

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 HANNOVER/SACHSEN-ANHALT E.V. TÜV CERT-ZERTIFIZIERUNGSSTELLE Am TÜV 1 30505 HANNOVER Germany	<b>0032</b>	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	<b>0035</b>	Active medical devices : - equipment for infusions - anaesthesia devices, respirators and oxygen therapy equipment - vital-parameter monitoring and plotting devices - surgical equipment and ancillary surgical equipment - stimulation devices - ophthalmological 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	EC Type-examination EC verification	Annex III Annex IV
RWTÜV e.V. ZERTIFIZIERUNGSSTELLE FÜR GERÄTESICHERHEIT, AUFZÜGE UND MEDIZINTECHNIK Langemarckstrasse, 20 45141 ESSEN Germany	<b>0044</b>	Non-active medical devices : - 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 - ophthalmological devices - dental equipment - prostheses and rehabilitation devices - disinfection and sterilization equipment - radiotherapy devices : . with ionizing radiation . with non-ionizing radiation - imaging equipment : . with ionizing radiation . 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

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
NATIONAL STANDARDS AUTHORITY OF IRELAND Glasnevin 9 DUBLIN Ireland	<b>0050</b>	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ (IMQ S.p.A.) Via Quintiliano, 43 20138 MILANO Italy	<b>0051</b>	Eye examination equipment Equipment for electrosurgery and accessories Anaesthetics equipment, incubators, ventilators, oxygen therapy equipment and accessories Equipment for extracorporeal circulation, infusion, transfusion, haemophoresis and accessories Equipment for dialysis and accessories Equipment for checking and recording vital functions and accessories Cardiac and muscular stimulation equipment and accessories Dental equipment and accessories Opthalmological equipment and accessories Disinfection and sterilization equipment Equipment for aerosol therapy and accessories Clinical imaging equipment using ionizing radiation, non-ionizing radiation and ultrasound Treatment equipment using ionizing radiation, non-ionizing radiation and ultrasound	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		Disposable syringes Urethral catheters, catheters for heart surgery and for the central circulatory system Bags for parenteral and enteral nutrition and accessories Contact lenses Solutions for contact lenses Auditory prostheses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
ISTITUTO DI RICERCHE E COLLAUDI M. MASINI SRL Via Moscova 11 20017 RHO Italy	<b>0068</b>	Equipment for aerosol therapy, humidification and 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	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
BRITISH STANDARDS INSTITUTION 389 Chiswick High Road W4 4AL LONDON United Kingdom	<b>0086</b>	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
LLOYD'S REGISTER QUALITY ASSURANCE (LRQA) LTD EUROPEAN DIRECTIVE SERVICES Middlemarch Office Village - Siskin Driv CV3 4FJ Hiramford - Coventry United Kingdom	<b>0088</b>	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
PHYSIKALISCH-TECHNISCHE BUNDESANSTALT-- BRAUNSCHWEIG (PTB) Bundesallee, 100 38116 BRAUNSCHWEIG Germany	<b>0102</b>	Active medical devices - patient-monitoring equipment and equipment for recording vital functions Electrocardiographs Blood pressure measurement devices Pulse frequency measurement devices Electrical thermometers for clinical use Pulse oxymeters Monitoring devices for clinical use	EC Type-examination EC verification	Annex III Annex IV
BAYERISCHES LANDESAMT FÜR MAß UND GEWICHT Franz-Schrank Straße, 9 80638 MÜNCHEN Germany	<b>0104</b>	Active medical devices : - measuring devices to determine body temperature - tonometers - non-invasive sphygmomanometers - audiometers - therapy dosimeters - diagnostic dosimeters	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
LANDESAMT FÜR MEß- UND EICHWESEN DES LANDES BRANDENBURG Berliner Straße, 52 14467 POSTDAM Germany	<b>0106</b>	Electrical thermometers for clinical use Non-invasive sphygmomanometers	EC verification	Annex IV
LANDESAMT FÜR MEß- UND EICHWESEN THÜRINGEN Unterpörlitzer Straße, 2 98693 ILMENAU Germany	<b>0118</b>	Active medical devices : - 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	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
SGS UNITED KINGDOM LIMITED Worle Park, Weston-Super-Mare BS22 OWA SOMERSET United Kingdom	0120	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		- condoms and contraceptive pessaries	EC Type-examination EC verification	Annex III Annex IV
		Infusion / syringe pumps - defibrillators Equipment and accessories for dialysis Electrocardiographs	EC Type-examination	Annex III
		General electro / mechanical equipment - stimulation devices Blood pressure measurement devices Electrical thermometers for clinical use	EC verification	Annex IV
TÜV PRODUCT SERVICE GMBH Ridlerstraße, 65 80339 MÜNCHEN Germany	0123	Non-active medical devices : - 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 . with non-ionizing radiation - imaging equipment : . with ionizing radiation . 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

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 70565 STUTTGART Germany	0124	Non-active medical devices : - 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 - ophthalmological devices - dental equipment - prostheses and rehabilitation devices - disinfection and sterilization equipment - radiotherapy devices : . with ionizing radiation . with non-ionizing radiation - imaging equipment : . with ionizing radiation . 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

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
LANDESGEWERBEANSTALT BAYERN PRÜFSTELLE FÜR GERÄTESICHERHEIT (LGA) Tillystraße, 2 90431 Nürnberg Germany	<b>0125</b>	Non-active medical devices : - orthopaedic implants - soft tissue implants - funtion 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 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 - ophthalmological devices - dental equipment - prostheses and rehabilitation devices - disinfection and sterilization equipment - radiotherapy devices : . with ionizing radiation . with non-ionizing radiation - imaging equipment : . with ionizing radiation . 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
DIN CERTCO GESELLSCHAFT FÜR KONFORMITÄTSBEWERTUNG MBH Burggrafenstraße 6 10787 BERLIN Germany	<b>0196</b>	Non-active medical devices : - condoms made from natural latex	EC Type-examination EC verification	Annex III Annex IV
		- disposable syringues - infusion and transfusion equipment and accessories - non-reusable medical gloves	EC Type-examination	Annex III
		- dental alloys	EC verification	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
TÜV RHEINLAND Product Safety GmbH Am Grauen Stein 51105 Köln Germany	0197	Active medical devices : - devices to ascertain vital functions - stimulation equipment - anaesthesia devices, incubators, respirators and oxygen therapy equipment - equipment for extracorporeal circuits, infusions and haemophoresis - ophthalmological 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 - imaging equipment : . with ionizing radiation . 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
		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

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	<b>0297</b>	Non-active medical devices: - soft tissue implants - function implants - disposable medical products - anaesthetic, orthopaedic and rehabilitation devices - 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 - ophthalmological 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	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
TÜV- ZERTIFIZIERUNGSGEMEINSCHAFT e.V. TÜV CERT Reuterstraße, 161 53113 BONN Germany	<b>0298</b>	Active medical devices : - devices to ascertain vital functions - equipment for extracorporeal circuits, infusions and haemoforesis - anaesthesia devices, incubators, respirators and oxygen therapy equipment - surgical equipment and ancillary surgical equipment - stimulation devices - ophthalmological devices - dental equipment - prostheses and rehabilitation devices - disinfection and sterilization equipment - radiotherapy devices : . with ionizing radiation . with non-ionizing radiation - imaging equipment : . with ionizing radiation . with non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
BUREAU VERITAS QUALITY INTERNATIONAL (BVQI) 2nd Floor, Tower Bridge Road, 224-226 SE1 2TX LONDON United Kingdom	<b>0301</b>	Functions relating to sterile / measuring Class I medical devices	Production quality assurance Product quality assurance	Annex V Annex VI
		All active medical devices Sterile single use medical devices (excluding implants) Wound dressings	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
BUREAU VERITAS QUALITY		Orthopaedic implants Dental materials and implants Suture material		
DIRECCION GENERAL DE FARMACIA Y PRODUCTOS SANITARIOS MINISTERIO DE SANIDAD Y CONSUMO PO. 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
TNO CERTIFICATION B.V. Schoemakerstraat 97 - Postbus 6080 2600 JA DELFT Netherlands	0336	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
KEMA REGISTERED QUALITY B.V. Utrechtseweg 310 ( Postbus 9035, 6800E 6812 AR 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
ITS TESTING AND CERTIFICATION LTD ITS House, Cleeve Road KT22 7SB Leatherhead United Kingdom	0359	Active medical devices but excluding : - blood gas analysers (invivo) - anaesthesia machines - lung ventilators - respiratory therapy equipment - breathing systems attachments and components - extracorporeal blood treatment equipment	EC Type-examination EC verification	Annex III 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	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
ISTITUTO SUPERIORE DI SANITA Viale Regina Elena, 299 00161 ROMA Italy	0373	All medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
ISTITUTO DI RICERCHE, PROVE E ANALISI SRL Via Artigiani, 63 25040 BIENNO Italy	0398	Single-use products	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Equipment for electrosurgery Apparatus and accessories for muscle stimulation Equipment and accessories for infusion, perfusion and transfusion Equipment and accessories for diagnosis and treatment using ultrasound Equipment and accessories for dialysis Equipment and accessories for diagnostic imaging, using ionising and non-ionising radiation	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
		Equipment and accessories for treatment using ionising and non-ionising radiation - patient-monitoring equipment and equipment for recording vital functions - disinfection and sterilization equipment		
SWEDISH NATIONAL TESTING AND RESEARCH INSTITUTE Box 857 501 15 BORAS Sweden	<b>0402</b>	Non active devices specifically intended for recording of X-ray diagnostic images. (Annex IX, 4.4. Rule 16) Equipment for anaesthesia and intensive care Bone anchored implants for dental and craniofacial reconstructions Diagnostic X-ray equipment Surgical instruments for single use Electromedical diagnostic equipment Dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		All Class I sterile devices Class I devices with a measuring function	Production quality assurance Product quality assurance	Annex V Annex VI
TÜV- ÖSTERREICH Krugerstrasse 16 1015 Wien Austria	<b>0408</b>	Active medical devices(including their accessories) 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	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
SEMKO AB Torshamnsgatan, 43 164 22 KISTA Sweden	<b>0413</b>	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
ISTITUTO RICERCHE BREDA - TÜV ITALIA - TÜV BAYERN (ITALCERT) Viale Sarca, 336 20126 MILANO Italy	<b>0426</b>	Devices in sterile packs	Production quality assurance Product quality assurance	Annex V Annex VI
		Measuring devices Single-use products	Full quality assurance system Production quality assurance	Annex II Annex V

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 RICERCHE BREDA - TÜV		<ul style="list-style-type: none"> <li>- dental materials</li> <li>- dental equipment</li> <li>- ultrasound equipment</li> <li>- electrocardiographs and electroencephalographs</li> <li>- contact lenses</li> <li>Non-invasive devices in contact with damaged skin</li> <li>Orthopaedic implants</li> <li>Devices for contact lens treatment</li> <li>Devices for the sterilisation of medical devices</li> <li>Invasive devices for natural orifices</li> <li>Invasive devices for surgical use</li> <li>Probes and catheters for urology, gastroenterology, respiratory tracts, surgical aspiration and oxygen therapy</li> <li>Devices for the administration to or removal from the patient's body of medicines, body fluids or other substances</li> <li>Contraceptives</li> <li>Blood bags</li> <li>Products and accessories for surgical use, such as suture needles, syringes, surgical gloves</li> <li>Apparatus and accessories for muscle stimulation</li> </ul>	Product quality assurance	Annex VI
ZERTIFIZIERUNGSSTELLE FÜR QUALITÄTSSICHERUNGSSYSTEME UND PRODUKTE DES STAATLICHEN MATERIALPRÜFUNGSAMT NORDRHEIN-WESTFALEN (MPA NRW) Marsbruchstraße 186 D-44287 DORTMUND Germany	<b>0432</b>	<ul style="list-style-type: none"> <li>Active medical devices</li> <li>- radiotherapy equipment with non-ionizing radiation</li> <li>- hearing aids and audiometers</li> <li>- ultrasound equipment</li> <li>- imaging equipment : <ul style="list-style-type: none"> <li>. with ionizing radiation</li> <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
DET NORSKE VERITAS REGION NORGE AS (DNV RN) Veritasveien 1 1322 HOVIK Norway	<b>0434</b>	All medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
GROUPEMENT POUR L'ÉVALUATION DES DISPOSITIFS MÉDICAUX 33, avenue du Général Leclerc BP n° 8 92260 FONTENAY-AUX-ROSES France	<b>0459</b>	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 Gaustadallen 30 - PO Box 73 Blindern 01314 OSLO Norway	<b>0470</b>	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	<b>0473</b>	All medical devices except equipment emitting ionising radiation	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
CERMET Via Aldo Moro, 22 40068 S. LAZZARO DI SAVENA Italy	0476	Electromedical apparatus for physiotherapy and rehabilitation Electromedical apparatus for cardiology Electromedical apparatus for anaesthesia and cardiac surgery Electromedical apparatus for dentistry and stomatology Electromedical apparatus for nephrology and dialysis Electromedical apparatus for pediatrics and neonatal care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Prostheses Dental prostheses Orthopaedic prostheses Infusion and withdrawal needles Cannulas, probes and tubes Catheters and accessories Tubular devices of synthetic material for administration and withdrawals Filters for blood or solutions; other filters Syringes Circuits and accessories for anaesthesia and resuscitation Equipment and accessories for dialysis Products for dental treatment	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
BIOLAB SPA - CENTRO DI ANALISI E RICERCHE BIOLOGICHE Via Bruno Buozzi, 2 20090 VIMODROME Italy	0477	Non-resorbable surgical implants Devices for infusion, transfusion, injection, withdrawal, extracorporeal circuits - 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	EC Type-examination EC verification	Annex III Annex IV
		All Class I sterile devices	Production quality assurance Product quality assurance	Annex V Annex VI
ECM-ZERTIFIZIERUNGSGESELLSCHAFT FÜR MEDIZINPRODUKTE IN EUROPA MBH Eifelstraße, 1C 52068 AACHEN Germany	0481	Non-active medical devices: - disposable medical products : . infusion / transfusion sets . catheters / catheter sets . drainage devices . tubing for extracorporeal circulation - OP products - bandages and dressings	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		- soft tissue implants - disinfection means - orthopaedic implants - contact lenses - contact lens care products	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
MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GmbH Vorsetzen 32 20459 HAMBURG Germany	<b>0482</b>	Non-active medical devices: - 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 : - patient storage and transport equipment - 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 anaesthetizing equipment - stimulation devices - ophthalmological devices - dental equipment - prostheses and rehabilitation devices - disinfection and sterilization equipment - radiotherapy equipment with non-ionizing radiation - 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
MDC MEDICAL DEVICE CERTIFICATION GmbH Krautstraße, 2 87700 MEMMINGEN Germany	<b>0483</b>	Non-active medical devices: - orthopaedic implants - soft tissue implants - function implants - disposable medical products - dental equipment and instruments - dental materials - dental implants - anaesthetic, orthopaedic and rehabilitation devices - non-energized medical instrumentation - reusable non-active medical instruments - bandages and dressings - suture material and clamps Soft tissue implants Functional implants Single-use 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 for the eye: - contact lenses -contact lens care devices - intraocular lenses - intraocular implants with no optical effect - internal tamponade fluids and gases - viscoelastic fluids as mechanical barriers in ophtalmic surgery	EC Type-examination	Annex III

Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures / modules	Annexes / articles of the directives
		<ul style="list-style-type: none"> <li>- rinsing fluids for ophtalmic surgery</li> <li>- tissue glues for ophtalmic surgery</li> <li>- implants and tampons for surgery of the lacrimal duct</li> <li>- keratoprotheses and bandage lenses</li> <li>- implants for glaucoma treatment</li> <li>- implants on the sclera</li> <li>- artificial eyes and internal prostheses</li> <li>- suture materials</li> </ul>		
SLG PRÜF UND ZERTIFIZIERUNGS GMBH Burgstädedter Strasse 20 09232 Hartmannsdorf Germany	<b>0494</b>	<ul style="list-style-type: none"> <li>- Narcosis devices, incubators, ventilators and oxygen therapy apparatus, except for devices for hyperbaric therapy</li> <li>- surgical equipment and ancillary surgical equipment</li> <li>- ophtalmological devices</li> <li>- dental equipment</li> <li>- disinfection and sterilization equipment</li> <li>- radiotherapy equipment with non-ionizing radiation</li> <li>- medical supply units</li> <li>- patient storage and transport equipment</li> <li>Equipment for measuring and/or monitoring and/or recording and/or analysing physiological parameters and vital functions</li> <li>Equipment for rehabilitation</li> <li>Auditory prostheses</li> <li>Software for operating medical devices</li> <li>- Devices for imaging processes with non-ionizing radiation, except for nuclear spin tomography devices</li> <li>- Radiation therapy devices using non-ionizing radiation, except for laser therapy devices</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
		<ul style="list-style-type: none"> <li>- stimulators</li> <li>- dental treatment devices</li> <li>- rehabilitation devices and active prostheses</li> <li>- patient storage and transport equipment</li> <li>- devices for medical care</li> </ul>	Full quality assurance system EC Type-examination EC verification Product quality assurance	Annex II Annex III Annex IV Annex VI
SERVICE DE L'ENERGIE DE L'ETAT B.P. 10 2010 LUXEMBOURG Luxembourg	<b>0499</b>	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 Brasi 1700 LISBOA Portugal	<b>0503</b>	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	<b>0510</b>	Medical devices for dentistry	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI

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	<b>0518</b>	All 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
EUROCAT - INSTITUTE FOR CERTIFICATION AND TESTING GMBH Wittichstrasse, 2 64295 DARMSTADT Germany	<b>0535</b>	Non-active medical devices : - 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 - ophthalmological 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 extracorporeal circulation, infusions and haemopheresis - radiotherapy devices : . with ionizing radiation . with non-ionizing radiation - imaging equipment : . with ionizing radiation . 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
VTT AUTOMAATIO (VTT AUTOMATION) P.O. Box 13071 FIN-02044 ESPOO Finland	<b>0537</b>	Active medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
		Non-active class I devices placed on the market in a sterile state Non-active class I devices with a measuring function	EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI
		Non-active class IIa and IIb devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI

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
ZDH-ZERT - VEREIN FÜR QUALITÄT IM HANDWERK UND IN DER GEWERBLICHEN WIRTSCHAFT E.V. - ZERTIFIZIERUNGSSTELLE MEDIZINPRODUKTE Postfach 1948 - Köningstraße 35 78628 Rottwell Germany	0538	Non-active medical devices - 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	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
DANSK GODKENDELSE AF MEDICINSK UDSTYR Kollegievej, 6 2920 CHARLOTTENLUND Denmark	0543	Non-active medical devices : - infusion devices - dental materials - bandages and dressings - dental implants - disinfection means - surgical articles - contact lenses - contact lens fluids - sutures and adhesives - 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 - surgical equipment and ancillary surgical equipment - dental equipment - disinfection and sterilization equipment - neonatal equipment - dental devices - hearing aids and audiometers - electrocardiographs and electroencephalographs - medical equipment sterilizers - defibrillators - equipment for measuring blood and anaesthetic gas - surgical lasers - ultrasound equipment - patient-monitoring equipment and equipment for recording vital functions - electrosurgical equipment - engangsartikler til hjerte-lunge maskiner - cardiovasculære implantater - suction 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

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	<b>0546</b>	Medical and measuring equipment with independent power supply or non-powered Dental products and materials and accessories, including powered accessories Ophthalmic products, e.g. spectacles and intraocular lenses Products and accessories for surgical use Products for endoscopy and laparoscopy Sensitive materials for medical use Products for extracorporeal circulation and accessories, including active accessories Catheters and non-disposable accessories Contraceptive products Artificial skin, etc. Products for disinfection of medical equipment and for the treatment of contact lenses Bandages, 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	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
MEDICAL PRODUCTS AGENCY (LÄKEMEDELSVERKET) Box 26 751 03 UPPSALA Sweden	<b>0562</b>	Non-active medical devices	Full quality assurance system Production quality assurance	Annex II Annex V
NATIONAL QUALITY ASSURANCE LTD Warwick House - Houghton Hall Park LU5 5ZX Houghton Regis, Dunstable United Kingdom	<b>0577</b>	Devices for the administration to or removal from the patient's body of medicines, body fluids or other substances - ultrasound equipment Electromedical equipment	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Anaesthetic and life support equipment	Full quality assurance system	Annex II
		Drainage and suction devices (non-powered) Surgical dressings (class IIa) Measuring and monitoring equipment Operating theatre equipment Diagnostic X-ray equipment Anaesthetic and respiratory equipment Blood contact devices Functions relating to sterile / measuring Class I medical devices	Production quality assurance Product quality assurance	Annex V Annex VI

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
INSTITUT FÜR MIKROTECHNIK UND MEDIZINTECHNIK DER TECHNISCHEN UNIVERSITÄT BERLIN PRÜFSTELLE FÜR MEDIZINISCHE GERÄTE Dovestrasse, 6 10587 BERLIN Germany	<b>0633</b>	Active medical devices: - 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 extracorporeal 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	EC Type-examination EC verification	Annex III Annex IV
PRÜFANSTALT FÜR MEDIZINISCHE GERÄTE Technische Universität Graz Inffeldgasse, 18 8010 GRAZ Austria	<b>0636</b>	Active medical devices and their accessories	EC Type-examination EC verification	Annex III Annex IV
RESEARCH CENTER FOR BIOMATERIALS S.A. "EKEVYL S.A." Smyrnis 15 165 62 GLYFADA Greece	<b>0653</b>	All medical devices	Production quality assurance Product quality assurance	Annex V Annex VI
		All medical devices	Full quality assurance system	Annex II
		Implantable and non-implantable orthopaedic materials and devices Other implantable devices Artificial limbs and related components for disabled Bandages, surgical dressings, medical grade cotton and other relevant products Dental devices	EC Type-examination	Annex III

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
		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		
	<b>0712</b>	- dental equipment and instruments - dental materials - dental implants - reusable non-active medical instruments	EC verification  Full quality assurance system Production quality assurance Product quality assurance	Annex IV  Annex II Annex V Annex VI
	<b>0713</b>	Non-active, non-sterile medical devices for orthopaedic treatment and the rehabilitation of the foot and leg (Category IIa)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
	<b>0805</b>	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
UL INTERNATIONAL (UK) LTD Womersley House Building C, the Guildway, GU3 1LR Guilford United Kingdom	<b>0843</b>	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
		Sterile single use medical devices excluding Class III devices, ophthalmic devices, implants and surgical dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		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	<b>0932</b>	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