

Decision No 1/2000

**of the Joint Committee established under the Agreement on Mutual Recognition
between the European Community and the United States of America**

**related to amending the Sectoral Annexes on Telecommunication Equipment,
Electromagnetic Compatibility, Pharmaceutical GMPs and Medical Devices**

THE JOINT COMMITTEE,

Having regard to the Agreement on Mutual Recognition between the European Community and the United States of America and in particular Article 14 and 21 thereof;

Whereas the Agreement should be amended to reflect changes in their respective legislation;

Whereas, pursuant to Article 21(2) any Sectoral Annex may, through the Joint Committee, be amended in writing by the Parties;

HAS DECIDED AS FOLLOWS:

1. Amendments to the Sectoral Annex for Telecommunications Equipment

The Sectoral Annex for Telecommunication Equipment is amended according to the following:

- (a) In Section I, under the EC column, the entire text is deleted and is replaced with the following:

"Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity"

- (b) In Section III, paragraph 2(c) "Directive 98/13/EC" is deleted and replaced with "Directive 1999/5/EC".

- (c) In Section III, paragraph 2 the following subparagraphs are added:

"(d) prescription of radio tests to be performed pursuant to annexes III and IV of Directive 1999/5/EC.

(e) issuing of an opinion on a technical file pursuant to annex V of Directive 1999/5/EC."

- (d) In Appendix I, "ACTE Approval Committee for Terminal Equipment", "ADLNB Association of Designated Laboratories and Notified Bodies" and "CTR Common Technical Regulations" are deleted.

2. Amendments to the Sectoral Annex for Electromagnetic Compatibility (EMC)

In Section IV, under the "U.S." column, "Federal Aviation Administration (FAA)" is deleted.

3. Amendments to the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs)

Article 1, paragraph 3 is deleted in its entirety and is replaced with the following text:

"3. 'Good Manufacturing Practices (GMPs)'

In the United States, GMPs means the requirements found in the legislation, regulations and administrative provisions for methods to be used in, and the facilities or controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

In the EC, GMPs are the part of quality assurance which ensures that products are consistently produced and controlled to a quality standard. GMPs include, therefore, the system whereby the manufacturer receives the specifications of the products and/or process from the marketing authorisation/product authorisation or license holder or applicant and ensures the product is made in compliance with its specifications (qualified person certification).

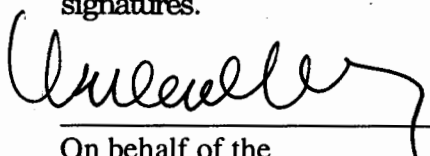
Because equivalence is the cornerstone of this Annex, the Authorities of the Parties will maintain their respective requirements and will carry out the inspections against their own requirements."

4. Amendments to the Sectoral Annex for Medical Devices

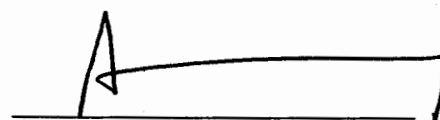
The Sectoral Annex for Medical Devices is amended according to the following:

- (a) Table 1 is deleted in its entirety and is replaced with the revised Table 1, attached hereto.
- (b) Table 2 is deleted in its entirety and is replaced with the revised Table 2, attached hereto.

This Decision, done in duplicate, shall be signed by representatives of the Joint Committee who are authorised to act on behalf of the Parties for purposes of amending the Agreement. This Decision shall be effective from the date of the later of these signatures.



On behalf of the
United States of America
Signed in Washington D.C. on



On behalf of the
European Community
Signed in Brussels on

22-11-2000

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TABLE 1
Class I products requiring premarket evaluations in the United States, included
in scope of product coverage at beginning of transition period

DENTAL PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
872.4200	DENTAL HANDPIECES AND ACCESSORIES EBW - CONTROLLER, FOOT, HANDPIECE AND CORD EFB - HANDPIECE, AIR-POWERED, DENTAL EFA - HANDPIECE, BELT AND/OR GEAR DRIVEN, DENTAL EGS - HANDPIECE, CONTRA- AND RIGHT-ANGLE ATTACHMENT, DENTAL EKX - HANDPIECE, DIRECT DRIVE, AC-POWERED EKY - HANDPIECE, WATER-POWERED
872.6250	DENTAL CHAIR AND ACCESSORIES KLC - CHAIR WITH A UNIT
872.6640	DENTAL OPERATIVE UNIT AND ACCESSORIES DYN - MOUTHPIECE, SALIVA EJECTOR EBR - UNIT, SUCTION OPERATORY EHZ - EVACUATOR, ORAL CAVITY EIA - UNIT, OPERATIVE DENTAL
872.6710	BOILING WATER STERILIZER ECG - STERILIZER, BOILING WATER

GASTROENTEROLOGY-UROLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
876.5160	UROLOGICAL CLAMPS FOR MALES FHA - CLAMP, PENILE

GENERAL AND PLASTIC SURGERY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
878.4460	SURGEON'S GLOVES KGO - SURGEON'S GLOVES
880.5090	LIQUID BANDAGE KMF - BANDAGE, LIQUID

GENERAL HOSPITAL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
880.5680	PEDIATRIC POSITION HOLDER FRP - HOLDER, INFANT POSITION
880.6250	PATIENT EXAMINATION GLOVE LZB - FINGER COT FMC - GLOVE, PATIENT EXAMINATION LYY - GLOVE, PATIENT EXAMINATION, LATEX LZA - GLOVE, PATIENT EXAMINATION, POLY LZC - GLOVE, PATIENT EXAMINATION, SPECIALITY LYZ - GLOVE, PATIENT EXAMINATION, VINYL
880.6375	PATIENT LUBRICANT KMJ - LUBRICANT, PATIENT MMS - LUBRICANT, VAGINAL, PATIENT

880.6760	PROTECTIVE RESTRAINT BRT - RESTRAINT, PATIENT, CONDUCTIVE FMQ - RESTRAINT, PROTECTIVE
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NEUROLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
882.1030	ATAXIAGRAPH GWW - ATAXIAGRAPH
882.1420	ELECTROENCEPHALOGRAM (EEG) SIGNAL SPECTRUM ANALYZER GWS - ANALYZER, SPECTRUM, ELECTROENCEPHALOGRAM SIGNAL
882.4060	VENTRICULAR CANNULA HCD - CANNULA, VENTRICULAR
882.4545	SHUNT SYSTEM IMPLANTATION INSTRUMENT GYK - INSTRUMENT, SHUNT SYSTEM IMPLANTATION

OBSTETRICS AND GYNECOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
884.2980	THERMOGRAPHIC SYSTEM LHQ - SYSTEM, TELETHERMOGRAPHIC (ADJUNCTIVE USE)
884.2982	LIQUID CRYSTAL TELETHERMOGRAPHIC SYSTEM LHM - SYSTEM, TELETHERMOGRAPHIC, LIQUID CRYSTAL KYA - SYSTEM, TELETHERMOGRAPHIC, LIQUID CRYSTAL, NONPOWERED (ADJUNCTIVE USE)

OPHTHALMOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
886.4070	POWERED CORNEAL BURR HQS - BURR, CORNEAL, AC-POWERED HOG - BURR, CORNEAL, BATTERY-POWERED HRG - ENGINE, TREPHINE, ACCESSORIES, AC-POWERED HRF - ENGINE, TREPHINE, ACCESSORIES, BATTERY-POWERED HLD - ENGINE, TREPHINE, ACCESSORIES, GAS-POWERED
886.4300	INTRAOCULAR LENS GUIDE KYB - LENS, GUIDE, INTRAOCULAR
886.4370	KERATOME HNO - KERATOME, AC-POWERED HMY - KERATOME, BATTERY-POWERED

ORTHOPEDIC PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
888.1500	GONIOMETER KQX - GONIOMETER, AC-POWERED

PHYSICAL MEDICINE PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
890.3850	MECHANICAL WHEELCHAIR LBE - STROLLER, ADAPTIVE IOR - WHEELCHAIR, MECHANICAL
890.5710	HOT OR COLD DISPOSABLE PACK IMD - PACK, HOT OR COLD, DISPOSABLE

RADIOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
892.1100	SCINTILLATION (GAMMA) CAMERA IYX - CAMERA, SCINTILLATION (GAMMA)
892.1110	POSITRON CAMERA IZC - CAMERA, POSITRON

TABLE 2**Class II medical devices included in the scope of product coverage at beginning of transitional period**

(US to develop guidance documents identifying US requirements and EC to identify standards needed to meet EV requirements)

ANESTHESIOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE – DEVICE NAME
868.5630	NEBULIZER CAF - NEBULIZER (DIRECT PATIENT INTERFACE)

CARDIOVASCULAR PANEL

SECTION NO	REGULATION NAME PRODUCT CODE – DEVICE NAME
870.1120	BLOOD PRESSURE CUFF DXQ - CUFF, BLOOD-PRESSURE
870.1130	NONINVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM (except non-oscillometric) DXN - SYSTEM, MEASUREMENT, BLOOD-PRESSURE, NON-INVASIVE
870.2300	CARDIAC MONITOR (INCLUDING CARDIOTACHOMETER AND RATE ALARM) DRT - MONITOR, CARDIAC (INCL. CARDIOTACHOMETER & RATE ALARM)
870.2330	ECHOCARDIOGRAPH DXK - ECHOCARDIOGRAPH
870.2340	ELECTROCARDIOGRAPH DPS - ELECTROCARDIOGRAPH MLC - MONITOR, ST SEGMENT (without alarm)
870.2350	ELECTROCARDIOGRAPH LEAD SWITCHING ADAPTOR DRW - ADAPTOR, LEAD SWITCHING, ELECTROCARDIOGRAPH
870.2360	ELECTROCARDIOGRAPH ELECTRODE DRX - ELECTRODE, ELECTROCARDIOGRAPH
870.2370	ELECTROCARDIOGRAPH SURFACE ELECTRODE TESTER KRC - TESTER, ELECTRODE, SURFACE, ELECTROCARDIOGRAPHIC
870.2880	ULTRASONIC TRANSDUCER JOP - TRANSDUCER, ULTRASONIC

DENTAL PANEL

SECTION NO	REGULATION NAME PRODUCT CODE – DEVICE NAME
872.3060	GOLD BASED ALLOYS AND PRECIOUS METAL ALLOYS FOR CLINICAL USE EJT - ALLOY, GOLD BASED, FOR CLINICAL USE EJS - ALLOY, PRECIOUS METAL, FOR CLINICAL USE
872.3200	RESIN TOOTH BONDING AGENT KLE - AGENT, TOOTH BONDING, RESIN
872.3275	DENTAL CEMENT EMA - CEMENT, DENTAL EMB - ZINC OXIDE EUGENOL
872.3660	IMPRESSION MATERIAL ELW - MATERIAL, IMPRESSION
872.3690	TOOTH SHADE RESIN MATERIAL EBF - MATERIAL, TOOTH SHADE, RESIN
872.3710	BASE METAL ALLOY EJH - METAL, BASE

GASTROENTEROLOGY-UROLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
876.1075	GASTROENTEROLOGY-UROLOGY BIOPSY INSTRUMENT KNW - INSTRUMENT, BIOPSY FCF - INSTRUMENT, BIOPSY, MECHANICAL, GASTROINTESTINAL FCK - INSTRUMENT, BIOPSY, SUCTION FCI - PUNCH, BIOPSY FCG - SET, BIOPSY NEEDLE AND NEEDLE, GASTRO-UROLOGY
#876.1500	ENDOSCOPE AND ACCESSORIES FEB - ACCESSORIES, CLEANING FOR ENDOSCOPE FER - ANOSCOPE, NON-POWERED FDP - APPARATUS, PNEUMOPERITONEUM, AUTOMATIC FDX - BRUSH, CYTOLOGY, FOR ENDOSCOPE
	FGS - CARRIER, SPONGE, ENDOSCOPIC FBN - CHOLEDOCHOSCOPE, FLEXIBLE OR RIGID FDF - COLONOSCOPE, GASTRO-UROLOGY FTJ - COLONOSCOPE, GENERAL AND PLASTIC SURGERY FFZ - CORD, ELECTRIC, FOR ENDOSCOPE FAJ - CYTOSCOPE, DIAGNOSTIC FBO - CYSTOURETHROSCOPE FDT - DUODEDOSCOPE, ESOPHAGO GASTRO KOG - ENDOSCOPE AND/OR ACCESSORIES GCP - ENDOSCOPE, AC-POWERED AND ACCESSORIES GCS - ENDOSCOPE, BATTERY-POWERED AND ACCESSORIES GCR - ENDOSCOPE, DIRECT VISION GDB - ENDOSCOPE, FIBER OPTIC GCQ - ENDOSCOPE, FLEXIBLE GCO - ENDOSCOPE, MIRROR GCN - ENDOSCOPE, PRISM GCM - ENDOSCOPE, RIGID FDA - ENTEROSCOPE GCL - ESOPHAGOSCOPE, GENERAL & PLASTIC SURGERY FDW - ESOPHAGOSCOPE, RIGID, GASTRO-UROLOGY FDS - GASTROSCOPE, GASTRO-UROLOGY GCK - GASTROSCOPE, GENERAL & PLASTIC SURGERY FFS - ILLUMINATOR, FIBEROPTIC, FOR ENDOSCOPE FCX - INSUFFLATOR, AUTOMATIC CARBON-DIOXIDE FOR ENDOSCOPE FHX - JELLY, LUBRICATING, FOR TRANSURETHRAL SURGICAL INSTRUMENT FTI - LAMP, ENDOSCOPE, INCANDESCENT GCI - LARYNGOSCOPE GCT - LIGHT SOURCE, ENDOSCOPIC, XENON ARC FCW - LIGHT SOURCE, FIBEROPTIC, ROUTINE FCQ - LIGHT SOURCE, INCANDESCENT, DIAGNOSTIC FCR - LIGHT SOURCE, PHOTOGRAPHIC, FIBEROPTIC GCH - MEDIASTINOSCOPE FBK - NEEDLE, ENDOSCOPIC FHP - NEEDLE, PNEUMOPERITONEUM, SIMPLE
	FHO - NEEDLE, PNEUMOPERITONEUM, SPRING LOADED FEC - OBTURATOR, FOR ENDOSCOPE FTK - PANCREATOSCOPE, BILIARY FAK - PANENDOSCOPE (GASTRODUODENOSCOPE) FAL - PANENDOSCOPE (URETHROSCOPE) GCG - PERITONEOSCOPE GCF - PROCTOSCOPE FEQ - PUMP, AIR, NON-MANUAL, FOR ENDOSCOPE FIL - RESECTOSCOPE FDC - RESECTOSCOPE, WORKING ELEMENT

	FCC - RETRIEVER, ENDOMAGNETIC FBI - RONGEUR, CYTOSCOPIC KDO - RONGEUR, CYSTOSCOPIC, HOT KGD - SCISSORS FOR CYTOSCOPE FDE - SET, LAPAROSCOPY FGA - SET, NEPHROSCOPE FED - SHEATH, FOR ENDOSCOPE FAM - SIGMOIDOSCOPE, FLEXIBLE FAN - SIGMOIDOSCOPE, RIGID, ELECTRICAL KDM - SIGMOIDOSCOPE, RIGID, NON-ELECTRICAL FDR - SPHYNCTEROSCOPE FET - TAPE, TELEVISION & VIDEO, CLOSED-CIRCUIT, USED DURING ENDOSCOPIC FBP - TELESCOPE, RIGID, ENDOSCOPIC GCW - TRANSFORMER, ENDOSCOPE FGB - URETEROSCOPE FGC - URETHROSCOPE
876.4500	MECHANICAL LITHOTRIPTER LQC - LITHOTRIPTER, BILIARY MECHANICAL FGK - TRIPSOR, STONE, BLADDER
876.5010	BILIARY CATHETER AND ACCESSORIES (biliary stone dislodger only) LQR - DISLODGER, STONE, BILIARY
876.5320	NONIMPLANTED ELECTRICAL CONTINENCE DEVICE KPI - STIMULATOR, ELECTRICAL FOR INCONTINENCE (NON- IMPLANTABLE)
876.5665	WATER PURIFICATION SYSTEM FOR HEMODIALYSIS FIP - SUBSYSTEM, WATER PURIFICATION

GENERAL HOSPITAL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
880.2910	CLINICAL ELECTRONIC THERMOMETER (except tympanic or pacifier) FLL - THERMOMETER, ELECTRONIC, CLINICAL
880.5400	NEONATAL INCUBATOR FMZ - INCUBATOR, NEONATAL
880.5410	NEONATAL TRANSPORT INCUBATOR FPL - INCUBATOR, NEONATAL TRANSPORT
880.5570	HYPODERMIC SINGLE LUMEN NEEDLE MMK - CONTAINER, SHARPS FMI - NEEDLE, HYPODERMIC, SINGLE LUMEN (except anti-stick and self- destruct)
880.5725	INFUSION PUMP (external only) MRZ - ACCESSORIES, PUMP, INFUSION FRN - PUMP, INFUSION LZF - PUMP, INFUSION, ANALYTICAL SAMPLING MEB - PUMP, INFUSION, ELASTOMERIC LZH - PUMP, INFUSION, ENTERAL MHD - PUMP, INFUSION, GALLSTONE DISSOLUTION MEA - PUMP, INFUSION, PCA (except for combination products regulated under the InterCenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health, or the InterCenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health.)
880.5860	PISTON SYRINGE FMF - SYRINGE, PISTON
880.6880	STEAM STERILIZER (greater than 2 cubic feet) FLE - STERILIZER, STEAM

NEUROLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
882.1240	ECHOENCEPHALOGRAPH GXW - ECHOENCEPHALOGRAPH
882.1320	CUTANEOUS ELECTRODE GXY - ELECTRODE, CUTANEOUS
882.1400	ELECTROENCEPHALOGRAPH GWQ - ELECTROENCEPHALOGRAPH
882.1480	NEUROLOGICAL ENDOSCOPE GWG - ENDOSCOPE, NEUROLOGICAL
882.5890	TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR FOR PAIN RELIEF GZJ - STIMULATOR, NERVE, TRANSCUTANEOUS, FOR PAIN RELIEF

OBSTETRICS AND GYNECOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
884.1690	HYSTEROSCOPE AND ACCESSORIES HIH - HYSTEROSCOPE (AND ACCESSORIES)
884.1720	GYNECOLOGIC LAPAROSCOPE AND ACCESSORIES HET - LAPAROSCOPE, GYNECOLOGIC (AND ACCESSORIES)
884.2225	OBSTETRIC-GYNECOLOGIC ULTRASONIC IMAGER HEN - CALIPER, FETAL HEAD, ULTRASONIC HHX - HOLOGRAPH, FETAL ACOUSTICAL HEM - IMAGER, ULTRASONIC OBSTETRIC-GYNECOLOGIC HHJ - LOCATOR, INTRACORPOREAL DEVICE, ULTRASONIC
#884.2660	FETAL ULTRASONIC MONITOR AND ACCESSORIES HEP - MONITOR, BLOOD-FLOW, ULTRASONIC HEL - MONITOR, HEART RATE, FETAL, ULTRASONIC HEK - MONITOR, HEART SOUND, FETAL, ULTRASONIC HEI - MONITOR, HEART-VALVE MOVEMENT, FETAL, ULTRASONIC HEJ - MONITOR, HEMIC SOUND, ULTRASONIC HEQ - MONITOR, PRESSURE, ARTERIAL, FETAL, ULTRASONIC KNG - MONITOR, ULTRASONIC, FETAL
884.2960	OBSTETRIC ULTRASONIC TRANSDUCER AND ACCESSORIES HGL - TRANSDUCER, ULTRASONIC, OBSTETRIC
884.5300	CONDOM HIS - CONDOM

OPHTHALMOLOGY PANEL

SECTION NO	REGULATION NAME PRODUCT CODE - DEVICE NAME
886.1570	OPHTHALMOSCOPE HLI - OPHTHALMOSCOPE, AC-POWERED HLJ - OPHTHALMOSCOPE, BATTERY-POWERED
886.1780	RETINOSCOPE HKL - RETINOSCOPE, AC-POWERED
886.1850	AC-POWERED SLIT-LAMP BIOMICROSCOPE HJO - BIOMICROSCOPE, SLIT-LAMP, AC-POWERED
886.4150	VITREOUS ASPIRATION AND CUTTING INSTRUMENT MMC - DILATOR, EXPANSIVE IRIS (ACCESSORY) HQE - INSTRUMENT, VITREOUS ASPIRATION AND CUTTING, AC-POWERED HKP - INSTRUMENT, VITREOUS ASPIRATION AND CUTTING, BATTERY-POWERED MLZ - VITRECTOMY, INSTRUMENT CUTTER

	MAA - MONITOR, FETAL DOPPLER ULTRASOUND
892.1000	MAGNETIC RESONANCE DIAGNOSTIC DEVICE MOS - COIL, MAGNETIC RESONANCE, SPECIALTY LNH - SYSTEM, NUCLEAR MAGNETIC RESONANCE IMAGING LNI - SYSTEM, NUCLEAR MAGNETIC RESONANCE SPECTROSCOPIC
892.1200	EMISSION COMPUTED TOMOGRAPHY SYSTEM KPS - SYSTEM, TOMOGRAPHY, COMPUTED, EMISSION
892.1310	NUCLEAR TOMOGRAPHY SYSTEM JWM - SYSTEM, TOMOGRAPHY, COMPUTED, EMISSION
892.1360	RADIONUCLIDE DOSE CALIBRATOR KPT - CALIBRATOR, DOSE, RADIONUCLIDE
892.1540	NONFETAL ULTRASONIC MONITOR JAF - MONITOR, ULTRASONIC, NONFETAL
892.1550	ULTRASONIC PULSED DOPPLER IMAGING SYSTEM IYN - SYSTEM, IMAGING, PULSED DOPPLER, ULTRASONIC
892.1560	ULTRASONIC PULSED ECHO IMAGING SYSTEM IYO - SYSTEM, IMAGING, PULSED ECHO, ULTRASONIC
892.1570	DIAGNOSTIC ULTRASONIC TRANSDUCER ITX - TRANSDUCER, ULTRASONIC, DIAGNOSTIC
892.1600	ANGIOGRAPHIC X-RAY SYSTEM IZI - SYSTEM, X-RAY, ANGIOGRAPHIC
892.1610	DIAGNOSTIC X-RAY BEAM LIMITING DEVICE IZS - APERTURE, RADIOGRAPHIC IZW - COLLIMATOR, AUTOMATIC, RADIOGRAPHIC IZX - COLLIMATOR, MANUAL, RADIOGRAPHIC IZT - CONE, RADIOGRAPHIC KPW - DEVICE, BEAM LIMITING, X-RAY, DIAGNOSTIC
892.1620	CINE OR SPOT FLUOROGRAPHIC X-RAY CAMERA IZJ - CAMERA, X-RAY, FLUOROGRAPHIC, CINE OR SPOT
892.1630	ELECTROSTATIC X-RAY IMAGING SYSTEM IXK - SYSTEM, IMAGING, X-RAY, ELECTROSTATIC
892.1650	IMAGE-INTENSIFIED FLUOROSCOPIC X-RAY SYSTEM (except solid state) JAA - SYSTEM, X-RAY, FLUOROSCOPIC, IMAGE-INTENSIFIED
892.1670	SPOT FILM DEVICE IXL - DEVICE, SPOT-FILM
892.1680	STATIONARY X-RAY SYSTEM KPR - SYSTEM, X-RAY, STATIONARY
892.1720	MOBILE X-RAY SYSTEM IZL - SYSTEM, X-RAY, MOBILE
892.1740	TOMOGRAPHIC X-RAY SYSTEM IZF - SYSTEM, X-RAY, TOMOGRAPHIC
892.1750	COMPUTED TOMOGRAPHY X-RAY SYSTEM JAK - SYSTEM, X-RAY, TOMOGRAPHY, COMPUTED

892.1820	PNEUMOENCEPHALOGRAPHIC CHAIR HBK - CHAIR, PNEUMOENCEPHALOGRAPHIC
892.1850	RADIOGRAPHIC FILM CASSETTE IXA - CASSETTE, RADIOGRAPHIC FILM
892.1860	RADIOGRAPHIC FILM/CASSETTE CHANGER KPX - CHANGER, RADIOGRAPHIC FILM/CASSETTE
892.1870	RADIOGRAPHIC FILM/CASSETTE CHANGER PROGRAMMER IZP - PROGRAMMER, CHANGER, FILM/CASSETTE, RADIOGRAPHIC
892.1900	AUTOMATIC RADIOGRAPHIC FILM PROCESSOR EGT - CONTROLLER, TEMPERATURE, RADIOGRAPHIC EGW - DRYER, FILM, RADIOGRAPHIC IXX - PROCESSOR, CINE FILM IXW - PROCESSOR, RADIOGRAPHIC-FILM, AUTOMATIC EGY - PROCESSOR, RADIOGRAPHIC-FILM, AUTOMATIC, DENTAL

GENERAL AND PLASTIC SURGERY PANEL

SECTION	REGULATION NAME PRODUCT CODE - DEVICE NAME
#876.1500	ENDOSCOPE AND ACCESSORIES GCJ - LAPAROSCOPE, GENERAL AND PLASTIC SURGERY
878.4400	ELECTROSURGICAL CUTTING AND COAGULATION DEVICE AND ACCESSORIES HAM - APPARATUS, ELECTROSURGICAL GEI - DEVICE, ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES JOS - ELECTRODE, ELECTROSURGICAL JOT - ELECTRODE, GEL, ELECTROSURGICAL DWG - ELECTROSURGICAL DEVICE BWA - UNIT, ELECTROSURGICAL AND COAGULATION, WITH ACCESSORIES
878.4580	SURGICAL LAMP HBI - ILLUMINATOR, FIBEROPTIC, SURGICAL FIELD FTF - ILLUMINATOR, NON-REMOTE FTG - ILLUMINATOR, REMOTE HJE - LAMP, FLUORESCIN, AC-POWERED FQP - LAMP, OPERATING-ROOM FTD - LAMP, SURGICAL GBC - LAMP, SURGICAL, INCANDESCENT FTA - LIGHT, SURGICAL, ACCESSORIES FSZ - LIGHT, SURGICAL, CARRIER FSY - LIGHT, SURGICAL, CEILING MOUNTED FSX - LIGHT, SURGICAL, CONNECTOR FSW - LIGHT, SURGICAL, ENDOSCOPIC FST - LIGHT, SURGICAL, FIBEROPTIC FSS - LIGHT, SURGICAL, FLOOR STANDING FSQ - LIGHT, SURGICAL, INSTRUMENT
878.4780	POWERED SUCTION PUMP JCX - APPARATUS, SUCTION, WARD USE, PORTABLE, AC-POWERED BTA - PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED)