

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 IIb active devices for administering gas and/or extracting medicines/substances	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
TÜV NORD CERT GMBH & CO. KG Am TÜV 1 30519 HANNOVER Germany	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 : - 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	EC Type-examination EC verification	Annex III Annex IV
RWTÜV ANLAGENTECHNIK GMBH Langemarkstrasse, 20 45138 ESSEN Germany	44	Non-active medical devices : - orthopaedic implants - soft tissue 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

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	<ul style="list-style-type: none"> - 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 : <ul style="list-style-type: none"> - 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 : <ul style="list-style-type: none"> . with ionizing radiation and with non-ionizing radiation . with non-ionizing radiation - imaging equipment : <ul style="list-style-type: none"> . 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
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 equipment Equipment for electrosurgery and accessories Anaesthetics equipment, incubators, ventilators, oxygen therapy equipment and accessories Equipment for extracorporeal circulation, infusion, transfusion, haemophoresis and accessories Equipment for dialysis and accessories Equipment for checking and recording vital functions and accessories Cardiac and muscular stimulation equipment and accessories Dental equipment and accessories Ophtalmological equipment and accessories Disinfection and sterilization equipment Equipment for aerosol therapy and accessories Clinical imaging equipment using ionizing radiation, non-ionizing radiation and ultrasound Treatment equipment using ionizing radiation, non-ionizing radiation and ultrasound	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
Disposable syringes Urethral catheters, catheters for heart surgery and for the central circulatory system Bags for parenteral and enteral nutrition and accessories Contact lenses Solutions for contact lenses Auditory prostheses		Full quality assurance system Production quality assurance Product quality assurance		
ISTITUTO DI RICERCHE E COLLAUDI M. MASINI SRL Via Moscova 11 20017 RHO Italy	68	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	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 RICERCHE E COLLAUDI M. MASINI SRL Via Moscova 11 20017 RHO Italy	68	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
BSI 389 Chiswick High Road W4 4AL LONDON United Kingdom	86	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	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 : - 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

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 : - 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
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 - Electrocardiographs	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
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	<p>Non-active medical devices :</p> <ul style="list-style-type: none"> - 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 <p>Active medical devices :</p> <ul style="list-style-type: none"> - 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 - disinfectants and antiseptics - radiotherapy devices : <ul style="list-style-type: none"> . with ionizing radiation and with non-ionizing radiation . with non-ionizing radiation - imaging equipment : <ul style="list-style-type: none"> . with 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
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	<p>Non-active medical devices :</p> <ul style="list-style-type: none"> - 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 <p>Active medical devices :</p> <ul style="list-style-type: none"> - 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 : <ul style="list-style-type: none"> . with ionizing radiation and with non-ionizing radiation . with non-ionizing radiation - imaging equipment : <ul style="list-style-type: none"> . 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			Full quality assurance system EC Type-examination EC verification	Annex II Annex III Annex IV
LGA - LANDESGEWERBEANSTALT BAYERN Tillystraße, 2 90431 Nürnberg Germany	125	<p>Non-active medical devices :</p> <ul style="list-style-type: none"> - orthopaedic implants - soft tissue implants - funtion implants - disposable medical devices - anaesthetic, orrthopaedic 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 <p>Active medical devices :</p> <ul style="list-style-type: none"> - 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 : <ul style="list-style-type: none"> . with ionizing radiation and with non-ionizing radiation . with non-ionizing radiation - imaging equipment : <ul style="list-style-type: none"> . 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

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TÜV RHEINLAND PRODUCT SAFETY GMBH Am Grauen Stein 51105 Köln Germany	197	<p>Active medical devices :</p> <ul style="list-style-type: none"> - 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 : <ul style="list-style-type: none"> . with non-ionizing radiation . with ionizing radiation and with non-ionizing radiation - imaging equipment : <ul style="list-style-type: none"> . with ionizing radiation . with non-ionizing radiation 	<p>Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance</p>	<p>Annex II Annex III Annex IV Annex V Annex VI</p>
		<p>Non-active medical devices :</p> <ul style="list-style-type: none"> - 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 	<p>Full quality assurance system EC Type-examination Production quality assurance Product quality assurance</p>	<p>Annex II Annex III Annex V Annex VI</p>
DEUTSCHE GESELLSCHAFT ZUR ZERTIFIZIERUNG VON MANAGEMENTSYSTEMEN MBH - QUALITÄTS- UND UMWELTGUTACHTER August-Schanz Straße, 21 60433 FRANKFURT AM-MAIN Germany	297	<p>Non-active medical devices:</p> <ul style="list-style-type: none"> - soft tissue implants - function implants 	<p>Full quality assurance system Production quality assurance Product quality assurance</p>	<p>Annex II Annex V Annex VI</p>

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	<ul style="list-style-type: none"> - 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 : <ul style="list-style-type: none"> - 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 : <ul style="list-style-type: none"> . 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	298	Active medical devices : <ul style="list-style-type: none"> - devices to ascertain vital functions - equipment for extracorporeal circuits, infusions and haemoforesis 	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
TÜV- ZERTIFIZIERUNGSGEMEINSCHAFT e.V. TÜV CERT Reuterstraße, 161 53113 BONN Germany	298	<ul style="list-style-type: none"> - 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 : <ul style="list-style-type: none"> . with ionizing radiation and with non-ionizing radiation . with non-ionizing radiation - imaging equipment : <ul style="list-style-type: none"> . 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	301	Functions relating to sterile / measuring Class I medical devices	Production quality assurance Product quality assurance	Annex V Annex VI
		<p>All active medical devices</p> <p>Sterile single use medical devices (excluding implants)</p> <p>Wound dressings</p> <p>Orthopaedic implants</p> <p>Dental materials and implants</p> <p>Suture material</p>	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
DIRECCION GENERAL DE FARMACIA Y PRODUCTOS SANITARIOS MINISTERIO 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. 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

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
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 : - blood gas analysers (invivo) - anaesthesia machines - lung ventilators - respiratory therapy equipment - breathing systems attachments and components - extracorporeal blood treatment equipment - electrosurgical equipment - medical laser equipment - defibrillators - radiotherapy equipment - radionuclide and magnetic resonance imaging	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	366	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	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 Apparatus and accessories for muscle stimulation	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 RICERCHE, PROVE E ANALISI SRL Via Artigiani, 63 25040 BIENNO Italy	398	Equipment and accessories for infusion, perfusion and transfusion Equipment and accessories for diagnosis and treatment using ultrasound Equipment and accessories for dialysis Equipment and accessories for diagnostic imaging, using ionising and non-ionising radiation Equipment and accessories for treatment using ionising and non-ionising radiation - patient-monitoring equipment and equipment for recording vital functions - disinfection and sterilization equipment	Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI
SP - SWEDISH NATIONAL TESTING AND RESEARCH INSTITUTE LTD Box 857 501 15 BORAS Sweden	402	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	408	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	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
TÜV- ÖSTERREICH Krugerstrasse 16 1015 Wien Austria	408	<ul style="list-style-type: none"> - Cleaning, disinfecting and sterilizing devices - Products for endoscopy and endoscopic surgery - Non-implantable products for orthopaedics and rehabilitation 	<ul style="list-style-type: none"> Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance 	<ul style="list-style-type: none"> Annex II Annex III Annex IV Annex V Annex VI
		All Class I sterile devices	Production quality assurance	Annex V
SEMKO AB Torshamnsgatan, 43 164 22 KISTA Sweden	413	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Full quality assurance system Production quality assurance Product quality assurance 	<ul style="list-style-type: none"> Annex II Annex V Annex VI
		<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> EC Type-examination EC verification 	<ul style="list-style-type: none"> Annex III Annex IV
		Class I devices with a measuring function	EC verification	Annex IV
		CONSORZIO ITALCERT Viale Sarca, 336 20126 MILANO Italy	426	<ul style="list-style-type: none"> Devices in sterile packs
<ul style="list-style-type: none"> Measuring devices Single-use products <ul style="list-style-type: none"> - dental materials - dental equipment - ultrasound equipment - electrocardiographs and electroencephalographs 	<ul style="list-style-type: none"> Full quality assurance system Production quality assurance Product quality assurance 			<ul style="list-style-type: none"> 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
<p>CONSORZIO ITALCERT Viale Sarca, 336 20126 MILANO Italy</p>	<p>426</p>	<p>- contact lenses</p> <p>Non-invasive devices in contact with damaged skin</p> <p>Orthopaedic implants</p> <p>Devices for contact lens treatment</p> <p>Devices for the sterilisation of medical devices</p> <p>Invasive devices for natural orifices</p> <p>Invasive devices for surgical use</p> <p>Probes and catheters for urology, gastroenterology, respiratory tracts, surgical aspiration and oxygen therapy</p> <p>Devices for the administration to or removal from the patient's body of medicines, body fluids or other substances</p> <p>Contraceptives</p> <p>Blood bags</p> <p>Products and accessories for surgical use, such as suture needles, syringes, surgical gloves</p> <p>Apparatus and accessories for muscle stimulation</p>	<p>Full quality assurance system Production quality assurance Product quality assurance</p>	<p>Annex II Annex V Annex VI</p>
<p>MATERIALPRÜFUNGSAMT NORDRHEIN-WESTFALEN (MPA NRW) Marsbruchstraße 186 D-44287 DORTMUND Germany</p>	<p>432</p>	<p>Active medical devices</p> <p>- radiotherapy equipment with non-ionizing radiation</p> <p>- hearing aids and audiometers</p> <p>- ultrasound equipment</p> <p>- imaging equipment :</p> <p>. with ionizing radiation</p> <p>. with non-ionizing radiation</p>	<p>Full quality assurance system Production quality assurance Product quality assurance</p>	<p>Annex II Annex V Annex VI</p>
<p>DET NORSKE VERITAS REGION NORGE AS (DNV RN) Veritasveien 1 1322 HOVIK Norway</p>	<p>434</p>	<p>All medical devices</p>	<p>Full quality assurance system Production quality assurance Product quality assurance</p>	<p>Annex II Annex V Annex VI</p>
<p>G-MED GROUPEMENT POUR L'ÉVALUATION DES DISPOSITIFS MÉDICAUX 33, avenue du Général Leclerc BP n° 8 92260 FONTENAY-AUX-ROSES France</p>	<p>459</p>	<p>All medical devices</p>	<p>Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance</p>	<p>Annex II Annex III Annex IV Annex V Annex VI</p>

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
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 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	477	Non-resorbable surgical implants Devices for infusion, transfusion, injection, withdrawal, extracorporeal circuits	EC Type-examination EC verification	Annex III Annex IV

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BIOLAB SPA - CENTRO DI ANALISI E RICERCHE BIOLOGICHE Via Bruno Buozzi, 2 20090 VIMODROME Italy	477	<ul style="list-style-type: none"> - ophthalmological devices - disinfectants and antiseptics Contact lenses maintenance products Non-resorbable suture materials and clamps Single-use products Dressings Devices, materials and apparatus for dental treatment Surgical instruments Gloves for medical use Contraceptives Devices for anaesthesia and ventilation Catheters, drains and probes Re-usable devices Devices for parenteral and enteral nutrition 	EC Type-examination EC verification	Annex III Annex IV
		All Class I sterile devices	Production quality assurance Product quality assurance	Annex V Annex VI
ECM-ZERTIFIZIERUNGSGESELLSCHAFT FÜR MEDIZINPRODUKTE IN EUROPA MBH Eifelstraße, 1C 52068 AACHEN Germany	481	Non-active medical devices: <ul style="list-style-type: none"> - disposable medical products : <ul style="list-style-type: none"> . 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
		<ul style="list-style-type: none"> - soft tissue implants - disinfection means - orthopaedic implants - contact lenses 	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
ECM-ZERTIFIZIERUNGSGESELLSCHAFT FÜR MEDIZINPRODUKTE IN EUROPA MBH Eifelstraße, 1C 52068 AACHEN Germany	481	- contact lens care products	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH Vorsetzen 32 20459 HAMBURG Germany	482	<p>Non-active medical devices:</p> <ul style="list-style-type: none"> - 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 <p>Active medical devices :</p> <ul style="list-style-type: none"> - 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 	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
<p>MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH Vorsetzen 32 20459 HAMBURG Germany</p>	<p>482</p>	<ul style="list-style-type: none"> - prostheses and rehabilitation devices - disinfection and sterilization equipment - radiotherapy equipment with non-ionizing radiation - medical supply units 	<p>Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance</p>	<p>Annex II Annex III Annex IV Annex V Annex VI</p>
<p>MDC MEDICAL DEVICE CERTIFICATION GMBH Heilbronner Strasse 43 70191 STUTTGART Germany</p>	<p>483</p>	<p>Non-active medical devices</p> <hr/> <p>Active medical devices :</p> <ul style="list-style-type: none"> - 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 : <ul style="list-style-type: none"> . with ionizing radiation . with non-ionizing radiation - stimulators, except external pacemakers and defibrillators - radiotherapy devices : <ul style="list-style-type: none"> . with ionizing radiation and with non-ionizing radiation - ophthalmological devices - dental equipment - rehabilitation devices and active prostheses - patient storage and transport equipment - medical supply units 	<p>Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance</p> <hr/> <p>EC Type-examination Production quality assurance Product quality assurance</p>	<p>Annex II Annex III Annex IV Annex V Annex VI</p> <hr/> <p>Annex III Annex V Annex VI</p>
<p>SLG PRÜF UND ZERTIFIZIERUNGS GMBH Burgstäedter Strasse 20 09232 Hartmannsdorf Germany</p>	<p>494</p>	<ul style="list-style-type: none"> - Narcosis devices, incubators, ventilators and oxygen therapy apparatus, except for devices for hyperbaric therapy - surgical equipment and ancillary surgical equipment - ophthalmological 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 	<p>Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance</p>	<p>Annex II Annex III Annex IV Annex V Annex VI</p>

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	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 Production quality assurance Product quality assurance Full quality assurance system EC Type-examination EC verification Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI 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 Brasi 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 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
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 III Annex IV Annex V Annex VI
EUROCAT - INSTITUTE FOR CERTIFICATION AND TESTING GMBH Wittichstrasse, 2 64295 DARMSTADT Germany	535	Non-active medical devices : - software for the operation of medical products - medical supply units - patient storage and transport equipment, excluding incubators	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
ZDH-ZERT [RECHTSNACHFOLGER IS DIE MDC MEDICAL DEVICE CERTIFICATION GMBH, KENN-NR 0483, STUTTGART] Heilbronner Strasse, 43 70191 STUTTGART Germany	538	<ul style="list-style-type: none"> - 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 (DGM) Kollegievej, 6 2920 CHARLOTTENLUND Denmark	543	Non-active medical devices : <ul style="list-style-type: none"> - 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) 	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
DANSK GODKENDELSE AF MEDICINSK UDSTYR (DGM) Kollegievej, 6 2920 CHARLOTTENLUND Denmark	543	<p>Active medical devices :</p> <ul style="list-style-type: none"> - 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 anaesthetic 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 	<p>Full quality assurance system EC Type-examination EC verification Production quality assurance Product quality assurance</p>	<p>Annex II Annex III Annex IV Annex V Annex VI</p>
ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ PER L'INDUSTRIA CHIMICA Via G. Giardino, 4 20123 MILANO Italy	546	<p>Medical and measuring equipment with independent power supply or non-powered</p> <p>Dental products and materials and accessories, including powered accessories</p> <p>Ophthalmic products, e.g. spectacles and intraocular lenses</p> <p>Products and accessories for surgical use</p> <p>Products for endoscopy and laparoscopy</p> <p>Sensitive materials for medical use</p> <p>Products for extracorporeal circulation and accessories, including active accessories</p> <p>Catheters and non-disposable accessories</p> <p>Contraceptive products</p> <p>Artificial skin, etc.</p>	<p>Full quality assurance system Production quality assurance Product quality assurance</p>	<p>Annex II Annex V Annex VI</p>

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 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	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	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 - ultrasound equipment Electromedical equipment Anaesthetic and life support equipment 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	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
BERLIN-CERT-PRÜF- UND ZERTIFIZIERSTELLE FÜR MEDIZINPRODUKTE GMBH AN DER TECHNISCHEM UNIVERSITÄT BERLIN Dovesstrasse, 6 10587 BERLIN Germany	633	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	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
BERLIN-CERT-PRÜF- UND ZERTIFIZIERSTELLE FÜR MEDIZINPRODUKTE GMBH AN DER TECHNISCHEM UNIVERSITÄT BERLIN Dovestrasse, 6 10587 BERLIN Germany	633	<ul style="list-style-type: none"> - 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 : <ul style="list-style-type: none"> - 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	636	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	653	<ul style="list-style-type: none"> All medical devices All medical devices Implantable and non-implantable orthopaedic materials and devices 	<ul style="list-style-type: none"> Production quality assurance Product quality assurance Full quality assurance system EC Type-examination 	<ul style="list-style-type: none"> Annex V Annex VI Annex II 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
RESEARCH CENTER FOR BIOMATERIALS S.A. "EKEVYL S.A." Smyrnis 15		Other implantable devices Artificial limbs and related components for disabled Bandages, surgical dressings, medical grade cotton and other relevant products Dental devices Disinfectants and antiseptics Disinfectants and antiseptics Contact lenses and solutions for contact lenses Absorbable and non-absorbable surgical sutures - disinfectants and antiseptics Absorbable and non-absorbable surgical sutures Sterile and non-sterile single use products Contraceptives Contact lenses maintenance products Absorbable and non-absorbable surgical sutures Sterile and non-sterile single use products Contraceptives		
		Only devices mentioned in § B	EC verification	Annex IV
INTERNATIONAL CERT ZERTIFIZIERUNG GMBH Straubinger Straße 2 94333 GEISELHÖRING Germany	712	- dental equipment and instruments - dental materials - dental implants - reusable non-active medical instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
PRÜF UND FORSCHUNGSINSTITUT FÜR DIE SCHUHHHERSTELLUNG E.V. Hans-Sachs-Straße 2 66955 PIRMASENS Germany	713	Non-active, non-sterile medical devices for orthopaedic treatment and the rehabilitation of the foot and leg (Category IIa)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
THERAPEUTIC GOODS ADMINISTRATION PO Box 100 ACT 2606 WODEN Australia	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
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

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 Womersley House Building C, Old Portsm. R. GU3 1LR GUILDFORD United Kingdom	843	Sterile single use medical devices excluding Class III devices, ophthalmic devices, (class IIa and above) and implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
		Wound dressings (Class IIa and IIb)	EC Type-examination EC verification	Annex III Annex IV
		Gloves for medical use Urethral catheters	EC verification	Annex IV
LABORATÓRIO DE ENSAIOS E METROLOGIA DA SAÚDE - LEMES Av. Padre Cruz, Complexo Inst. Ricardo J 1699 Lisboa Codex Portugal	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 : - 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 - insuline syringues/pen injectors - non-reusable medical gloves - condoms made from natural latex - Catheters	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
ORVOS- ÉS KÓRHÁZTECHNIKAI INTÉZET (ORKI) (INSTIT. FOR MEDICAL AND HOSPITAL ENGIN.) Diós Árok 3 1125 Budapest Hungary	1011	<ul style="list-style-type: none"> - 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 mattresses for medical use - equipment for extracorporally induced lithotripsy - medical gas supply system and parts (units) thereof - medical equipment sterilizers - Equipment for endoscopy - operation microscopes - ophtalmological devices - operation and examination lamps 	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 style="list-style-type: none"> - fever thermometers (active) - wheelchairs (electrically operated) 		