for recording vital functions		
		- electrosurgical equipment		
		- single use products for heart-lung machines - cardiovascular implants		
		- suction equipment		
		Diagnostic X-ray equipment		
ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ PER L'INDUSTRIA CHIMICA Via G. Giardino, 4 20123 MILANO Italy	546	Medical and measuring equipment with independent power supply or non-powered	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Dental products and materials and accessories, including powered accessories		
		Ophtalmic products, e.g. spectacles and intraocular lenses		

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
ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ PER L'INDUSTRIA CHIMICA Via G. Giardino, 4 20123 MILANO Italy	546	Products and accessories for surgical use	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		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		
		Disposable products		
		Products for anaesthesia, reanimation and respiration		
		Orthopaedic and rehabilitation products and materials and accessories, including powered accessories		
MEDICAL PRODUCTS AGENCY (LÄKEMEDELSVERKET) Box 26 751 03 UPPSALA Sweden	562	Non-active medical devices	Full quality assurance system Production quality assurance	Annex II Annex V
NATIONAL QUALITY ASSURANCE LTD Gainsborough House - Houghton Hall Park W5 5XZ Houghton Regis, Dunstable United Kingdom	577	Devices for the administration to or removal from the patient's body of medicines, body fluids or other substances	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		- ultrasound equipment		
		Electromedical equipment		
		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	Production quality assurance Product quality assurance	Annex V Annex VI
		Functions relating to sterile / measuring Class I 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
BERLIN-CERT-PRÜF- UND ZERTIFIZIERSTELLE FÜR MEDIZINPRODUKTE GMBH AN DER TECHNISCHEN UNIVERSITÄT BERLIN Dovestrasse, 6 10587 BERLIN Germany	633	Active medical devices:	EC Type-examination EC verification	Annex III Annex IV
		- Narcosis devices, incubators, ventilators and oxygen therapy apparatus, except for devices for hyperbaric therapy		
		- Surgical devices and aids, except for lithotripsy, ultrasound and laser surgery devices		
		- anaesthetic, orthopaedic and rehabilitation devices		
		- prostheses and rehabilitation devices		
		- dental equipment		
		- non-energized medical instrumentation		
		- reusable non-active medical instruments		
		- radiotherapy equipment with non-ionizing radiation		
		- medical supply units		
		- patient storage and transport equipment		
		- dental equipment and instruments		
		- devices to monitor and determine vital signs		
		- Radiation therapy devices using non-ionizing radiation, except for laser therapy devices		
		- Devices for imaging processes with non-ionizing radiation, except for nuclear spin tomography devices		
		- devices for extracorporal circulation, infusions and haemopheresis - dental treatment devices Non-active medical devices: - dental materials - dental implants - condoms made from natural latex - stimulators - patient storage and transport equipment - devices for medical care - Dressings - Cleaning, disinfecting and sterilizing devices Orthopaedic implants Soft tissue implants Functional implants Single-use medical devices		
PRÜFANSTALT FÜR MEDIZINISCHE GERÄTETECHNISCHE UNIVERSITÄT GRAZ Inffeldgasse, 18 8010 GRAZ Austria	636	Active medical devices and their accessories	EC Type-examination EC verification	Annex III Annex IV

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
RESEARCH CENTER FOR BIOMATERIALS S.A. "EKEVYL S.A." Smyrnis 15 165 62 GLYFADA Greece	653	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	EC Type-examination	Annex III
		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		
		Only devices mentioned in § B	EC verification	Annex IV
INTERNATIONAL CERT ZERTIFIZIERUNG GMBH Straubinger Straße 2 94333 GEISELHÖRING Germany	712	- dental equipment and instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		- dental materials		
		- dental implants		
		- reusable non-active medical instruments		
PRÜF UND FORSCHUNGSINSTITUT FÜR DIE SCHUHHERSTELLUNG E.V. Hans-Sachs-Straße 2 66955 PIRMASENS Germany	713	Non-active, non-sterile medical devices for orthopaedic treatement 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	805	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

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 INTERNATIONAL (UK) LTD Wonersh House Building C, Old Portsm. R. GU3 1LR GUILDFORD United Kingdom	843	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	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Sterile single use medical devices excluding Class III devices, ophthalmic devices, (class IIa and above) and implants		
		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	932	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
ORVOS- ÉS KÓRHÁZTECHNIKAI INTÉZET (ORKI) (INSTIT. FOR MEDICAL AND HOSPITAL ENGIN.) Diós Árok 3 1125 Budapest Hungary	1011	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
		- 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 syringues		
		- sterile needles for syringues		

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
ORVOS- ÉS KÓRHÁZTECHNIKAI INTÉZET (ORKI) (INSTIT. FOR MEDICAL AND HOSPITAL ENGIN.) Diós Árok 3 1125 Budapest Hungary	1011	- insuline syringues/pen injectors	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-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 - 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 matresses for medical use		

## 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
		- medical gas supply system and parts (units) thereof - medical equipment sterilizers - Equipment for endoscopy - operation microscopes - ophtalmological devices - operation and examination lamps - fever thermometers (active) - wheelchairs (electrically operated)		