AGREEMENT

on mutual recognition between the European Community and the United States of America

TABLE OF CONTENTS

The EUROPEAN COMMUNITY, and THE UNITED STATES OF AMERICA, hereinafter referred to as 'the Parties',

CONSIDERING the traditional links of friendship that exist between the United States of America (US) and the European Community (EC);

DESIRING to facilitate bilateral trade between them;

RECOGNISING that mutual recognition of conformity assessment activities is an important means of enhancing market access between the Parties;

RECOGNISING that an agreement providing for mutual recognition of conformity assessment activities is of particular interest to small and medium-sized businesses in the US and the EC;

RECOGNISING that any such mutual recognition also requires confidence in the continued reliability of the other Party's conformity assessments;

RECOGNISING the importance of maintaining each Party's high levels of health, safety, environmental and consumer protection;

RECOGNISING that mutual recognition agreements can positively contribute in encouraging greater international harmonisation of standards;

NOTING that this Agreement is not intended to displace private sector bilateral and multilateral arrangements among conformity assessment bodies or to affect regulatory regimes allowing for manufacturers' self-assessments and declarations of conformity;

BEARING IN MIND that the Agreement on Technical Barriers to Trade, an agreement annexed to the Agreement establishing the World Trade Organization (WTO), imposes obligations on the Parties as Contracting Parties to the WTO, and encourages such Contracting Parties to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment;

RECOGNISING that any such mutual recognition needs to offer an assurance of conformity with applicable technical regulations or standards equivalent to the assurance offered by the Party's own procedures;

RECOGNISING the need to conclude an Agreement on Mutual Recognition (MRA) in the field of conformity assessment with sectoral annexes; and

BEARING in mind the respective commitments of the Parties under bilateral, regional and multilateral environment, health, safety and consumer protection agreements.

HAVE AGREED AS FOLLOWS:

Article 1

Definitions

1. The following terms and definitions shall apply to this Agreement only:

— 'Designating Authority' means a body with power to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies as specified under this Agreement.

— 'Designation' means the identification by a Designating Authority of a conformity assessment body to perform conformity assessment procedures under this Agreement.

— 'Regulatory Authority' means a government agency or entity that exercises a legal right to control the use or sale of products within a Party's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.

2. Other terms concerning conformity assessment used in this Agreement shall have the meaning given elsewhere in this Agreement or in the definitions contained in Guide 2 (1996 edition) of the International Organization for Standardisation (ISO) and the International Electrotechnical Commission (IEC). In the event of an inconsistency between ISO/IEC Guide 2 and definitions in this Agreement, the definitions in this Agreement shall prevail.

Article 2

Purpose of the Agreement

This Agreement specifies the conditions by which each Party will accept or recognise results of conformity assessment procedures, produced by the other Party's conformity assessment bodies or authorities, in assessing conformity to the importing Party's requirements, as specified on a sector-specific basis in the Sectoral Annexes, and to provide for other related cooperative activities. The objective of such mutual recognition is to provide effective market access throughout the territories of the Parties with regard to conformity assessment for all products covered under this Agreement. If any obstacles to such access arise, consultations will promptly be held. In the absence of a satisfactory outcome of such consultations, the Party alleging its market access has been denied, may, within 90 days of such consultation, invoke its right to terminate the Agreement in accordance with Article 21.

Article 3

General obligations

1. The United States shall, as specified in the Sectoral Annexes, accept or recognise results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the United States, produced by the other Party's conformity assessment bodies and/or authorities.

2. The European Community and its Member States shall, as specified in the Sectoral Annexes, accept or recognise results of specified procedures, used in assessing conformity to specified legislative, regulatory and administrative provisions of the European Community and its Member States, produced by the other Party's conformity assessment bodies and/or authorities.

3. Where sectoral transition arrangements have been specified in Sectoral Annexes, the above obligations will apply following the successful completion of those sectoral transition arrangements, with the understanding that the conformity assessment procedures utilised assure conformity to the satisfaction of the receiving Party, with applicable legislative, regulatory and administrative provisions of that Party, equivalent to the assurance offered by the receiving Party's own procedures.

Article 4

General coverage of the Agreement

1. This Agreement applies to conformity assessment procedures for products and/or processes and to other related cooperative activities as described in this Agreement.

2. Sectoral Annexes may include:

(a) a description of the relevant legislative, regulatory and administrative provisions pertaining to the conformity assessment procedures and technical regulations;

(b) a statement on the product scope and coverage;

(c) a list of Designating Authorities;

(d) a list of agreed conformity assessment bodies or authorities or a source from which to obtain a list of such bodies or authorities and a statement of the scope of the conformity assessment procedures for which each has been agreed;

(e) the procedures and criteria for designating the conformity assessment bodies;

(f) a description of the mutual recognition obligations;

(g) a sectoral transition arrangement;

(h) the identity of a sectoral contact point in each Party's territory; and

(i) a statement regarding the establishment of a Joint Sectoral Committee.

3. This Agreement shall not be construed to entail mutual acceptance of standards or technical regulation of the Parties and, unless otherwise specified in a Sectoral Annex, shall not entail the mutual recognition of the equivalence of standards or technical regulations.

Article 5

Transitional arrangements

The Parties agree to implement the transitional commitments on confidence building as specified in the Sectoral Annexes.

1. The Parties agree that each sectoral transition arrangement shall specify a time period for completion.

2. The Parties may amend any transition arrangement by mutual agreement.

3. Passage from the transitional phase to the operational phase shall proceed as specified in each Sectoral Annex, unless either Party documents that the conditions provided in such Sectoral Annex for a successful transition are not met.

Article 6

Designating Authorities

The Parties shall ensure that the Designating Authorities specified in the Sectoral Annexes have the power and competence in their respective territories to carry out decisions under this Agreement to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies.

Article 7

Designation and listing procedures

The following procedures shall apply with regard to the designation of conformity assessment bodies and the inclusion of such bodies in the list of conformity assessment bodies in a Sectoral Annex:

(a) The Designating Authority identified in a Sectoral Annex shall designate conformity assessment bodies in accordance with the procedures and criteria set forth in that Sectoral Annex;

(b) A Party proposing to add a conformity assessment body to the list of such bodies in a Sectoral Annex shall forward its proposal of one or more designated conformity assessment bodies in writing to the other Party with a view to a decision by the Joint Committee;

(c) Within 60 days following receipt of the proposal, the other Party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the inclusion in the Sectoral Annex of the proposed conformity assessment body or bodies shall take effect; and

(d) In the event that the other Party contests on the basis of documented evidence the technical competence or compliance of a proposed conformity assessment body, or indicates in writing that it requires an additional 30 days to more fully verify such evidence, such conformity assessment body shall not be included on the list of conformity assessment bodies in the applicable Sectoral Annex. In this instance, the Joint Committee may decide that the body concerned be verified. After the completion of such verification, the proposal to list the conformity assessment body in the Sectoral Annex may be resubmitted to the other Party.

Article 8

Suspension of listed conformity assessment bodies

The following procedures shall apply with regard to the suspension of a conformity assessment body listed in a Sectoral Annex:

(a) A Party shall notify the other Party of its contestation of the technical competence or compliance of a conformity assessment body listed in a Sectoral Annex and the contesting Party's intent to suspend such conformity assessment body. Such contestation shall be exercised when justified in an objective and reasoned manner in writing to the other Party;

(b) The conformity assessment body shall be given prompt notice by the other Party and an opportunity to present information in order to refute the contestation or to correct the deficiencies which form the basis of the contestation;

(c) Any such contestation shall be discussed between the Parties in the relevant Joint Sectoral Committee. If there is no Joint Sectoral Committee, the contesting Party shall refer the matter directly to the Joint Committee. If agreement to suspend is reached by the Joint Sectoral Committee or, if there is no Joint Sectoral Committee, by the Joint Committee, the conformity assessment body shall be suspended;

(d) Where the Joint Sectoral Committee or Joint Committee decides that verification of technical competence or compliance is required, it shall normally be carried out in a timely manner by the Party in whose territory the body in question is located, but may be carried out jointly by the Parties in justified cases;

(e) If the matter has not been resolved by the Joint Sectoral Committee within 10 days of the notice of contestation, the matter shall be referred to the Joint Committee for a decision. If there is no Joint Sectoral Committee, the matter shall be referred directly to the

Joint Committee. If no decision is reached by the Joint Committee within 10 days of the referral to it, the conformity assessment body shall be suspended upon the request of the contesting Party;

(f) Upon the suspension of a conformity assessment body listed in a Sectoral Annex, a Party is no longer obligated to accept or recognise the results of conformity assessment procedures performed by that conformity assessment body subsequent to suspension. A Party shall continue to accept the results of conformity assessment procedures performed by that conformity assessment body prior to suspension, unless a Regulatory Authority of the Party decides otherwise based on health, safety or environmental considerations or failure to satisfy other requirements within the scope of the applicable Sectoral Annex; and

(g) The suspension shall remain in effect until agreement has been reached by the Parties upon the future status of that body.

Article 9

Withdrawal of listed conformity assessment bodies

The following procedures shall apply with regard to the withdrawal from a Sectoral Annex of a conformity assessment body:

(a) A Party proposing to withdraw a conformity assessment body listed in a Sectoral Annex shall forward its proposal in writing to the other Party;

(b) Such conformity assessment body shall be promptly notified by the other Party and shall be provided a period of at least 30 days from receipt to provide information in order to refute or to correct the deficiencies which form the basis of the proposed withdrawal;

(c) Within 60 days following receipt of the proposal, the other Party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the withdrawal from the list in the Sectoral Annex of the conformity assessment body shall take effect;

(d) In the event the other Party opposes the proposal to withdraw by supporting the technical competence and compliance of the conformity assessment body, the conformity assessment body shall not at that time be withdrawn from the list of conformity assessment bodies in the applicable Sectoral Annex. In this instance, the Joint Sectoral Committee or the Joint Committee may decide to carry out a joint verification of the body concerned. After the completion of such verification, the proposal for withdrawal of the conformity assessment body may be resubmitted to the other Party; and

(e) Subsequent to the withdrawal of a conformity assessment body listed in a Sectoral Annex, a Party shall continue to accept the results of conformity assessment procedures performed by that conformity assessment body prior to withdrawal, unless a Regulatory Authority of the Party decides otherwise based on health, safety and environmental considerations or failure to satisfy other requirements within the scope of the applicable Sectoral Annex.

Article 10

Monitoring of conformity assessment bodies

The following shall apply with regard to the monitoring of conformity assessment bodies listed in a Sectoral Annex:

(a) Designating Authorities shall assure that their conformity assessment bodies listed in a Sectoral Annex are capable and remain capable of properly assessing conformity of products or processes, as applicable, and as covered in the applicable Sectoral Annex. In this regard, Designating Authorities shall maintain, or cause to maintain, ongoing surveillance over their conformity assessment bodies by means of regular audit or assessment;

(b) The Parties undertake to compare methods used to verify that the conformity assessment bodies listed in the Sectoral Annexes comply with the relevant requirements of the Sectoral Annexes. Existing systems for the evaluation of conformity assessment bodies may be used as part of such comparison procedures;

(c) Designating Authorities shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures. With the consent of both Parties, this consultation may include joint participation in audits/inspections related to conformity assessment activities or other assessments of conformity assessment bodies listed in a Sectoral Annex; and;

(d) Designating Authorities shall consult, as necessary, with the relevant Regulatory Authorities of the other Party to ensure that all technical requirements are identified and are satisfactorily addressed.

Article 11

Conformity assessment bodies

Each Party recognises that the conformity assessment bodies listed in the Sectoral Annexes fulfil the conditions of eligibility to assess conformity in relation to its requirements as specified in the Sectoral Annexes. The Parties shall specify the scope of the conformity assessment procedures for which such bodies are listed.

Article 12

Exchange of information

1. The Parties shall exchange information concerning the implementation of the legislative, regulatory, and administrative provisions identified in the Sectoral Annexes.

2. Each Party shall notify the other Party of legislative, regulatory and administrative changes related to the subject matter of this Agreement at least 60 days before their entry into force. Where considerations of safety, health or environmental protection require more urgent action a Party shall notify the other Party as soon as practicable.

3. Each Party shall promptly notify the other Party of any changes to its Designating Authorities and/or conformity assessment bodies.

4. The Parties shall exchange information concerning the procedures used to ensure that the listed conformity assessment bodies under their responsibility comply with the legislative, regulatory, and administrative provisions outlined in the Sectoral Annexes.

5. Regulatory Authorities identified in the Sectoral Annexes shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures and to ensure that all technical requirements are identified and are satisfactorily addressed.

Article 13

Sectoral contact points

Each Party shall appoint and confirm in writing contact points to be responsible for activities under each Sectoral Annex.

Article 14

Joint Committee of the Parties

1. The Parties hereby establish a Joint Committee consisting of representatives of each Party. The Joint Committee comprised shall be responsible for the effective functioning of the Agreement.

2. The Joint Committee may establish Joint Sectoral Committees comprised of appropriate Regulatory Authorities and others deemed necessary.

3. Each Party shall have one vote in the Joint Committee. The Joint Committee shall make its decisions by unanimous consent. The Joint Committee shall determine its own rules and procedures.

4. The Joint Committee may consider any matter relating to the effective functioning of this Agreement. In particular it shall be responsible for:

(a) listing, suspension, withdrawal and verification of conformity assessment bodies in accordance with this Agreement;

(b) amending transitional arrangements in Sectoral Annexes;

(c) resolving any questions relating to the application of this Agreement and its Sectoral Annexes not otherwise resolved in the respective Joint Sectoral Committees;

(d) providing a forum for discussion of issues that may arise concerning the implementation of this Agreement;

(e) considering ways to enhance the operation of this Agreement;

(f) coordinating the negotiation of additional Sectoral Annexes; and

(g) considering whether to amend this Agreement or its Sectoral Annexes in accordance with Article 21.

5. When a Party introduces new or additional conformity assessment procedures affecting a Sectoral Annex, the Parties shall discuss the matter in the Joint Committee with a view to bringing such new or additional procedures within the scope of this Agreement and the relevant Sectoral Annex.

Article 15

Preservation of regulatory authority

1. Nothing in this Agreement shall be construed to limit the authority of a Party to determine, through its

legislative, regulatory and administrative measures, the level of protection it considers appropriate for safety; for protection of human, animal, or plant life or health; for the environment; for consumers; and otherwise with regard to risks within the scope of the applicable Sectoral Annex.

2. Nothing in this Agreement shall be construed to limit the authority of a Regulatory Authority to take all appropriate and immediate measures whenever it ascertains that a product may: (a) compromise the health or safety of persons in its territory; (b) not meet the legislative, regulatory, or administrative provisions within the scope of the applicable Sectoral Annex; or (c) otherwise fail to satisfy a requirement within the scope of the applicable Sectoral Annex. Such measures may include withdrawing the products from the market, prohibiting their placement on the market, restricting their free movement, initiating a product recall, and preventing the recurrence of such problems, including through a prohibition on imports. If the Regulatory Authority takes such action, it shall inform its counterpart authority and the other Party within 15 days of taking such action, providing its reasons.

Article 16

Suspension of recognition obligations

Either Party may suspend its obligations under a Sectoral Annex, in whole or in part, if:

(a) a Party suffers a loss of market access for the Party's products within the scope of the Sectoral Annex as a result of the failure of the other Party to fulfil its obligations under the Agreement;

(b) the adoption of new or additional conformity assessment requirements as referenced in Article 14(5) results in a loss of market access for the Party's products within the scope of the Sectoral Annex because conformity assessment bodies designated by the Party in order to meet such requirements have not been recognized by the Party implementing the requirements; or;

(c) the other Party fails to maintain legal and regulatory authorities capable of implementing the provisions of this Agreement.

Article 17

Confidentiality

1. Each Party agrees to maintain, to the extent required under its laws, the confidentiality of information exchanged under this Agreement.

2. In particular, neither Party shall disclose to the public, nor permit a conformity assessment body to disclose to the public, information exchanged under this Agreement that constitutes trade secrets, confidential commercial or financial information, or information that relates to an ongoing investigation.

3. A Party or a conformity assessment body may, upon exchanging information with the other Party or with a conformity assessment body of the other Party, designate the portions of the information that it considers to be exempt from disclosure.

4. Each Party shall take all precautions reasonably necessary to protect information exchanged under this Agreement from unauthorised disclosure.

Article 18

Fees

Each Party shall endeavour to ensure that fees imposed for services under this Agreement shall be commensurate with the services provided. Each Party shall ensure that, for the sectors and conformity assessment procedures covered under this Agreement, it shall charge no fees with respect to conformity assessment services provided by the other Party.

Article 19

Agreements with other countries

Except where there is written agreement between the Parties, obligations contained in mutual recognition agreements concluded by either Party with a party not a signatory to this Agreement (a third party) shall have no force and effect with regard to the other Party in terms of acceptance of the results of conformity assessment procedures in the third party.

Article 20

Territorial application

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European

Community is applied, and under the conditions laid down in that Treaty and, on the other hand, to the territory of the United States.

Article 21

Entry into force, amendment and termination

1. This Agreement including its Sectoral Annexes on Telecommunication Equipment, Electromagnetic Compatibility, Electrical Safety, Recreational Craft, Pharmaceutical Good Manufacturing Practices (GMPs), and Medical Devices shall enter into force on the first day of the second month following the date on which the Parties have exchanged letters confirming the completion of their respective procedures for the entry into force of this Agreement.

2. This Agreement including any Sectoral Annex may, through the Joint Committee, be amended in writing by the Parties. The Parties may add a Sectoral Annex upon the exchange of letters. Such Annex shall enter into force 30 days following the date on which the Parties have exchanged letters confirming the completion of their respective procedures for the entry into force of the Sectoral Annex.

3. Either Party may terminate this Agreement in its entirety or any individual Sectoral Annex thereof by giving the other Party six months notice in writing. In the case of termination of one or more Sectoral Annexes, the Parties will seek to achieve by consensus to amend this Agreement, with a view to preserving the remaining Sectoral Annexes, in accordance with the procedures in this Article. Failing such consensus, the Agreement shall terminate at the end of six months from the date of notice.

4. Following termination of the Agreement in its entirety or any individual Sectoral Annex thereof, a Party shall continue to accept the results of conformity assessment procedures performed by conformity assessment bodies under this Agreement prior to termination, unless a Regulatory Authority in the Party decides otherwise based on health, safety and environmental considerations or failure to satisfy other requirements within the scope of the applicable Sectoral Annex.

Article 22

Final provisions

1. The Sectoral Annexes referred to in Article 21(1), as well as any New Sectoral Annexes added pursuant to Article 21(2), shall form an integral part of this Agreement.

2. For a given product or sector, the provisions contained in the relevant Sectoral Annexes shall apply in the first place, and the provisions of this text in addition to those provisions. In the case of any inconsistency between the provisions of a Sectoral Annex and this text, the Sectoral Annex shall prevail, to the extent of that inconsistency.

3. This Agreement shall not affect the rights and obligations of the Parties under any other international agreement.

4. In the case of the Sectoral Annex on Medical Devices, the Parties shall review the status of such Annex at the end of three years from entry into force.

This Agreement and the Sectoral Annexes are drawn up in two original in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish and Swedish languages, each text being equally authentic. In the event of inconsistencies of interpretation, the English text shall be determinative.

Hecho en Londres, el dieciocho de mayo de mil novecientos noventa y ocho.

Udfærdiget i London den attende maj nitten hundrede og otteoghalvfems.

Geschehen zu London am achtzehnten Mai neunzehnhundertachtundneunzig.

Έγινε στο Λονδίνο, στις δέκα οκτώ Μαΐου χίλια εννιακόσια ενενήντα οκτώ.

Done at London on the eighteenth day of May in the year one thousand nine hundred and ninety-eight.

Fait à Londres, le dix-huit mai mil neuf cent quatre-vingt-dix-huit.

Fatto a Londra, addì diciotto maggio millenovecentonovantotto.

Gedaan te Londen, de achttiende mei negentienhonderd achtennegentig.

Feito em Londres, em dezoito de Maio de mil novecentos e noventa e oito.

Tehty Lontoossa kahdeksantenatoista päivänä toukokuuta vuonna tuhatyhdeksänsataayhdeksänkymmentäkahdeksan.

Som skedde i London den artonde maj nittonhundranittioåtta.

Por la Comunidad Europea

For Det Europæiske Fællesskab

Für die Europäische Gemeinschaft

Για την Ευρωπαϊκή Κοινότητα

For the European Community

Pour la Communauté européenne

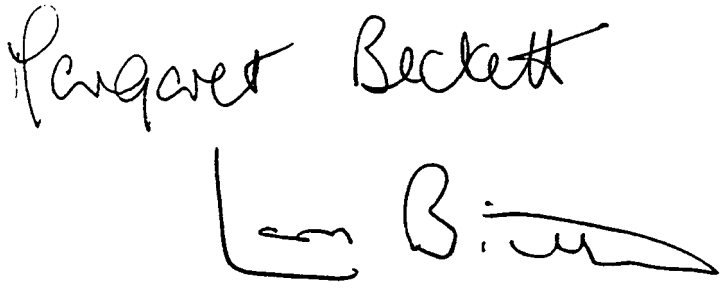
Per la Comunità europea

Voor de Europese Gemeenschap

Pela Comunidade Europeia

Euroopan yhteisön puolesta

På Europeiska gemenskapens vägnar



Por los Estados Unidos de América

For Amerikas Forenede Stater

Für die Vereinigten Staaten von Amerika

Για τις Ηνωμένες Πολιτείες της Αμερικής

For the United States of America

Pour les États-Unis d'Amérique

Per gli Stati Uniti d'America

Voor de Verenigde Staten van Amerika

Pelos Estados Unidos da América

Amerikan yhdysvaltojen puolesta

På Amerikas förenta staternas vägnar

SECTORAL ANNEX FOR TELECOMMUNICATION EQUIPMENT

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition of Conformity Assessment between the United States and the European Community.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

EC	USA
Directive 98/13/EC of the European Parliament and of the Council of 12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity, and interpretation thereof;	Communications Act of 1934, as amended by the Telecommunication Act of 1996, (Title 47 of the United States Code). The US regulatory and administrative provisions in respect of telecommunication equipment, including 47 CFR Part 68, and FCC interpretation thereof;
(The Parties recognize that the Handbook on the implementation of Directive 98/13/EC (ADLNB and ACTE approved), provides useful guidelines for the implementation of conformity assessment procedures falling under this Directive.);	(The Parties recognize that the FCC Form 730 Application Guide provides useful guidelines for the implementation of conformity assessment procedures for telecommunication terminal equipment falling within these regulations.);
Commission Decisions (CTRs) established under Directive 98/13/EC; The EC Member States' legislation and regulations in respect of: (a) non-harmonised analogue connection to the public telecommunications network ([1]); (b) non-harmonised radio transmitters for which there is a civilian equipment authorisation requirement;	The US regulatory and administrative provisions in respect of all radio transmitters subject to an equipment authorisation requirement. A non-exclusive list of FCC regulations are contained in Section II;
For electrical safety, see Electrical Safety Sectoral Annex to the Agreement;	For electrical safety, see Electrical Safety Sectoral Annex to the Agreement;
For electromagnetic compatibility aspects, see Electromagnetic Compatibility (EMC) Sectoral Annex to the Agreement.	For electromagnetic compatibility aspects, see Electromagnetic Compatibility (EMC) Sectoral Annex to the Agreement.

([1]) The EC agrees to seek authority to include non-harmonised digital connections;

SECTION II

SCOPE AND COVERAGE

1. This Sectoral Annex shall apply to equipment, interfaces, and services subject to Section I. In general terms the provisions of this Sectoral Annex shall apply to the following types of telecommunication terminal equipment, satellite terminal equipment, radio transmitters, and information technology equipment:

   (a) equipment intended for connection to the public telecommunications network in order to send, process or receive information, whether the equipment is to be connected directly to the 'termination' of the network or to inter-work with such a network, being connected directly or indirectly to the termination point. The system of connection may be wire, radio, optical or other electro-magnetic means;

   (b) equipment capable of being connected to a public telecommunications network even if it is not its intended purpose, including information technology equipment having a communication port; and

   (c) all radio transmitters subject to an equipment authorisation procedure by either Party.

2. The following is a non-exclusive list of the equipment, interfaces, and services included within the scope of this Sectoral Annex:

EC	USA
The following equipment categories are included: ISDN Basic Rate Access ISDN Primary Rate Access ISDN Telephony X21/V.24/V.35 Access X25 Access PSTN Non-Voice PSTN Voice Band (Analog) ONP Leased Line Terminal types: — 64 kbits/sec — 2048 kbit/s unstructured — 2048 kbit/s structured — 34 Mbits/s access — 140 Mbits/s access — 2 wire analogue — 4 wire analogue	Equipment categories covered under 47 CFR, Part 68, including: ISDN Basic Access ISDN Primary Rate Access Digital Service Access: — 2.4 kbps — 3.2 kbps (2.4 kbps with Secondary Channel) — 4.8 kbps — 6.4 kbps (4.8 kbps with SC) — 9.6 kbps — 12.8 kbps (9.6 kbps with SC) — 19.2 kbps — 25.0 kbps (19.2 kbps with SC) — 56.0 kbps — 64.0 kbps (uses 72 kbps channel) — 72.0 kbps (56.0 kbps with SC) — 1.544 Mbps 2-wire analog tie trunks/ops 4-wire analog tie trunks/ops PSTN Voice Band (Analog) Access Private Line (Analog) Access

EC	USA	
Radio transmitters subject to an equipment authorisation requirement, including:	Radio transmitters subject to an equipment authorisation requirement, including:	
— Short range devices, including low power devices such as cordless telephones/microphones;	Commercial Mobile Radio	(Part 20)
— Land mobile, including:	Domestic Public Fixed	(Part 21)
— Private Mobile Radio (PMR/PAMR)	Domestic Mobile	(Part 22)
— Mobile telecom	Personal Communication Service	(Part 24)
— Paging systems	Satellite Communications	(Part 25)
— Terrestrial fixed	Broadcast	(Part 73)
— Satellite mobile	Auxiliary Broadcast	(Part 74)
— Satellite fixed	Cable Television Radio	(Part 78)
— Broadcast	Maritime	(Part 80)
— Radio determination	GMDSS	(Part 80W)
	Private Land Mobile	(Part 90)
	Private-Fixed Microwave	(Part 94)
	Personal Radio Services	(Part 95)
	IVDS	(Part 95 F)
	Amateur Radio	(Part 97)
	Radio Frequency Devices	(Part 15)
	Fixed Microwave Services	(Part 101)

Note: A list of acronyms and a glossary is contained in Appendix I to this Sectoral Annex.

SECTION III

CONFORMITY ASSESSMENT PROCEDURES FOR TELECOMMUNICATION EQUIPMENT

1. **Description of Mutual Recognition Obligations**

In accordance with the provisions of the Agreement, the result of the conformity assessment procedures produced by a Party's conformity assessment bodies listed in Section V shall be recognised by the Regulatory Authorities of the other Party without any further conformity assessment of the products, pursuant to Section I.

2. **Conformity Assessment Procedures**

Taking into account the legislative, regulatory, and administrative provisions as identified in Section I, each Party recognises that the conformity assessment bodies of the other Party, listed in Section V, are authorised to perform the following procedures with regard to the importing Party's technical requirements for telecommunication terminal, satellite terminal equipment, radio transmitters or information technology equipment:

(a) testing and issuing of test reports;

(b) issuing certificates of conformity to the requirements of the laws and regulations applicable in the territories of the Parties for products covered under this Sectoral Annex; and

(c) performing quality assurance certification pursuant to Directive 98/13/EC.

SECTION IV

AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

EC	USA
— *Belgium* Institut belge des services postaux et des télécommunications Belgisch instituut voor postdiensten en telecommunicatie — *Denmark* Telestyrelsen — *Germany* Bundesministerium für Wirtschaft — *Greece* Υπουργείο Μεταφορών και Επικοινωνιών Ministry of Transport and Communications — *Spain* Ministerio de Fomento — *France* Ministère de l'économie, des finances et de l'industrie — *Ireland* Department of Transport, Energy and Communications — *Italy* Ministero delle Communicazioni — DGROS e ISETI (Radiotransmettitori) — *Luxembourg* Administration des Postes et Télécommunications — *Netherlands* De Minister van Verkeer en Waterstaat — *Austria* Bundesministerium für Wissenschaft und Verkehr — *Portugal* Instituto das Comunicações de Portugal — *Finland* Liikenneministeriö/Trafikministeriet Telehallintokeskus/Teleförvaltningscentralen — *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *United Kingdom* Department of Trade and Industry	National Institute of Standards and Technology (NIST) Federal Communications Commission (FCC)

SECTION V

CONFORMITY ASSESSMENT BODIES

EC access to the US market	US access to the EC market
Conformity assessment bodies located in the EC shall be designated by the Authorities identified in Section IV following the procedures set out in Section VI of this Annex.	Conformity assessment bodies located in the US shall be designated by the Authorities identified in Section IV following the procedures set out in Section VI of this Annex.
(to be provided by the EC)	(to be provided by the US)

SECTION VI

DESIGNATING, LISTING, SUSPENDING, WITHDRAWING AND MONITORING CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

EC access to the US market	US access to the EC market
EC Authorities identified in Section IV shall designate conformity assessment bodies located in the EC in accordance with the US legislative, regulatory, and administrative provisions identified in Section I that govern designation of conformity assessment bodies, based on compliance with the appropriate ISO/IEC Guides (e. g. Guide 22, 25, 28, 58, 61, 62, 65, etc.) or the comparable EN-45000 Series Standards.	US Authorities identified in Section IV shall designate conformity assessment bodies located in the US in accordance with the EC legislative, regulatory, and administrative provisions identified in Section I that govern designation of conformity assessment bodies, based on compliance with the appropriate EN-45000 Series Standards or the comparable ISO/IEC Guides (e. g. 22, 25, 28, 58, 61, 62, 65, etc.)
Procedures for designating, listing, suspending, withdrawing, and monitoring a conformity assessment body listed in Section V shall be undertaken pursuant to Articles 7, 8, 9 and 10 of the Agreement.	Procedures for designating, listing, suspending, withdrawing, and monitoring a conformity assessment body listed in Section V shall be undertaken pursuant to Articles 7, 8, 9 and 10 of the Agreement.

SECTION VII

ADDITIONAL PROVISIONS

1. **Sub-contracting**

1.1. Any sub-contracting by conformity assessment bodies shall be in accordance with the sub-contracting requirements of the other Party. Notwithstanding the use of sub-contracting, the final results of conformity assessment remain the full responsibility of the listed conformity assessment body. In the EC, these requirements are described in Council Decision 93/465/EEC.

1.2. The conformity assessment bodies shall record and retain details of their investigation of the competence and compliance of their subcontractors and maintain a register of all sub-contracting. These details will be available to the other Party on request.

2. **Post-market surveillance, border measures and internal movement**

2.1. For the purpose of post-market surveillance, the Parties may maintain any existing labelling and numbering requirements. The assignment of the numbers may take place in the territory of the

exporting Party. The numbers will be allocated by the importing Party. Numbering and labelling systems shall not introduce additional requirements within the meaning of this Sectoral Annex.

2.2. Nothing in this Sectoral Annex shall prevent the Parties from removing products from the market that do not in fact conform to the requirements for approval.

2.3. The Parties agree that border inspections and checks of products which have been certified, labelled or marked as conforming with the importing Party's requirements specified in Section I shall be completed as expeditiously as possible. With regard to any inspections related to internal movement within their respective territories, the Parties agree that these shall be completed in no less a favourable manner than for like domestic goods.

3. **Joint Sectoral Committee**

3.1. A combined Joint Sectoral Committee for this Sectoral Annex and the Electromagnetic Compatibility (EMC) Sectoral Annex is hereby established (the JSC). The JSC shall operate during the transitional period and after completion of the transitional arrangement. The JSC shall meet as appropriate to discuss technical, conformity assessment and technology issues relating to this Sectoral Annex and the EMC Sectoral Annexes. The JSC shall determine its own rules of procedure.

3.2. The JSC consists of representatives of the US and the EC for telecommunications and EMC. JSC representatives may each invite manufacturers and other entities as deemed necessary. The representatives for the US shall have one vote in the JSC. The representatives of the EC shall have one vote in the JSC. Decisions of the JSC shall be made by unanimous consent. In the event of disagreement either the US or EC representative may raise the matter in the Joint Committee.

3.3. The JSC may address any matter related to the effective functioning of this Sectoral Annex, including:

(a) providing a forum for discussion of issues and resolving problems that may arise concerning the implementation of this Sectoral Annex;

(b) developing a mechanism for ensuring consistency of interpretations of legislation, regulations, standards, and conformity assessment procedures;

(c) advising the Parties on matters relating to this Sectoral Annex; and

(d) providing guidance and, if necessary, developing guidelines during the transitional period to facilitate the successful completion of the transitional period.

4. **Contact point**

Each Party shall establish a contact point to provide answers to all reasonable inquiries from the other Party regarding procedures, regulations, and complaints under this Sectoral Annex.

5. **Regulatory changes and updating the Sectoral Annex**

In the event that there are changes to the legislative, regulatory, and administrative provisions referenced in Section I or the introduction of new legislative, regulatory, and administrative provisions affecting either Party's conformity assessment procedures under the Agreement, such changes shall take effect for the purpose of this Sectoral Annex at the same time they take effect domestically within the territory of each Party. The parties shall update this Sectoral Annex to reflect the changes.

SECTION VIII

TRANSITIONAL ARRANGEMENT

1. There shall be a transitional period of 24 months.

2. The purpose of this transitional arrangement is to provide a means whereby the Parties to the Agreement can build confidence in and an understanding of each other's system for designating and

listing conformity assessment bodies and in the ability of these bodies to test and certify products. Successful completion of the transitional arrangement should result in the determination that conformity assessment bodies listed in Section V comply with the applicable criteria and are competent to conduct conformity assessment activities on behalf of the other Party. Upon successful completion of the transition period, the results of conformity assessment procedures performed by the exporting Party's conformity assessment bodies listed in Section V of the exporting country shall be accepted by the importing Party.

3. This transitional period shall be used by the Parties:

   (a) to consider new legislative changes needed to support the objectives of the Agreement;

   (b) to initiate regulatory changes needed to support the objectives of the Agreement;

   (c) to exchange information on and develop better understanding of their respective regulatory requirements;

   (d) to develop mutually agreed mechanisms for exchanging information on changes in technical requirements or methods of designating conformity assessment bodies; and

   (e) to monitor and evaluate the performance of the listed conformity assessment bodies during the transitional period.

4. Parties may designate, list, suspend and withdraw conformity assessment bodies during the transitional period according to the procedures in Section VI of this Sectoral Annex.

5. During the transitional period each Party shall accept and evaluate test reports and related documents issued by designated conformity assessment bodies of the other Party. To this end, the Parties shall ensure that:

   (a) on receipt of tests reports, related documents and a first evaluation of conformity, the dossiers are promptly examined for completeness;

   (b) the applicant is informed in a precise and complete manner of any deficiency;

   (c) any request for additional information is limited to omissions, inconsistencies or variances from the technical regulations or standards; and

   (d) procedures for assessing the conformity for equipment, modified subsequent to a determination of compliance, are limited to procedures necessary to determine continued conformance.

6. Each Party ensures that issuance of approvals, certificates, or advice to the applicant shall be given no later than six weeks from receipt of the test report and evaluation from a designated conformity assessment body in the territory of the other Party.

7. Any proposal made during or at the end of the transitional period to limit the scope of recognition of any designated conformity assessment body or to exclude it from the list of bodies designated under this Sectoral Annex shall be based on objective criteria and documented. Any such body may apply for reconsideration once the necessary corrective action has been taken. To the extent possible, the Parties shall implement such action prior to the expiry of the transitional period.

8. The Parties may jointly sponsor two seminars, one in the US and one in the European Community, concerning the relevant technical and product approval requirements during the first year after this Sectoral Annex enters into force.

9. Passage from the transitional phase into the operational phase in this Sectoral Annex shall take place provided that a representative number of conformity assessment bodies have been accepted for recognition under the Electrical Safety Annex.

Appendix 1

Lists of acronyms and glossary

ACTE	Approvals Committee for Terminal Equipment
ADLNB	Association of Designated Laboratories and Notified Bodies
CAB	Conformity Assessment Body
CFR	U.S. Code of Federal Regulations, Title 47 CFR
CTR	Common Technical Regulation
EC	European Community
EEC	European Economic Community
EN	Norme Européenne (European Standard)
EU	European Union
FCC	Federal Communications Commission
IEC	International Electrotechnical Commission
ISDN	Integrated Services Digital Network
ISO	International Standards Organization
ITU	International Telecommunications Union
MRA	Mutual Recognition Agreement
MS	Member States (of the European Union)
NB	Notified Bodies
NIST	National Institute of Standards and Technology
OJ	Official Journal (of the European Union)
ONP	Open Network Provision
PSTN	Public Switched Telephone Network
STG	Sectoral Technical Group for Telecommunications
TBR	Technical Basis for Regulation
X21	ITU-T Recommendation X21
X25	ITU-T Recommendation X25

SECTORAL ANNEX FOR ELECTROMAGNETIC COMPATIBILITY (EMC)

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition of Conformity Assessment between the United States and the European Community.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

EC	USA
Council Directive 89/336/EEC, as amended by Council Directive 92/31/EEC, and Directive 98/13/EC of the European Parliament and of the Council and interpretation thereof.	Communications Act of 1934, as amended by the Telecommunication Act of 1996, (Title 47 of the United States Code), The US regulatory and administrative provisions in respect of equipment subject to electromagnetic requirements including: — 47 CFR Part 15 — 47 CFR Part 18, and FCC interpretation thereof.
For electrical safety aspects see Electrical Safety Sectoral Annex to the Agreement.	For electrical safety aspects see Electrical Safety Sectoral Annex to the Agreement.
For telecommunication equipment and radio transmitters, see also Telecommunication Equipment Sectoral Annex to the Agreement.	For telecommunication equipment and radio transmitters, see also Telecommunication Equipment Sectoral Annex to the Agreement.

SECTION II

SCOPE AND COVERAGE

US access to the EC market	EC access to the US market
Any product falling under the scope of Council Directive 89/336/EEC.	Any products falling under the scope of 47 CFR Part 15 and 18.

SECTION III

CONFORMITY ASSESSMENT PROCEDURES FOR EQUIPMENT IDENTIFIED IN SECTION II

1. **Description of Mutual Recognition Obligations**

In accordance with the provisions of the Agreement, the results of the conformity assessment procedures produced by a Party's conformity assessment bodies listed in Section V, shall be recognised by the Regulatory Authorities of the other Party without any further conformity assessment of the products, pursuant to Section I.

2. **Conformity Assessment Procedures**

Taking into account the legislative, regulatory, and administrative provisions as identified in Section I, each Party recognises that the conformity assessment bodies of the other Party, listed in Section V, are authorised to perform the following procedures with regard to the importing Party's technical requirements for equipment identified in Section II:

(a) testing and issuing of the test reports,

(b) issuing certificates of conformity to the requirements of the laws and regulations applicable in the territories of the Parties for products covered under this Sectoral Annex.

SECTION IV

AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

EC	USA
— *Belgium* Ministère des Affaires Economiques Ministerie van Economische Zaken — *Denmark* for telecommunication equipment: Telestyrelsen for other equipment: Danmarks Elektriske Materielkontrol (DEMKO) — *Germany* Bundesministerium für Wirtschaft — *Greece* Υπουργείο Μεταφορών και Επικοινωνιών Ministry of Transport and Communications — *Spain* for telecommunication equipment: Ministerio de Fomento for other equipment: Ministerio de Industria y Energía — *France* Ministère de l'économie, des finances et de l'industrie — *Ireland* Department of Transport, Energy and Communications	National Institute for Standards and Technology (NIST) Federal Communications Commission (FCC) Federal Aviation Administration (FAA)

EC	USA
— *Italy* Ministero dell'Industria, del Commercio e dell'Artigianato — *Luxembourg* Ministère des Transports — *Netherlands* De Minister van Verkeer en Waterstaat — *Austria* for telecommunication equipment: Bundesministerium für Wissenschaft und Verkehr for other equipment: Bundesministerium für wirtschaftliche Angelegenheiten — *Portugal* Instituto das Comunicações de Portugal — *Finland* for telecommunication equipment: Liikenneministeriö/Trafikministeriet for other equipment: Kauppa- ja teollisuusministeriö/Handels- och industriministeriet — *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *United Kingdom* Department of Trade and Industry	

SECTION V

CONFORMITY ASSESSMENT BODIES

EC access to the US market	US access to the EC market
Conformity assessment bodies located in the EC shall be designated by the Authorities identified in Section IV following the procedures set out in Section VI of this Annex. (to be provided by the EC)	Conformity assessment bodies located in the US shall be designated by the Authorities identified in Section IV following the procedures set out in Section VI of this Annex. (to be provided by the US)

SECTION VI

DESIGNATING, LISTING, SUSPENDING, WITHDRAWING AND MONITORING CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

EC access to the US market	US access to the EC market
EC Authorities identified in Section IV shall designate conformity assessment bodies located in the EC in accordance with the US legislative, regulatory, and administrative provisions identified in Section I that govern designation of conformity assessment bodies, based upon compliance with the appropriate ISO/IEC Guides (e.g. Guide 22, 25, 28, 58, 61, 62, 65, etc.) or the comparable EN-45000 Series Standards.	US Authorities identified in Section IV shall designate conformity assessment bodies located in the US in accordance with the EC legislative, regulatory, and administrative provisions identified in Section I that govern designation of conformity assessment bodies, based on compliance with the appropriate EN-45000 Series Standards or the comparable ISO/IEC Guides (e.g. Guide 22, 25, 28, 58, 61, 62, 65, etc.).
Procedures for designating, listing, suspending, withdrawing, and monitoring a conformity assessment body listed in Section V shall be undertaken pursuant to Articles 7, 8, 9, and 10 of the Agreement.	Procedures for designating, listing, suspending, withdrawing, and monitoring a conformity assessment body listed in Section V shall be undertaken pursuant to Articles 7, 8, 9, and 10 of the Agreement.

SECTION VII

ADDITIONAL PROVISIONS

1. **Sub-contracting**

1.1. Any sub-contracting by conformity assessment bodies shall be in accordance with the sub-contracting requirements of the other Party. Notwithstanding the use of sub-contracting, the final results of conformity assessment remain the full responsibility of the listed conformity assessment body. In the EC, these requirements are described in Council Directive 93/465/EEC.

1.2. The conformity assessment bodies shall record and retain details of its investigation of the competence and compliance of its sub-contractors and maintain a register of all sub-contracting. These details will be available to the other Party on request.

2. **Post-market surveillance, border measures and internal movement**

2.1. For the purpose of post-market surveillance, the Parties may maintain any existing labeling and numbering requirements. The assignment of the numbers may take place in the territory of the exporting Party. The numbers will be allocated by the importing Party. Numbering and labeling systems shall not introduce additional requirements within the meaning of this Sectoral Annex.

2.2. Nothing in this Sectoral Annex shall prevent the Parties from removing products from the market that do not in fact conform to the requirements for approval.

2.3. The Parties agree that border inspections and checks of products which have been certified, labeled or marked as conformity with the importing Party's requirements specified in Section I shall be completed as expeditiously as possible. With regard to any inspections related to internal movement within their respective territories, the Parties agree that these shall be completed in no less a favorable manner than for like domestic goods.

3. **Joint Sectoral Committee**

3.1. A combined Joint Sectoral Committee for this Sectoral Annex and the Telecommunications Equipment Sectoral Annex is hereby established (the JSC). The JSC shall operate during the

transitional period and after completion of the transitional arrangement. The JSC shall meet as appropriate to discuss technical, conformity assessment and technology issues relating to this Sectoral Annex and the Telecommunications Equipment Sectoral Annex. The JSC shall determine its own rules of procedure.

3.2. The JSC consists of representatives of the US and the EC for telecommunications and EMC. JSC representatives may each invite manufacturers and other entities as deemed necessary. The representatives for the US shall one vote in the JSC. The representatives of the EC shall have one vote in the JSC. Decisions of the JSC shall be made by unanimous consent. In the event of disagreement either the US or EC representatives may raise the matter in the Joint Committee.

3.3. The JSC may address any matter related to the effective functioning of this Sectoral Annex, including:

(a) providing a forum for discussion of issues and resolving problems that may arise concerning the implementation of this Sectoral Annex;

(b) developing a mechanism for ensuring consistency of interpretations of legislation, regulations, standards, and conformity assessment procedures;

(c) advising the Parties on matters relating to this Sectoral Annex;

(d) providing guidance and, if necessary, developing guidelines during the transitional period to facilitate the successful completion of the transitional period.

4. **Contact point**

Each Party shall establish a contact point to provide answers to all reasonable inquiries from the other Party regarding procedures, regulations and complaints under this Sectoral Annex.

5. **Regulatory changes and updating the Sectoral Annex**

In the event that there are changes to the legislative, regulatory and administrative provisions referenced in Section I or the introduction of new legislative, regulatory and administrative provisions affecting either Party's conformity assessment procedures under the Agreement, such changes shall take effect for the purpose of this Sectoral Annex at the same time they take effect domestically within the territory of each Party. The Parties shall update this Sectoral Annex to reflect the changes.

SECTION VIII

TRANSITIONAL ARRANGEMENT

1. There shall a transitional period of 24 months.

2. The purpose of this transitional arrangement is to provide a means whereby the Parties to the Agreement can build confidence in and understanding of each others system for designating and listing conformity assessment bodies and in the ability of these bodies to test and certify products. Successful completion of the transition arrangement should result in the determination that conformity assessment bodies listed in Section V comply with the applicable criteria and are competent to conduct conformity assessment activities on behalf of the other Party. Upon completion of the transition period, the results of conformity assessment procedures performed by the exporting Party's conformity assessment bodies listed in Section V shall be accepted by the importing Party.

3. This transitional period shall be used by the Parties:

(a) to consider new legislative changes needed to support the objectives of the Agreement;

(b) to initiate regulatory changes needed to support the objectives of the Agreement;

(c) to exchange information on and develop better understanding of their respective regulatory requirements;

(d) to develop mutually agreed mechanisms for exchanging information on changes in technical requirements or methods of designating conformity assessment bodies; and

(e) to monitor and evaluate the performance of the listed conformity assessment bodies during the transitional period.

4. Parties may designate, list, suspend and withdraw conformity assessment bodies during the transitional period according to the procedures in Section VI of this Sectoral Annex.

5. During the transitional period each Party shall accept and evaluate test reports and related documents issued by designated conformity assessment bodies of the other Party. To this end, the Parties shall ensure that:

(a) on receipt of test reports, related documents and a first evaluation of conformity, the dossiers are promptly examined for completeness;

(b) the applicant is informed in a precise and complete manner of any deficiency;

(c) any request for additional information is limited to omissions, inconsistencies or variances from the technical regulations or standards;

(d) procedures for assessing the conformity for equipment modified subsequent to a determination of compliance, are limited to procedures necessary to determine continued conformance.

6. Each Party ensures that issuance of approvals, certificates or advice to the applicant shall be given no later than six weeks from receipt of the test report and evaluation from a designated conformity assessment body in the territory of the other Party.

7. Any proposal made during or at the end of the transitional period to limit the scope of recognition of any designated conformity assessment body or to exclude it from the list of bodies designated under this Sectoral Annex shall be based on objective criteria and documented. Any such body may apply for reconsideration once the necessary corrective action has been taken. To the extent possible, the Parties shall implement such action prior to the expiry of the transitional period.

8. The Parties may jointly sponsor two seminars, one in the US and one in the European Community, concerning the relevant technical and product approval requirements during the first year after this Sectoral Annex enters into force.

9. Passage from the transitional phase into the operational phase in this Sectoral Annex shall take place provided that a representative number of conformity assessment bodies have been accepted for recognition under the Electrical Safety Annex.

SECTORAL ANNEX FOR ELECTRICAL SAFETY

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition between the United States and the European Community.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

US access to the EC market	EC access to the US market
Council Directive 73/23/EEC of 19 February 1973 as amended by Directive 98/13/EC of the European Parliament and of the Council.	29 USC 651 et seq. US 29 CFR 1910.7 Products that are certified or approved under the Federal Mine Safety and Health Act (30 USC 801 et seq.) or its regulations and used in areas under the authority of the Mine Safety and Health Administration, are not covered under this Annex. Occupational Safety and Health Administration (OSHA) will consider regulatory and legislative changes needed to support the objectives of the MRA.
For medical devices, see the Medical Devices Sectoral Annex to this Agreement.	For medical devices, see the Medical Devices Sectoral Annex to this Agreement.
For electromagnetic compatibility aspects, see the Electromagnetic Compatibility (EMC) Sectoral Annex to this Agreement.	For electromagnetic compatibility aspects, see the Electromagnetic Compatibility (EMC) Sectoral Annex to this Agreement.
For telecommunication equipment, see the Telecommunication Equipment Sectoral Annex to this Agreement.	For telecommunication equipment, see the Telecommunication Equipment Sectoral Annex to this Agreement.

SECTION II

SCOPE AND COVERAGE

US access to the EC market	EC access to the US market
The electrical safety requirements of products falling under the scope of Council Directive 73/23/EEC on the harmonisation of the laws of the Member States relating to electrical equipment designed or use within certain voltage limits.	The electrical safety requirements of products falling under the scope of 29 CFR 1910 subpart S. This includes the electrical safety aspects for workplace safety of medical equipment and telecommunication terminal equipment within the scope of those Sectoral Annexes. Products that are certified or approved under the Federal Mine Safety and Health Act (30 USC 801 et seq.) or its regulations and used in areas under the authority of the Mine Safety and Health Administration, are not covered under this Annex.

SECTION III

DESCRIPTION OF MUTUAL RECOGNITION OBLIGATIONS

In accordance with the provisions of the Agreement, EC conformity assessment bodies listed in Section V of this Annex shall be recognised to test, certify and mark products within the scope of their Nationally Recognised Testing Laboratory (NRTL) recognition for assessing conformity to US requirements.

With regard to US conformity assessment bodies listed in Section V of this Annex, in the event of a challenge within the European Community under Article 8(2) of Council Directive 73/23/EEC of 19 February 1973, test reports issued by such conformity assessment bodies shall be accepted by the European Community Authorities in the same way that reports from European Community notified bodies are accepted. That is, (listed conformity assessment bodies) in the US shall be recognised under Article 11 of Council Directive 73/23/EEC as 'bodies which may make a report in accordance with Article 8.'

SECTION IV

AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

EC access to the US market	US access to the EC market
— *Belgium* Ministère des Affaires Economiques Ministerie van Economische Zaken — *Denmark* Bygge- og Boligstyrelsen Danmarks Elektriske Materielkontrol (DEMKO) — *Germany* Bundesministerium für Arbeit und Sozialordnung — *Greece* Υπουργείο Ανάπτυξης Ministry of Development — *Spain* Ministerio de Industria y Energía — *France* Ministère de l'économie, des finances et de l'industrie — *Ireland* Department of Enterprise and Employment — *Italy* Ministero dell'Industria, del Commercio e dell'Artigianato — *Luxembourg* Ministère des Transports — *Netherlands* De Minister van Volksgezondheid, Welzijn en Sport	National Institute for Standards and Technology (NIST)

EC access to the US market	US access to the EC market
— *Austria* Bundesministerium für wirtschaftliche Angelegenheiten — *Portugal* Under the authority of the Government of Portugal: Instituto Português da Qualidade — *Finland* Kauppa- ja teollisuusministeriö/Handels- och industriministeriet — *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *United Kingdom* Department of Trade and Industry	

SECTION V

CONFORMITY ASSESSMENT BODIES

EC access to the US market	US access to the EC market
The names and scope of responsibilities of Conformity Assessment Bodies located in the EC and listed in accordance with this Sectoral Annex: (to the provided by the EC)	The names and scope of responsibilities of Conformity Assessment Bodies located in the US and listed in accordance with this Sectoral Annex: (to be provided by the U.S.)

SECTION VI

DESIGNATING, LISTING, SUSPENDING AND WITHDRAWING CONFORMITY ASSESSMENT BODIES

EC access to the US market	US access to the EC market
Conformity assessment bodies from the EC shall be designated by the EC Authorities identified in Section IV and recognised by the Joint Committee, in accordance with the recognition procedures in the Agreement and this Annex. Conformance with the appropriate ISO/IEC Guides or the corresponding EN-45000 series of standards shall be deemed consistent with US requirements identified in Section I.	Conformity assessment bodies from the US shall be designated by the US Authority identified in Section IV and recognised by the Joint Committee, in accordance with the recognition procedures in the Agreement and Council Directive 73/23/EEC. Conformance with the appropriate EN-45000 series of standards or the corresponding ISO/IEC Guides shall be deemed consistent with the requirements of Council Directive 73/23/EEC.

EC access to the US market	US access to the EC market
For purposes of designation and listing, EC Designating Authorities identified in Section IV shall designate conformity assessment bodies located in the EC by filing a properly prepared proposal for listing, which includes a complete lab assessment under the US OSHA procedures. OSHA shall notify the EC Designating Authority normally within 30 days as to whether the proposal is complete or whether additional information is required.	For purposes of designating and listing, the US Designating Authority identified in Section IV shall designate conformity assessment bodies located in the US by filing a properly prepared proposal for listing with the EC, which includes a complete lab assessment under the following EC or Member State procedures, as appropriate.
OSHA shall rely on the EC Designating Authorities identified in Section IV for conducting on-site reviews at the respective Member States' conformity assessment bodies.	The EC shall notify the US Designating Authority within 30 days as to whether the proposal is complete and shall indicate, where applicable, any additional information that is required.
Upon receipt of a complete proposal, the US exercising its authority under its law shall: (a) prior to the passage from the transitional phase into the operational phase in the Telecommunication Equipment and Electromagnetic Compatibility (EMC) Sectoral Annexes, give notice of its consent or objection to a proposed conformity assessment body to the Joint Committee. The listing of an agreed conformity assessment body in Section V of this Sectoral Annex shall only occur upon such passage from the transitional phase into the operational phase of those Sectoral Annexes; (b) subsequent to passage from the transitional phase into the operational phase in the Telecommunication Equipment and Electromagnetic Compatibility (EMC) Sectoral Annexes, give notice of its consent or objection to a proposed conformity assessment body to the Joint Committee normally within 120 business days. The listing of an agreed conformity assessment body in Section V of this Sectoral Annex shall occur upon notice of consent to the Joint Committee and the Joint Committee's decision to list such body. These listing procedures shall supersede the procedures in Article 7(c) of the Agreement in its entirety and the time periods set out in Article 7(d) of the Agreement.	Upon receipt of a complete proposal, the EC shall give notice of consent or objection to the Joint Committee within 60 days. The Joint Committee shall monitor the recognition of conformity assessment bodies and confirm such a recognition by listing them in Section V of this Sectoral Annex.
EC conformity assessment bodies listed in Section V shall have NRTL status in the US.	The US conformity assessment bodies listed in Section V shall have Notified Body status within the EC.

EC access to the US market	US access to the EC market
With regard to the suspension of a conformity assessment body listed in this Sectoral Annex, the period specified in Article 8(e) of the Agreement shall begin to run after a Party has notified the Joint Sectoral Committee or the Joint Committee, pursuant to Article 8(c) of the Agreement, that it proposes to revoke the conformity assessment body's recognition in accordance with its procedures under its applicable domestic law. Except as provided for in this Section, procedures for designation, listing, suspension and withdrawal of conformity assessment bodies under this Sectoral Annex shall be carried out in accordance with Articles 7, 8 and 9 of the Agreement.	

SECTION VII

JOINT SECTORAL COMMITTEE FOR ELECTRICAL SAFETY

1. The Joint Sectoral Committee for Electrical Safety (JSC/ES) consists of representatives of the US and the EC. OSHA shall represent the US on this Joint Sectoral Committee. The EC and OSHA may invite the participation of others as deemed necessary. Each Party shall have one vote and decisions shall be made by unanimous consent, unless otherwise specified herein. The Joint Sectoral Committee shall determine its own rules of procedure.

2. The Joint Committee may address any matter related to the effective functioning of this Sectoral Annex, including:

   — developing improved procedures and criteria for designation in order to facilitate the assessment and preparation of proposals by Designating Authorities, with a view towards expediting the period between designation and listing;

   — providing a forum for discussion of issues that may arise concerning the implementation of this Sectoral Annex;

   — advising the Parties on matters relating to this Sectoral Annex; and

   — enhancing the operation of this Sectoral Annex.

SECTORAL ANNEX FOR RECREATIONAL CRAFT

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition between the United States and the European Community.

The purpose of this Sectoral Annex is to establish a framework to accept certificates of conformity issued in the territory of one Party in accordance with the regulatory requirements of the other Party as referenced in this Sectoral Annex.

To facilitate that purpose, a transitional period of 18 months is arranged to build confidence as defined in this Sectoral Annex, Section VI.

SECTION I

LEGISLATIVE, REGULATORY, AND ADMINISTRATIVE REQUIREMENTS

1. For the European Community:

   Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations, and administrative provisions of the Member States relating to recreational craft.

2. For the US:

   46 USC Chapter 43, 33 CFR 81, 84, 159, 179, 181, 183 and 46 CFR 58.

SECTION II

SCOPE AND COVERAGE

1. This Sectoral Annex applies to all recreational craft which in the European Community or the United States are subject to conformity assessment by a conformity assessment body or an approval procedure, as applicable, before being put on the market.

2. The product coverage for each Party shall be determined by the following relevant requirements:

   (a) for the European Community:

   Recreational craft as defined in Directive 94/25/EC;

   (b) for the United States:

   Any product falling under the scope of 46 USC Chapter 43, 33 CFR 81, 84, 159, 179, 181, 183 and 46 CFR 58.

3. The Parties agree that for mutual recognition to operate under this Sectoral Annex, the following arrangements shall apply:

   (a) for approvals to European Community requirements, conformity assessment bodies designated by the US shall establish compliance as required to be demonstrated by Directive 94/25/EC. This demonstration of compliance shall be recognised in the European Community and products so certified shall have unrestricted access to the EC market for sale as recreational craft, pursuant to Section I;

   (b) for approvals to United States requirements, conformity assessment bodies designated by the European Community shall establish compliance as required to be demonstrated as set forth in paragraph 2(b) of this Section, and products so certified shall have unrestricted access to the US market for sale as recreational craft, pursuant to Section I.

SECTION III

AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES

EC access to the US market	US access to the EC market
— *Belgium* Ministère des Communications et de l'infrastructure Ministerie van Verkeer en Infrastructuur — *Germany* Bundesministerium für Wirtschaft — *Spain* Ministerio de Fomento — *France* Ministère de l'Equipment, des Transports et du Logement — *Italy* Ministero dell'Industria, del Commercio e dell'Artigianato — *Netherlands* De Minister van Verkeer en Waterstaat — *Finland* Merenkulkuhallitus/sjöfartsstyrelsen — *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *United Kingdom* Department of Trade and Industry	National Institute for Standards and Technology (NIST)

SECTION IV

DESIGNATING, LISTING, SUSPENDING AND WITHDRAWING CONFORMITY ASSESSMENT BODIES

1. For the purpose of this Sectoral Annex, each Party shall designate competent conformity assessment bodies to carry out conformity assessment and approval to the requirements of the other Party. Such designation shall be carried out according to the procedures set out in Article 7 of the Agreement. A list of conformity assessment bodies together with the products and procedures for which they have been listed, is set out in Section V below.

2. Each Party agrees that the listed conformity assessment bodies comply with the requirements for such bodies established by the other Party. These are:

   (a) for the European Community, bodies which are Notified Bodies in accordance with Directive 94/25/EC, are deemed to be in compliance with US requirements;

   (b) for the US, in accordance with the requirements set out in the regulations listed in Section I, the conformity assessment bodies listed in Section V are designated by NIST using the evaluation procedures contained in the appropriate EN-45000 series of standards or the corresponding ISO/IEC Guides.

3. With regard to the designation, listing, suspension and withdrawal of conformity assessment bodies under this Sectoral Annex, the specific procedures in Articles 7, 8 and 9 of the Agreement shall be followed.

SECTION V

CONFORMITY ASSESSMENT BODIES

EC access to the US market	US access to the EC market
The names and scope of responsibilities of Conformity Assessment Bodies located in the EC and listed in accordance with this Sectoral Annex: (to be provided by EC)	The names and scope of responsibilities of Conformity Assessment Bodies located in the US and listed in accordance with this Sectoral Annex: (to be provided by the US)

SECTION VI

TRANSITIONAL ARRANGEMENT

1. There shall be a transitional period of 18 months prior to the operations of this Sectoral Annex.

2. The purpose of the transitional arrangement is to provide a mean whereby the Parties to this Agreement can cooperate to establish a system for designating conformity assessment bodies and can mutually build confidence in the abilities of these bodies. Successful completion of this transitional arrangement is intended to result in a determination that conformity assessment bodies comply with the applicable criteria and to have the equipment approved by the conformity assessment bodies of the exporting country accepted by the approval authority of the importing country.

3. During this transitional period, the parties shall:

   (a) exchange information on technical data and conformity assessment criteria and procedures, thus developing greater familiarity with their respective regulatory requirements; and

   (b) carry out or recommend any applicable policy, legislative and regulatory changes necessary for the provisions of this Annex.

4. *Product Scope*

   All products covered by Section II of this Annex.

5. *Cooperation*

   During this transitional period, both Parties shall endeavour to sponsor jointly seminars for the purpose of improving the understanding of technical specifications applicable in each Party's jurisdiction.

6. *Inspections*

   Inspections or audits shall be permitted to verify compliance of conformity assessment bodies with their responsibilities under this Agreement. The scope of these inspections or audits shall be agreed upon in advance by both Parties.

SECTION VII

ADDITIONAL PROVISIONS

1. In accordance with the relevant provisions of the Agreement, the Parties shall ensure the continued availability of the names of their respective notified bodies or conformity assessment bodies, and shall regularly supply details of certifications issued in order to facilitate post market surveillance.

2. The Parties note that, to the extent that requirements for electrical safety or electromagnetic compatibility may apply to products covered by this Sectoral Annex, the provisions of the Sectoral Annexes on Electrical Safety and Electromagnetic Compatibility apply.

SECTION VIII

DEFINITIONS

'Notified Body' means a third party authorised to perform the conformity assessment tasks specified in Directive 94/25/EC, which has been appointed by a Member State from the bodies falling within its jurisdiction. The Notified Body has the necessary qualifications to meet requirements laid down in Directive 94/25/EC and has been notified to the Commission and to the other Member States.

SECTORAL ANNEX FOR PHARMACEUTICAL GOOD MANUFACTURING PRACTICES (GMPs)

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition between the United States and the European Community.

CHAPTER 1

DEFINITIONS, PURPOSE, SCOPE AND COVERAGE

Article 1

Definitions

1. 'Equivalence' of the regulatory systems means that the systems are sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. 'Equivalence' does not require that the respective regulatory systems have identical procedures.

2. 'Enforcement' means action taken by an authority to protect the public from products of suspect quality, safety and efficacy or to assure that products are manufactured in compliance with appropriate law, regulations, standards and commitments made as part of the approval to market a product.

3. 'Good Manufacturing Practices' (GMPs): (The US and EC have agreed to revisit these concepts)

GMPs mean the requirements found in the respective legislations, 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.

GMPs are that part of quality assurance which ensures that products are consistently produced and controlled to quality standards. For the purpose of this Annex, GMPs include therefore the system whereby the manufacturer receives the specifications of the product 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 in the EC).

4. 'Inspection' means an on-site evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with Good Manufacturing Practices and/or commitments made as part of the approval to market a product.

5. 'Inspection Report' means the written observations and Good Manufacturing Practices compliance assessment completed by an authority listed in Appendix 2.

6. 'Regulatory System' means the body of legal requirements for Good Manufacturing Practices, inspections, and enforcements that ensure public health protection and legal authority to assure adherence to these requirements.

Article 2

Purpose

The provisions of this Annex govern the exchange between the Parties and normal endorsement by the receiving authority of official Good Manufacturing Practices (GMPs) inspection reports after a transitional period aimed at determination of the equivalence of the regulatory systems of the Parties, which is the cornerstone of this Annex.

Article 3

Scope

The provisions of this Annex shall apply to pharmaceutical inspections carried out in the United States and Member States of the European Community before products are marketed (hereafter referred to as 'pre-approval inspections' as well as during their marketing (hereafter referred to as 'post-approval inspections').

Appendix 1 names the laws, regulations and administrative provisions governing these inspections and the GMPs requirements.

Appendix 2 lists the authorities participating in activities under this Annex.

Articles 6, 7, 8, 9, 10 and 11 of the Agreement do not apply to this Annex.

Article 4

Product coverage

These provisions will apply to medicinal products for human or animal use, intermediates and starting materials (as referred to in the EC) and to drugs for human or animal use, biological products for human use, and active pharmaceutical ingredients (as referred to in the United States), only to the extent they are regulated by the authorities of both Parties as listed in Appendix 2.

Human blood, human plasma, human tissues and organs, and veterinary immunologicals are excluded from the scope of this Annex. Human plasma derivatives (such as immunoglobulins and albumin), investigational medicinal products/new drugs, human radiopharmaceuticals and medicinal gases are also excluded during the transition phase, their situation will be reconsidered at the end of the transition period. Products regulated by the Center for Biologics Evaluation and Research as devices are not covered under this Annex.

Appendix 3 contains an indicative list of products covered by this Annex.

CHAPTER 2

TRANSITION PERIOD

Article 5

Length of transition period

A three-year transition period will start immediately after the effective date of the Agreement.

Article 6

Equivalence assessment

1. The criteria to be used by the Parties to assess equivalence are listed in Appendix 4. Information pertaining to the criteria under Community competence will be provided by the Community.

2. The authorities of the parties will establish and communicate to each other their draft programmes for assessing the equivalence of the respective regulatory systems in terms of quality assurance of the products and consumer protection. These programmes will be carried out, as deemed necessary by the authorities, for post- and pre-approval inspections and for various product classes or processes.

3. The equivalence assessment shall include information exchanges (including inspection reports), joint training, and joint inspections for the purpose of assessing regulatory systems and the authorities' capabilities. In conducting the equivalence assessment, the Parties will ensure that efforts are made to save resources.

4. Equivalence assessment for authorities added to Appendix 2 after the effective date of this agreement will be conducted as described in this Annex, as soon as practicable.

Article 7

Participation in the equivalence assessment and determination

The authorities listed in Appendix 2 will actively participate in these programs to build a sufficient body of evidence for their equivalence determination. Both parties will exercise good faith efforts to complete equivalence assessment as expeditiously as possible to the extent the resources of the authorities allow.

Article 8

Other transition activities

As soon as possible, the authorities will jointly determine the essential information which must be present in inspection reports and will cooperate to develop mutually agreed inspection report format(s).

CHAPTER 3

END OF TRANSITION PERIOD

Article 9

Equivalence determination

Equivalence is established by having in place regulatory systems covering the criteria referred to in Appendix 4, and a demonstrated pattern of consistent performance in accordance with these criteria. A list of authorities determined as equivalent shall be agreed to by the Joint Sectoral Committee at the end of the transition period, with reference to any limitation in terms of inspection type (e. g. post-approval or pre-approval) or product classes or processes.

The Parties will document insufficient evidence of equivalence lack of opportunity to assess equivalence or a determination of non-equivalence, in sufficient detail to allow the authority being assessed to know how to attain equivalence.

Article 10

Authorities not currently listed as equivalent

Authorities not currently listed as equivalent, or not equivalent for certain types of inspections, product classes or processes may apply for reconsideration of their status once the necessary corrective measures have been taken or additional experience is gained.

CHAPTER 4

OPERATIONAL PERIOD

Article 11

Start of the operational period

The operational period shall start at the end of the transition period and its provisions apply to inspection reports generated by authorities listed as equivalent for the inspections performed in their territory.

In addition, when an authority is not listed as equivalent based on adequate experience gained during the transition period, the Food and Drug Administration (FDA) will accept for normal endorsement (as provided in Article 12) inspection reports generated as a result of inspections conducted jointly by that authority on its territory and another authority listed as equivalent, provided that the authority of the Member State in which the inspection is performed can guarantee enforcement of the findings of the inspection report and require that corrective measures be taken when necessary. FDA has the option to participate in these inspections, and based on experience gained during the transition period, the Parties will agree on procedures for exercising this option.

In the EC, the qualified person will be relieved of responsibility for carrying out the controls laid down in Article 22 paragraph 1(b) of Council Directive 75/319/EEC provided that these controls have been carried out in the United States and that each batch/lot is accompanied by a batch certificate (in accordance with the WHO certification scheme on the quality of medicinal products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorisation and signed by the person responsible for releasing the batch/lot.

Article 12

Nature of recognition of inspection reports

Inspection reports (containing information as established under Article 8), including a GMP compliance assessment, prepared by authorities listed as equivalent, will be provided to the authority of the importing Party. Based on the determination of equivalence in light of the experience gained, these inspection reports will normally be endorsed by the authority of the importing Party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in an inspection report, quality defects identified in the post-market surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the authority of the importing Party may request clarification from the authority of the exporting Party which may lead to a request for re-inspection. The authorities will endeavour to respond to requests for clarification in a timely manner.

Where divergence is not clarified in this process, an authority of the importing country may carry out an inspection of the production facility.

Article 13

Transmission of post-approval inspection reports

Post-approval GMP inspection reports concerning products covered by this Annex will be transmitted to the authority of the importing country within 60 calendar days of the request. Should a new inspection be needed, the inspection report will be transmitted within 90 calendar days of the request.

Article 14

Transmission of pre-approval inspection reports

A preliminary notification that an inspection may have to take place will be made as soon as possible.

Within 15 calendar days, the relevant authority will acknowledge receipt of the request and confirm its ability to carry out the inspection. In the EC, requests will be sent directly to the relevant authority, with a copy to the European Agency for the Evaluation of Medicinal Products (EMEA). If the authority receiving the request cannot carry out the inspection as requested, the requesting authority shall have the right to conduct the inspection.

Reports of pre-approval inspections will be sent within 45 calendar days of the request that transmitted the appropriate information and detailed the precise issued to be addressed during the inspection. A shorter time may be necessary in exceptional cases and these will be described in the request.

Article 15

Monitoring continued equivalence

Monitoring activities for the purpose of maintaining equivalence shall include review of the exchange of inspection reports and their quality and timeliness; performance of a limited number of joint inspections and the conduct of common training sessions.

Article 16

Suspension

Each Party has the right to contest the equivalence of an authority. This right will be exercised in an objective and reasoned manner in writing to the other Party. The issue shall be discussed in the Joint Sectoral Committee promptly upon such notification. Where the JSC determines that verification of equivalence is required, it may be carried out jointly by the Parties in a timely manner, pursuant to Article 6.

Efforts will be made by the Joint Sectoral Committee to reach unanimous consent on the appropriate action. If agreement to suspend is reached in the Joint Sectoral Committee, an authority may be suspended immediately thereafter. If no agreement is reached in the Joint Sectoral Committee, the matter is referred to the Joint Committee. If no unanimous consent is reached within 30 days after such notification, the contested authority will be suspended.

Upon the suspension of an authority previously listed as equivalent, a Party is no longer obligated to endorse normally the inspection reports of the suspended authority. A Party shall continue to endorse normally the inspection reports of that authority prior to suspension, unless the authority of the receiving party decides otherwise based on health or safety considerations. The suspension will remain in effect until unanimous consent has been reached by the Parties on the future status of that authority.

CHAPTER 5

JOINT SECTORAL COMMITTEE

Article 17

Role and composition of the Joint Sectoral Committee

A Joint Sectoral Committee is set up to monitor the activities under both the transitional and operational phases of this Annex.

The Committee will be co-chaired by a representative of FDA for the U.S. and a representative of the EC who each will have one vote. Decisions will be taken by unanimous consent.

The Joint Sectoral Committee's functions will include:

1. making a joint assessment, which must be agreed by both Parties, of the equivalence of the respective authorities;

2. developing and maintaining the list of equivalent authorities, including any limitation in terms of inspecting type or products, and communicating the list to all authorities and the Joint Committee;

3. providing a forum to discuss issues relating to this Annex, including concerns that an authority may be no longer equivalent and opportunity to review product coverage;

4. consideration of the issue of suspension.

The Joint Sectoral Committee shall meet at the request of either Party and, unless the co-chairs otherwise agree, at least once each year. The Joint Committee will be kept informed of the agenda and conclusions of meetings of the Joint Sectoral Committee.

CHAPTER 6

INFORMATION EXCHANGE

Article 18

Regulatory collaboration

The Parties and authorities shall inform and consult one another, as permitted by law, on proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

The Parties shall notify each other in writing of any changes to Appendix 2.

Article 19

Information relating to quality aspects

The authorities will establish an appropriate means of exchanging information on any confirmed problem reports, corrective actions, recalls, rejected import consignments and other regulatory and enforcement problems for products subject to this Annex.

Article 20

Alert System

The details of an alert system will be developed during the transitional period. The system will be maintained in place at all times. Elements to be considered in developing such a system are described in Appendix 5.

Contact points will be agreed between both Parties to permit authorities to be made aware with the appropriate speed in case of quality defect, recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

CHAPTER 7

SAFEGUARD CLAUSE

Article 21

Each Party recognises that the importing country has a right to fulfil its legal responsibilities by taking actions necessary to ensure the protection of human and animal health at the level of protection it deems appropriate. This includes the suspension of the distribution, product detention at the border of the importing country, withdrawal of the batches and any request for additional information or inspection as provided in Article 12.

Appendix 1

List of applicable laws, regulations and administrative provisions

For the European Community:

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, as extended, widened and amended.

Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, as extended, widened and amended.

Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, as widened and amended.

Council Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.

Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use.

Guide to Good Distribution Practice (94/C 63/03).

Current version of the Guide to Good Manufacturing Practice, Rules Governing Medicinal Products in the European Community, Volume IV.

For the United States:

Relevant sections of the United States Federal Food, Drug, and Cosmetic Act and the United States Public Health Service Act.

Relevant sections of Title 21, United States Code of Federal Regulations (CFR) Parts 1-99, Parts 200-299, Parts 500-599, and Parts 600-799.

Relevant sections of the FDA Investigations Operations Manual, the FDA Regulatory Procedures Manual, the FDA Compliance Policy Guidance Manual, the FDA Compliance Program Guidance Manual, and other FDA guidances.

Appendix 2

List of Authorities

UNITED STATES:

In the United States, the regulatory authority is the Food and Drug Administration.

EUROPEAN COMMUNITY:

In the European Community, the regulatory authorities are the following:

BELGIUM	Inspection générale de la Pharmacie Algemene Farmaceutische Inspectie
DENMARK	Lægemiddelstyrelsen
GERMANY	Bundesministerium für Gesundheit
GREECE	Εθνικός Οργανισμός Φαρμάκου Ministry of Health and Welfare National Drug Organization (E.O.F)
SPAIN	for medicinal products for human use: Ministerio de Sanidad y Consumo Subdirección General de Control Farmacéutico for medicinal products for veterinary use: Ministerio de Agricultura, Pesca y Alimentación (MAPA) Dirección General de la Producción Agraria
FRANCE	for medicinal products for human use: Agence du Médicament for veterinary medicinal products: Agence Nationale du Médicament Vétérinaire
IRELAND	Irish Medicines Board
ITALY	for medicinal products for human use: Ministero della Sanità Dipartimento Farmaci e Farmacovigilanza for medicinal products for veterinary use: Ministero della Sanità Dipartimento alimenti e nutrizione e sanità pubblica veterinaria — Div. IX
LUXEMBOURG	Division de la Pharmacie et des Médicaments
NETHERLANDS	Staat der Nederlanden
AUSTRIA	Bundesministerium für Arbeit, Gesundheit und Soziales

PORTUGAL	for human and veterinary (non-immunologicals): Instituto da Farmácia e do Medicamento — INFARMED for veterinary immunologicals: Direcção — Geral de Veterinaria
FINLAND	Lääkelaitos/Läkemedelsverket (National Agency for Medicines)
SWEDEN	Läkemedelsverket — Medical Products Agency
UNITED KINGDOM	for human and veterinary (non-immunologicals): Medicines Control Agency for veterinary immunologicals: Veterinary Medicines Directorate
EUROPEAN COMMUNITY	Commission of the European Communities European Agency for the Evaluation of Medicinal Products (EMEA)

Appendix 3

Indicative list of Products covered by the Sectoral Annex

Recognising that precise definitions of medicinal products and drugs are to be found in the legislation referred to above, an indicative list of products covered by the agreement is given below:

— human medicinal products including prescription and non-prescription drugs,

— human biologicals including vaccines, and immunologicals,

— veterinary pharmaceuticals, including prescription and non-prescription drugs, with the exclusion of veterinary immunologicals,

— pre-mixes for the preparation of veterinary medicated feeds (EC), Type A medicated articles for the preparation of veterinary medicated feeds (US),

— intermediate products and active pharmaceutical ingredients or bulk pharmaceuticals (US)/starting materials (EC).

Appendix 4

Criteria for Assessing Equivalence for Post- and Pre-Approval

I. Legal/Regulatory authority and structures and procedures providing for post- and pre-approval:

A. Appropriate statutory mandate and jurisdiction.

B. Ability to issue and update binding requirements and GMPs and guidance documents.

C. Authority to make inspections, review and copy documents, and to take samples and collect other evidence.

D. Ability to enforce requirements and to remove products found in violation of such requirements from the market.

E. Substantive current good manufacturing requirements.

F. Accountability of the regulatory authority.

G. Inventory of current products and manufacturers.

H. System for maintaining or accessing inspection reports, samples and other analytical data, and other firm/product information relating to matters covered by this Sectoral Annex.

II. Mechanisms in place to assure appropriate professional standards and avoidance of conflicts of interest.

III. Administration of the regulatory authority:

A. Standards of education/qualification and training.

B. Effective quality assurance systems measures to ensure adequate job performance.

C. Appropriate staffing and resources to enforce laws and regulations.

IV. Conduct of Inspections:

A. Adequate pre-inspection preparation, including appropriate expertise of investigator/team, review of firm/product and databases, and availability of appropriate inspection equipment.

B. Adequate conduct of inspection, including statutory access to facilities, effective response to refusals, depth and competence of evaluation of operations, systems and documentation; collection of evidence; appropriate duration of inspection and completeness of written report of observations to firm management.

C. Adequate post-inspection activities, including completeness of inspectors' report, inspection report review where appropriate, and conduct of follow-up inspections and other activities where appropriate, assurance of preservation and retrieval of records.

V. Execution of regulatory enforcement actions to achieve corrections, designed to prevent future violations, and to remove products found in violation of requirements from the market.

VI. Effective Use of Surveillance Systems:

A. Sampling and analysis.

B. Recall monitoring.

C. Product defect reporting system.

D. Routine surveillance inspections.

E. Verification of approved manufacturing process changes to marketing authorisations/approved applications.

VII. Additional specific criteria for pre-approval inspections

A. Satisfactory demonstration through a jointly developed and administered training program and joint inspections to assess the authorities' capabilities.

B. Pre-inspection preparation includes the review of appropriate records, including site plans and drug master file or similar documentation to enable adequate inspections.

C. Ability to verify chemistry, manufacturing and control data supporting an application is authentic and complete.

D. Ability to access and evaluate research and development data as scientifically sound, especially transfer technology of pilot, scale up and full scale production batches.

E. Ability to verify conformity of the on site processes and procedures with those described in the application.

F. Review and evaluate equipment installation, operational and performance qualification data, and evaluate test method validation.

Appendix 5

Elements to be Considered in Developing a Two-way Alert System

1. *Documentation*
   - — Defintion of a crisis/emergency and under what circumstances an alert is required,
   - — Standard Operating Procedures (SOPs),
   - — Mechanism of health hazards evaluation and classification,
   - — Language of communication and transmission of information.

2. *Crisis Management System*
   - — Crisis analysis and communication mechanisms,
   - — Establishment of contact points,
   - — Reporting mechanisms.

3. *Enforcement Procedures*
   - — Follow-up mechanisms,
   - — Corrective action procedures.

4. *Quality Assurance System*
   - — Pharmacovigilance programme,
   - — Surveillance/monitoring of implementation of corrective action.

5. *Contact points*

   For the purpose of this agreement, the contact points for the alert system will be:

   for the European Community:

   the Executive Director of the European Agency for the Evaluation of Medicinal Products,
   7, Westferry Circus,
   Canary Wharf
   UK - London E14 4HB,
   England.
   Telephone +44- 171- 418 8400,
   Fax 418 8416.

   for the United States:

   (to be provided by the U.S.)

SECTORAL ANNEX ON MEDICAL DEVICES

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition in Regulation to Conformity Assessment between the United States and the European Community.

Carrying out the provisions of this Annex will further public health protection, will be an important means of facilitating commerce in medical devices and will lead to reduced costs for regulators and manufacturers of both Parties.

CHAPTER 1

PURPOSE, SCOPE AND COVERAGE OF THE SECTORAL ANNEX

Article 1

Purpose

1. The purpose of this Annex is to specify the conditions under which a Party will accept the results of quality system-related evaluations and inspections and premarket evaluations of the other Party with regard to medical devices as conducted by listed conformity assessment bodies (CABs) and to provide for other related cooperative activities.

2. This Annex is intended to evolve as programmes and policies of the Parties evolve. The Parties will review this Annex periodically, in order to assess progress and identify potential enhancements to this Annex as Food and Drug Administration (FDA) and EC policies evolve over time.

Article 2

Scope

1. The provisions of this Annex shall apply to the exchange and, where appropriate, endorsement of the following types of reports from CABs assessed to be equivalent:

(a) under the US system, surveillance/post-market and initial/pre-approval inspection reports;

(b) under the US system, premarket (510(k)) product evaluation reports;

(c) under the EC system, quality system evaluation reports; and

(d) under the EC system, EC type examination and verification reports.

Appendix 1 names the legislation, regulations, and related procedures under which:

(a) products are regulated as medical devices by each Party;

(b) CABs are designated and confirmed; and

(c) these reports are prepared.

2. For purposes of this Annex, equivalence means that: CABs in the EC are capable of conducting product and quality systems evaluations against US regulatory requirements in a manner equivalent to those conducted by FDA; and CABs in the US are capable of conducting product and quality systems evaluations against EC regulatory requirements in a manner equivalent to those conducted by EC CABs.

Article 3

Product Coverage

There are three components to this agreement each covering a discrete range of products:

1. *Quality System Evaluations* — US-type surveillance/post-market and initial/pre-approval inspection reports and EC-type quality system evaluation reports will be exchanged with regard to all products regulated under both US and EC law as medical devices.

2. *Product Evaluation* — US-type premarket (510(k)) product evaluation reports and EC-type-testing reports will be exchanged only with regard to those products classified under the US system as Class I/Class II — Tier 2 medical devices which are listed in Appendix 2.

3. *Post-Market Vigilance Reports* — Post-market vigilance reports will be exchanged with regard to all products regulated under both US and EC law as medical devices.

Additional products and procedures may be made subject to this Annex by agreement of the Parties.

Article 4

Regulatory Authorities

The regulatory authorities shall have the responsibility of implementing the provisions of this Annex, including the designation and monitoring of CABs. Regulatory authorities are specified in Appendix 3. Each Party will promptly notify the other Party in writing of any change in the regulatory authority for a country.

CHAPTER 2

TRANSITION PERIOD

Article 5

Length and purpose of transition period

There will be a three-year transition period immediately following the date of entry into force of the Agreement. During the transition period, the Parties will engage in confidence-building activities for the purpose of obtaining sufficient evidence to make determinations concerning the equivalence of CABs of the other Party with respect to the ability to perform quality system and product evaluations or other reviews resulting in reports to be exchanged under this Annex.

Article 6

Listing of CABs

Each Party shall designate CABs to participate in confidence-building activities by transmitting to the other Party a list of CABs which meet the criteria for technical competence and independence, as identified in Appendix 1. The list shall be accompanied by supporting evidence. Designated CABs will be listed in Appendix 4 for participation in the confidence building activities once confirmed by the importing Party. Non-confirmation would have to be justified based on documented evidence.

Article 7

Confidence Building Activities

1. At the beginning of the transitional period, the Joint Sectoral Group will establish a joint confidence building programme calculated to provide sufficient evidence of the capabilities of the designated CABs to perform quality system or product evaluations to the specifications of the Parties.

2. The joint confidence building program should include the following actions and activities:

(a) seminars designed to inform the Parties and CABs about each Party's regulatory system, procedures, and requirements;

(b) workshops designed to provide the Parties with information regarding requirements and procedures for the designation and surveillance of CABs;

(c) exchange of information about reports prepared during the transition period;

(d) joint training exercises; and

(e) observed inspections.

3. During the transition period, any significant problem that is identified with a CAB may be the subject of cooperative activities, as resources allow and as agreed to by the regulatory authorities, aimed at resolving the problem.

4. Both Parties will exercise good faith efforts to complete the confidence building activities as expeditiously as possible to the extent that the resources of the Parties allow.

5. Both the EC and the US will each prepare annual progress reports which will describe the confidence building activities undertaken during each year of the transition period. The form and content of the reports will be determined by the Parties through the Joint Sectoral Committee.

Article 8

Other transition period activities

1. During the transition period, the Parties will jointly determine the necessary information which must be present in quality system and product evaluation reports.

2. The Parties will jointly develop a notification and alert system to be used in case of defects, recalls, and other problems concerning product quality that could necessitate additional actions (e.g., inspections by the Parties of the importing country) or suspension of the distribution of the product.

CHAPTER 3

END OF TRANSITION PERIOD

Article 9

Equivalence Assessment

1. In the final six months of the transition period, the Parties shall proceed to a joint assessment of the equivalence of the CABs that participated in the confidence building activities. CABs will be determined to be equivalent provided they have demonstrated proficiency through the submission of a sufficient number of adequate reports. CABs may be determined to be equivalent with regard to the ability to perform any type of quality system or product evaluation covered by this Annex and with regard to any type of product covered by this Annex. The parties shall develop a list contained in Appendix 5 of CABs determined to be equivalent which shall contain a full explanation of the scope of the equivalency determination, including any appropriate limitations, with regard to performing any type of quality system or product evaluation.

2. The Parties shall allow CABs not listed for participation in the MRA, or listed for participation only as to certain types of evaluations, to apply for participation in this MRA once the necessary measures have been taken or sufficient experience has been gained, in accordance with Article 16.

3. Decisions concerning the equivalence of CABs must be agreed to by both Parties.

CHAPTER 4

OPERATIONAL PERIOD

Article 10

Start of the operational period

1. The operational period will start at the end of the transition period after the Parties have developed the list of CABs found to be equivalent. The provisions of this Chapter will apply only with regard to listed CABs and only to the extent of any specifications and limitations contained on the list with regard to a CAB.

2. The operational period will apply to quality system evaluation reports and product evaluation reports generated by CABs listed in accordance with this Annex for the evaluations performed in the respective territories of the Parties, except if the Parties agree otherwise.

Article 11

Exchange and endorsement of quality system evaluation reports

1. Listed EC CABs will provide FDA with reports of quality system evaluations, as follows:

(a) for pre-approval quality system evaluations, EC CABs will provide full reports; and

(b) for surveillance quality system evaluations, EC CABs will provide abbreviated reports.

2. Listed US CABs will provide to the EC Notified Body of the manufacturer's choice:

(a) full reports of initial quality system evaluations;

(b) abbreviated reports of quality systems surveillance audits.

3. If the abbreviated reports do not provide sufficient information, the importing Party may request additional clarification from the CAB.

4. Based on the determination of equivalence in light of the experience gained, the quality system evaluation reports prepared by the CABs listed as equivalent will normally be endorsed by the importing Party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in a report, quality defects identified in post-market surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the importing Party may request clarification from the exporting Party which may lead to a request for re-inspection. The Parties will endeavour to respond to requests for clarification in a timely manner. Where divergence is not clarified in this process, the importing Party may carry out the quality system evaluation.

Article 12

Exchange and endorsement of product evaluation reports

1. EC CABs listed for this purpose will, subject to the specifications and limitations on the list, provide to the FDA 510(k) premarket notification assessment reports prepared to US medical device requirements.

2. US CABs will, subject to the specifications and limitations on the list, provide to the EC notified body of the manufacturer's choice, type examination and verification reports prepared to EC medical device requirements.

3. Based on the determination of equivalence in light of the experience gained, the product evaluation reports prepared by the CABs listed as equivalent will normally be endorsed by the importing Party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies, inadequacies, or incompleteness in a product evaluation report, or other specific evidence of serious concern in relation to product safety, performance, or quality. In such cases, the importing Party my request clarification from the exporting Party which may lead to a request for a re-evaluation. The parties will endeavour to respond to requests for clarification in timely manner. Endorsement remains the responsibility of the importing Party.

Article 13

Transmission of quality system evaluation reports

Quality system evaluation reports covered by Article 11 concerning products covered by this Annex shall be transmitted to the importing Party within 60 calendar days of a request by the importing Party. Should a new inspection be requested the time period shall be extended by an additional 30 calendar days. A Party may request a new inspection, for cause, identified to the other Party. If the exporting Party cannot perform an inspection within a specified period time, the importing Party may perform an inspection on its own.

Article 14

Transmission of product evaluation reports

Transmission of product evaluation reports will take place according to the importing Party's specified procedures.

Article 15

Monitoring continued equivalence

Monitoring activities will be carried out in accordance with Article 10 of the Agreement.

Article 16

Listing of Additional CABs

1. During the operational period, additional CABs will be considered for equivalence using the procedures and criteria described in Articles 6, 7, and 9 of this Annex, taking into account the level of confidence gained in the overall regulatory system of the other Party.

2. Once a designating authority considers that such CABs, having undergone the procedures of Articles 6, 7, and 9 of this Annex, may be determined to be equivalent, it will then designate those bodies on an annual basis. Such procedures satisfy the procedures of Articles 7(a) and (b) of the Agreement.

3. Following such annual designations, the procedures for confirmation of CABs under Articles 7(c) and (d) of the Agreement shall apply.

CHAPTER 5

JOINT SPECIAL COMMITTEE

Article 17

Role and composition of the Joint Sectoral Committee

1. A Joint Sectoral Management Committee is set up to monitor the activities under both the transitional and operational phases of this Annex.

2. The Committee will be co-chaired by a representative of the FDA for the US and a representative of the EC who will each have one vote. Decisions will be taken by unanimous consent.

3. The JSC's functions will include:

(a) making a joint assessment of the equivalent of CABs;

(b) developing and maintaining the list of equivalent CABs, including any limitation in terms of their scope of activities and communicating the list of all authorities and the Joint Committee;

(c) providing a forum to discuss issues relating to this Annex, including concerns that a CAB may no longer be equivalent and opportunity to review product coverage; and

(d) consideration of the issue of suspension.

CHAPTER 6

HARMONISATION AND INFORMATION EXCHANGE

Article 18

Harmonisation

During both the transitional and operational phases of this Agreement, both Parties intend to continue to participate in the activities of the Global Harmonisation Task Force and utilise the results of those activities to the extent possible. Such participation involves developing and reviewing documents developed by the Global Harmonisation Task Force and jointly determining whether they are applicable to the implementation of this Agreement.

Article 19

Regulatory cooperation

The Parties and authorities shall inform one another, as permitted by law, of, and consult one another on, proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

The Parties shall notify each other in writing of any changes to Appendix 1.

Article 20

Alert system and exchange of post-market vigilance reports

1. An alert system will be set up during the transition period and maintained thereafter by which the Parties will notify each other when there is an immediate danger to public health. Elements of such a system will be described in an Appendix to be attached to this Sectoral Annex. As part of that system, each Party shall notify the other Party of any confirmed problem reports, corrective actions, or recalls. These reports are regarded as part of ongoing investigations.

2. Contact points will be agreed between both Parties to permit authorities to be made aware with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

Appendix 1

Relevant legislation, regulations and procedures

1. For the European Community the following legislation applies to Article 2(1):

   (a) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices. Conformity assessment procedures.

   — Annex II (with the exception of section 4),

   — Annex IV,

   — Annex V;

   (b) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Conformity assessment procedures.

   — Annex II (with the exception of section 4),

   — Annex III,

   — Annex IV,

   — Annex V,

   — Annex VI.

2. For the United States, the following legislation applies to Article 2(1):

   (a) The Federal Food, Drug and Cosmetic Act, 21. U.S.C. §§ 321 *et seq*.;

   (b) The Public Health Service Act, 42 U.S.C. §§ 201 *et seq*.;

   (c) Regulations of the United States Food and Drug Administration found at 21 C.F.R., in particular, Parts 800 to 1299;

   (d) Medical Devices; Third-Party Review of Selected Premarket Notifications; Pilot Program, 61 Fed. Reg. 14,789-14,796 (April 3, 1996).

Appendix 2

Scope of product coverage

1. Initial Coverage of the Transition Period:

   Upon entry into force of this Annex [1], products qualifying for the transitional arrangements under this Agreement include:

   (a) all Class I products requiring premarket evaluations in the United States — see Table 1;

   (b) those Class II products listed in Table 2.

2. During the transition period:

   The Parties will jointly identify additional product groups, including their related accessories, in line with their respective priorities as follows:

   (a) those for which review may be based primarily on written guidance which the Parties will use their best efforts to prepare expeditiously; and

   (b) those for which review may be based primarily on international standards, in order for the Parties to gain the requisite experience.

   The corresponding additional product lists will be phased in on an annual basis. The Parties may consult with industry and other interested Parties in determining which products will be added.

3. Commencement of the Operational Period:

   (a) at the commencement of the operational period, product coverage shall extend to all Class I/II products covered during the transition period;

   (b) the FDA will expand the program to categories of Class II devices as is consistent with the results of the pilot, and with the FDA's ability to write guidance documents if the device pilot for the third party review of medical devices is successful. The MRA will cover to the maximum extent feasible all Class II devices listed in Table 3 for which FDA-accredited third-party review is available in the US.

4. Unless explicitly included by joint decision of the Parties, this agreement does not cover any US Class II-tier 3 or any Class III product under either system.

[1] It is understood that the date of entry into force will not occur prior to 1 June 1998, unless the Parties decide otherwise.

TABLE 1

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

Section No	Regulation Name Product Code — Device Name
	ANESTHESIOLOGY PANEL (868)
868.1910	Esophageal stethoscope BZW — Stethoscope, esophageal
868.5620	Breathing mouthpiece BYP — Mouthpiece, breathing
868.5640	Medicinal nonventilatory nebulizer (atomizer) CCQ — Nebulizer, medicinal, non-ventilatory (atomizer)
868.5675	Rebreathing device BYW — Device, rebreathing
868.5700	Nonpowered oxygen tent FOG — Hood, oxygen, infant BYL — Tent, oxygen
868.6810	Tracheobronchial suction catheter BSY — Catheters, suction, tracheobronchial
	CARDIOVASCULAR PANEL
	(None)
	DENTAL PANEL (872)
872.3400	Karaya and sodium borate with or without acacia denture adhesive KOM — Adhesive, denture, acacia and karaya with sodium borate
872.3700	Dental mercury (USP) ELY — Mercury
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
872.6640	Dental operative unit EIA — Unit, operative dental
	EAR, NOSE, AND THROAT PANEL (874)
874.1070	Short increment sensitivity index (SISI) adapter ETR — Adapter, short increment sensitivity index (SISI)
874.1500	Gustometer ETM — Gustometer

Section No	Regulation Name Product Code — Device Name
874.1800	Air or water caloric stimulator KHH — Stimulator, caloric-air ETP — Stimulator, caloric-water
874.1925	Toynbee diagnostic tube ETK — Tube, toynbee diagnostic
874.3300	Hearing aid LRB — Face plate hearing-aid ESD — Hearing-aid, air-conduction
874.4100	Epistaxis balloon EMX — Balloon, epistaxis
874.5300	ENT — Examination and treatment unit ETF — Unit, examining/treatment, ent
874.5550	Powered nasal irrigator KMA — Irrigator, powered nasal
874.5840	Anti-stammering device KTH — Device, anti-stammering
	GASTROENTEROLOGY — UROLOGY PANEL (876)
876.5160	Urological clamps for males FHA — Clamp, penile
876.5210	Enema kit FCE — Kit, enema, (for cleaning purpose)
876.5250	Urine collector and accessories FAQ — Bag, urine collection, leg, for external use
	GENERAL HOSPITAL PANEL (880)
880.5270	Neonatal eye pad FOK — Pad, neonatal eye
880.5420	Pressure infuser for I.V. bag KZD — Infusor, pressure, for I.V. bags
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
880.6760	Protective restraint BRT — Restraint, patient, conductive FMQ — Restraint, protective

Section No	Regulation Name Product Code — Device Name
	NEUROLOGY PANEL (882)
882.1030	Ataxiagraph GWW — Ataxiagraph
882.1420	Electroencephalogram (EEG) signal spectrum analyser GWS — Analyser, spectrum, electroencephalogram signal
882.4060	Ventricular cannula HCD — Cannula, ventricular
882.4545	Shunt system implantation instrument GYK — Instrument, shunt system implantation
882.4650	Neurosurgical suture needle HAS — Needle, neurosurgical suture
882.4750	Skull punch GXJ — Punch, skull
	OBSTETRICS AND GYNECOLOGY PANEL
	(None)
	OPHTHALMOLOGY PANEL (886)
886.1780	Retinoscope HKM — Retinoscope, battery-powered
886.1940	Tonometer sterilizer HKZ — sterilizer, tonometer
886.4070	Powered corneal burr HQS — Burr, corneal, ac-powered HOG — Burr, corneal, battery-powered HRG — Engine, trephine, accessories, ac-powered HFR — Engine, trephine, accessories, battery-powered HLD — Engine, trephine, accessories, gas-powered
886.4300	Keratone HNO — Keratone, ac-powered HMY — Keratone, battery-powered
886.5850	Sunglasses (non-prescription) HQY — Sunglasses (non-prescription including photosensitive)
	ORTHOPEDIC PANEL (888)
888.1500	Ac-powered goniometer KQX — Goniometer, ac-powered
888.4150	Callipers for clinical use KTZ — Calliper
	PHYSICAL MEDICINE PANEL (890)
890.3850	Mechanical wheelchair LBE — Stroller, adaptive IOR — Wheelchair, mechanical
890.5180	Manual patient rotation bed INY — Bed, patient rotation, manual
890.5710	Hot or cold disposable pack IMD — Pack, hot or cold, disposable

Section No	Regulation Name Product Code — Device Name
	RADIOLOGY PANEL (892)
892.1100	Scintillation gamma camera IYX — Camera, scintillation (gamma)
892.1110	Positron camera IZC — Camera, positron
892.1300	Nuclear rectilinear scanner IYW — Scanner, rectilinear, nuclear
892.1320	Nuclear uptake probe IZD — Probe, uptake, nuclear
892.1330	Nuclear whole body scanner JAM — Scanner, whole body, nuclear
892.1410	Nuclear electrocardiograph synchroniser IVY — Synchroniser, electrocardiograph, nuclear
892.1890	Radiographic-film illuminator IXC — Illuminatore radiographic-film JAG — Illuminatore radiographic-film, explosion-proof
892.1910	Radiographic grid IXJ — Grid, radiographic
892.1960	Radiographic intensifying screen WAM — Screen, intensifying, radiographic
892.1970	Radiographic ECG/respirator synchroniser IXO — Synchroniser, ECG/respirator, radiographic
892.5650	Manual radionuclide applicator system IWG — System, applicator, radionuclide, manual
	GENERAL AND PLASTIC SURGERY PANEL (878)
878.4200	Introduction/drainage catheter and accessories KGZ — Accessories, catheter GCE — Adaptor, catheter FGY — Cannula, injection GBA — Catheter, balloon type GBZ — Catheter, cholangiography GBQ — Catheter, continuous irrigation GBY — Catheter, eustachian, general & plastic surgery JCY — Catheter, infusion GBX — Catheter, irrigation GBP — Catheter, multiple lumen GBO — Catheter, nephrostomy, general & plastic surgery GBN — Catheter, pediatric, general & plastic surgery GBW — Catheter, peritoneal GBS — Catheter, ventricular, general & plastic surgery GCD — Connector, catheter GCC — Dilator, catheter GCB — Needle, catheter

Section No	Regulation Name Product Code — Device Name
878.4320	Removable skin clip FZQ — Clip, removable (skin)
878.4460	Surgeon's gloves KGO — Surgeon's gloves
878.4680	Nonpowered, single patient, portable suction apparatus GCY — Apparatus, suction, single patient use, portable, nonpowered
878.4760	Removable skin staple GDT — Staple, removable (skin)
878.4820	Ac-powered, battery-powered, and pneumatically powered surgical instrument motor GFG — Bit, surgical GFA — Blade, saw, general and plastic surgery DWH — Blade, saw, surgical, cardiovascular BRZ — Board, arm (with cover) GFE — Brush, dermabrasion GFF — Bur, surgical, general and plastic surgery KDG — Chisel (osteotome) GFD — Dermatome GFC — Driver, surgical, pin GFB — Head, surgical, hammer GEY — Motor, surgical instrument, ac-powered GET — Motor, surgical instrument, pneumatic powered DWI — Saw, electrically powered KFK — Saw, pneumatically powered HAB — Saw, powered, and accessories
878.4960	Air or ac-powered operating table and air or ac-powered operating chair and accessories GBB — Chair, surgical, ac-powered FQO — Tabel, operating-room, ac-powered GDC — Tabel, operating-room, electrical FWW — Tabel, operating-room, pneumatic JEA — Tabel, surgical with orthopedic accessories, ac-powered
880.5090	Liquid bandage KMF — Bandage, liquid

TABLE 2

Class II medical devices included in scope of product coverage at beginning of transition period

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

RA	892.1000	Magnetic resonance diagnostic device MOS — Coil, magnetic resonance, specialty LNH — System, nuclear magnetic resonance imaging LNI — System, nuclear magnetic resonance spectroscopic

DIAGNOSTIC ULTRASOUND

RA	892.1540	Nonfetal ultrasonic monitor JAF — Monitor, ultrasonic, nonfetal
RA	892.1550	Ultrasonic pulsed doppler imaging system IYN — System, imaging, pulsed doppler, ultrasonic
RA	892.1560	Ultrasonic pulsed echo imaging system IYO — System, imaging, pulsed echo, ultrasonic
RA	892.1570	Diagnostic ultrasonic transducer ITX — Transducer, ultrasonic, diagnostic

DIAGNOSTIC X — RAY IMAGING DEVICES

(except mammographic x-ray systems)

RA	892.1600	Angiographic x-ray system IZI — System, x-ray, angiographic
RA	892.1650	Image-intensified fluoroscopic x-ray system MQB — Solid state x-ray imager (flat panel/digital imager) JAA — System, x-ray, fluoroscopic, image-intensified
RA	892.1680	Stationary x-ray system KPR — System, x-ray, stationary
RA	892.1720	Mobile x-ray system IZL — System, x-ray, mobile
RA	892.1740	Tomographic x-ray system IZF — System, x-ray, tomographic
RA	892.1750	Computed tomography x-ray system JAK — System, x-ray, tomography, computed

ECG-RELATED DEVICES

CV	870.2340	Electrocardiograph DPS — Electrocardiograph MLC — Monitor, st segment
CV	870.2350	Electrocardiograph lead switching adaptor DRW — Adaptor, lead switching, electrocardiograph
CV	870.2360	Electrocardiograph electrode DRX — Electrode, electrocardiograph
CV	870.2370	Electrocardiograph surface electrode tester KRC — Tester, electrode, surface, electrocardiographic
NE	882.1400	Electroencephalograph GWQ — Electroencephalograph
HO	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 LZG — Pump, infusion, insulin MEA — Pump, infusion, pca

OPHTHALMIC INSTRUMENTS

OP	886.1570	Ophthalmoscope HLI — Ophthalmoscope, ac-powered HLJ — Ophthalmoscope, battery-powered
OP	886.1780	Retinoscope HKL — Retinoscope, ac-powered
OP	886.1850	Ac-powered slit-lamp biomicroscope HJO — Biomicroscope, slit-lamp, ac-powered
OP	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
OP	886.4670	Phacofragmentation system HQC — Unit, phacofragmentation

SU	878.4580	Surgical lamp HBI — Illuminator, fiberoptic, surgical field FTF — Illuminator, non-remote FTG — Illuminator, remote HJE — Lamp, fluorescent, 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
NE	882.5890	Transcutaneous electrical nerve stimulator for pain relief GZJ — Stimulator, nerve, transcutaneous, for pain relief

NON-INVASIVE BLOOD PRESSURE MEASUREMENT DEVICES

CV	870.1120	Blood pressure cuff DXQ — Cuff, blood-pressure
CV	870.1130	Non-invasive blood pressure measurement system (except non-oscillometric) DXN — System, measurement, blood-pressure, non-invasive
HO	880.6880	Steam steriliser (greater than 2 cubic feet) FLE — Steriliser, steam

CLINICAL THERMOMETERS

HO	880.2910	Clinical electronic thermometer (except tympanic or pacifier) FLL — Thermometer, electronic, clinical
AN	868.5630	Nebuliser CAF — Nebuliser (direct patient interface)
AN	868.5925	Powered Emergency ventilator

HYPODERMIC NEEDLES AND SYRINGES

(except anti-stick and self-destruct)

HO	880.5570	Hypodermic single lumen needle MMK — Container, sharpes FMI — Needle, hypodermic, single lumen MHC — Port, intraosseous, implanted

HO	880.5860	Piston syringe FMF — Syringe, piston
OR	888.3020	Intramedullary fixation rod HSB — Rod, fixation, intramedullary and accessories

EXTERNAL FIXATORS

(except devices with no external components)

OR	888.3030	Single/multiple component metallic bone fixation appliances and accessories KTT — Appliance, fixation, nail/blade/plate combination, multiple component
OR	888.3040	Smooth or threaded metallic bone fixation fastener HTY — Pin, fixation, smooth JDW — Pin, fixation, threaded

SELECTED DENTAL MATERIALS

DE	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
DE	872.3200	Resin tooth bonding agent KLE — Agent, tooth bonding, resin
DE	872.3275	Dental cement EMA — Cement, dental EMB — Zinc oxide eugenol
DE	872.3660	Impression material ELW — Material, impression
DE	872.3690	Tooth shade resin material EBF — Material, tooth shade, resin
DE	872.3710	Base metal alloy EJH — Metal, base

LATEX CONDOMS

OB	884.5300	Condom HIS — Condom

TABLE 3

Medical devices for possible inclusion in scope of product coverage during operational period

Product Family	Section No	Device Name	Tier
		ANAESTHESIOLOGY PANEL	
Anesthesia Devices	868.5160	Gas machine for anesthesia or analgesia	2
	868.5270	Breathing system heater	2
	868.5440	Portable oxygen generator	2
	868.5450	Respiratory gas humidifier	2
	868.5630	Nebuliser	2
	868.5710	Electrically powered oxygen tent	2
	868.5880	Anesthetic vaporiser	2
Gas Analyzer	868.1040	Powered Algesimeter	2
	868.1075	Argon gas analyser	2
	868.1400	Carbon dioxide gas analyser	2
	868.1430	Carbon monoxide gas analyser	2
	868.1500	Enflurane gas analyser	2
	868.1620	Halothane gas analyser	2
	868.1640	Helium gas analyser	2
	868.1670	Neon gas analyser	2
	868.1690	Nitrogen gas analyser	2
	868.1700	Nitrous oxide gas analyser	2
	868.1720	Oxygen gas analyser	2
	868.1730	Oxygen uptake computer	2
Peripheral Nerve Stimulators	868.2775	Electrical peripheral nerve stimulator	2
Respiratory Monitoring	868.1750	Pressure plethysmograph	2
	868.1760	Volume plethysmograph	2
	868.1780	Inspiratory airway pressure meter	2
	868.1800	Rhinoanemometer	2
	868.1840	Diagnostic spirometer	2
	868.1850	Monitoring spirometer	2
	868.1860	Peak-flow meter for spirometry	2
	868.1880	Pulmonary-function data calculator	2
	868.1890	Predictive pulmonary-function value calculator	2
	868.1900	Diagnostic pulmonary-function interpretation calculator	2

Product Family	Section No	Device Name	Tier
	868.2025	Ultrasonic air embolism monitor	2
	868.2375	Breathing frequency monitor (except apnea detectors)	2
	868.2480	Cutaneous carbon dioxide ($PcCO_2$) monitor	2
	868.2500	Cutaneous oxygen monitor (for an infant not under gas anesthesia)	2
	868.2550	Pneumotachomometer	2
	868.2600	Airway pressure monitor	2
	868.5665	Powered percussor	2
	868.5690	Incentive spirometer	2
Ventilator	868.5905	Nonconinuous ventilator (IPPB)	2
	868.5925	Powered emergency ventilator	2
	868.5935	External negative pressure ventilator	2
	868.5895	Continuous ventilator	2
	868.5955	Intermittent mandatory ventilation attachment	2
	868.6250	Portable air compressor	2

CARDIOVASCULAR PANEL

Cardiovascular Diagnostic	870.1425	Programmable diagnostic computer	2
	870.1450	Densitometer	2
	870.2310	Apex cardiograph (vibrocardiograph)	2
	870.2320	Ballistocardiograph	2
	870.2340	Electrocardiograph	2
	870.2350	Electrocardiograph lead switching adaptor	1
	870.2360	Electrocardiograph electrode	2
	870.2370	Electrocardiograph surface electrode tester	2
	870.2400	Vectorcardiograph	1
	870.2450	Medical cathode-ray tube display	1
	870.2675	Oscillometer	2
	870.2840	Apex cardiographic transducer	2
	870.2860	Heart sound transducer	2
Cardiovascular Monitoring		Valve, pressure relief, cardiopulmonary bypass	
	870.1100	Blood pressure alarm	2
	870.1110	Blood pressure computer	2

Product Family	Section No	Device Name	Tier
	870.1120	Blood pressure cuff	2
	870.1130	Non-invasive blood pressure measurement system	2
	870.1140	Venous blood pressure manometer	2
	870.1220	Electrode recording catheter or electrode recording probe	2
	870.1270	Intracavitary phonocatheter system	2
	870.1875	Stethoscope (electronic)	2
	870.2050	Biopotential amplifier and signal conditioner	2
	870.2060	Transducer signal amplifier and conditioner	2
	870.2100	Cardiovascular blood flow-meter	2
	870.2120	Extravascular blood flow probe	2
	870.2300	Cardiac monitor (including) cardiotachometer and rate alarm)	2
	870.2700	Oximeter	2
	870.2710	Ear oximeter	2
	870.2750	Impedance phlebograph	2
	870.2770	Impedance plethysmograph	2
	870.2780	Hydraulic, pneumatic, or photoelectric plethysmographs	2
	870.2850	Extravascular blood pressure transducer	2
	870.2870	Catheter tip pressure transducer	2
	870.2880	Ultrasonic transducer	2
	870.2890	Vessel occlusion transducer	2
	870.2900	Patient transducer and electrode cable (including connector)	2
	870.2910	Radiofrequency physiological signal transmitter and receiver	2
	870.2920	Telephone electrocardiograph transmitter and receiver	2
	870.4205	Cardiopulmonary bypass bubble detector	2
	870.4220	Cardiopulmonary bypass heart-lung machine console	2
	870.4240	Cardiovascular bypass heat exchanger	2
	870.4250	Cardiopulmonary bypass temperature controller	2
	870.4300	Cardiopulmonary bypass gas control unit	2
	870.4310	Cardiopulmonary bypass coronary pressure gauge	2
	870.4330	Cardiopulmonary bypass on-line blood gas monitor	2
	870.4340	Cardiopulmonary bypass level sensing monitor and/or control	2

Product Family	Section No	Device Name	Tier
	870.4370	Roller-type cardiopulmonary bypass blood pump	2
	870.4380	Cardiopulmonary bypass pump speed control	2
	870.4410	Cardiopulmonary bypass in-line blood gas sensor	2
Cardiovascular Therapeutic	870.5050	Patient care suction apparatus	2
	870.5900	Thermal regulation system	2
Defibrillator	870.5300	DC-defibrillator (including paddles)	2
	870.5325	Defibrillator tester	2
Echocardiograph	870.2330	Echocardiograph	2
Pacemaker and Accessories	870.1750	External programmable pacemaker pulse generator	2
	870.3630	Pacemaker generator function analyser	2
	870.3640	Indirect pacemaker generator function anlayser	2
	870.3720	Pacemaker electrode function tester	2
Miscellaneous	870.1800	Withdrawal-infusion pump	2
	870.2800	Medical magnetic tape recorder	2
	None	Batteries, rechargeable, Class II devices	2

DENTAL PANEL

Dental Equipment	872.1720	Pulp tester	2
	872.1740	Caries detection device	2
	872.4120	Bone cutting instrument and accessories	2
	872.4465	Gas-powered jet injector	2
	872.4475	Spring-powered jet injector	2
	872.4600	Intraoral ligature and wire lock	2
	872.4840	Rotary scaler	2
	872.4850	Ultrasonic scaler	2
	872.4920	Dental electrosurgical unit and accessories	2
	872.6070	Ultraviolet activator for polymerisation	2
	872.6350	Ultraviolet detector	2
Dental Material	872.3050	Amalgam alloy	2
	872.3060	Gold-based alloys and precious metal alloys for clinical use	2

Product Family	Section No	Device Name	Tier
	872.3200	Resin tooth bonding agent	2
	872.3250	Calcium hydroxide cavity liner	2
	872.3260	Cavity varnish	2
	872.3275	Dental cement (other than zinc oxide-eugenol)	2
	872.3300	Hydrophilic resin coating for dentures	2
	872.3310	Coating material for resin fillings	2
	872.3590	Preformed plastic denture tooth	2
	872.3660	Impression material	2
	872.3690	Tooth shade resin material	2
	872.3710	Base metal alloy	2
	872.3750	Bracket adhesive resin and tooth conditioner	2
	872.3760	Denture relining, repairing, or rebasing resin	2
	872.3765	Pit and fissure sealant and conditioner	2
	872.3770	Temporary crown and bridge resin	2
	872.3820	Root canal filling resin (other than chloroform use)	2
	872.3920	Porcelain tooth	2
Dental x-ray	872.1800	Extraoral source x-ray system	2
	872.1810	Intraoral source x-ray system	2
Dental Implants	872.4880	Intraosseous fixation screw or wires	2
	872.3890	Endodontic stabilising splint	2
Orthodontic	872.5470	Orthodontic plastic bracket	2

EAR/NOSE/THROAT PANEL

Diagnostic Equipment	874.1050	Audiometer	2
	874.1090	Auditory impedance tester	2
	874.1120	Electronic noise generator for audiometric testing	2
	874.1325	Electroglottograph	2
	874.1820	Surgical nerve stimulator/locator	2
Hearing Aids	874.3300	Hearing aid (for bone-conduction)	2
	874.3310	Hearing aid calibrator and analysis system	2

Product Family	Section No	Device Name	Tier
	874.3320	Group hearing aid or group auditory trainer	2
	874.3330	Master hearing aid	2
Surgical Equipment	874.4250	Ear, nose, and throat electric or pneumatic surgical drill	1
	874.4490	Argon laser for otology, rhinology, and laryngology	2
	874.4500	ENT microsurgical carbon dioxide laser	2

GASTROENTEROLOGY/UROLOGY PANEL

Endoscope (including angioscopes, laparscopes, ophtalmic endoscopes)	876.1500	Endoscope and accessories	2
	876.4300	Endoscopic electrosurgical unit and accessories	2
Gastroenterology	876.1725	Gastrointestinal motility monitoring system	1
Hemodialysis	876.5600	Sorbent regenerated dialysate delivery system for hemodialysis	2
	876.5630	Peritoneal dialysis system and accessories	2
	876.5665	Water purification system for hemodialysis	2
	876.5820	Hemodialysis system for accessories	2
	876.5830	Hemodialyser with disposable insert (kiil-type)	2
Lithotriptor	876.4500	Mechanical lithotriptor	2
Urology Equipment	876.1620	Urodynamics measurement system	2
	876.5320	Nonimplanted electrical continence device	2
	876.5880	Isolated kidney perfusion and transport system and accessories	2

GENERAL HOSPITAL PANEL

Infusion Pumps and Systems	880.2420	Electronic monitor for gravity flow infusion systems	2
	880.2460	Electrically powered spinal fluid pressure monitor	2
	880.5430	Nonelectrically powered fluid injector	2
	880.5725	Infusion pump	2

Product Family	Section No	Device Name	Tier
Neonatal Incubators	880.5400	Neonatal incubator	2
	880.5410	Neonatal transport incubator	2
	880.5700	Neonatal phototherapy unit	2
Piston Syringes	880.5570	Hypodermic single lumen needle	1
	880.5860	Piston syringe (except anti-stick)	1
	880.6920	Syringe needle introducer	2
Miscellaneous	880.2910	Clinical electronic thermometer	2
	880.2920	Clinical mercury thermometer	2
	880.5100	AC-powered adjustable hospital bed	1
	880.5500	AC-powered patient lift	2
	880.6880	Steam Steriliser (greater than 2 cubic feet)	2

NEUROLOGY PANEL

	882.1020	Rigidity analyser	2
	882.1610	Alpha monitor	2
Neuro-Diagnostic	882.1320	Cutaneous electrode	2
	882.1340	Nasopharyngeal electrode	2
	882.1350	Needle electrode	2
	882.1400	Electroencephalograph	2
	882.1460	Nystagmograph	2
	882.1480	Neurological endoscope	2
	882.1540	Galvanic skin response measurement device	2
	882.1550	Nerve conduction velocity measurement device	2
	882.1560	Skin potential measurement device	2
	882.1570	Powered direct-contact temperature measurement device	2
	882.1620	Intracranial pressure monitoring device	2
	882.1835	Physiological signal amplifier	2
	882.1845	Physiological signal conditioner	2
	882.1855	Electroencephalogram (EEG) telemetry system	2
	882.5050	Biofeedback device	2
Echoencephalography	882.1240	Echoencephalograph	2
RPG	882.4400	Radiofrequency lesion generator	2

Product Family	Section No	Device Name	Tier
Neuro Surgery	none	Electrode, spinal epidural	2
	882.4305	Powered compound cranial drills, burrs, trephines and their accessories	2
	882.4310	Powered simple cranial drills, burrs, trephines and accessories	2
	882.4360	Electric cranial drill motor	2
	882.4370	Pneumatic cranial drill motor	2
	882.4560	Sterotaxic instrument	2
	882.4725	Radiofrequency lesion probe	2
	882.4845	Powered rongeur	2
	882.5500	Lesion temperature monitor	2
Stimulators	882.1870	Evoked response electrical stimulator	2
	882.1880	Evoked response mechanical stimulator	2
	882.1890	Evoked response photic stimulator	2
	882.1900	Evoked response auditory stimulator	2
	882.1950	Tremor transducer	2
	882.5890	Transcutaneous electrical nerve stimulator for pain relief	2

OBSTETRICS/GYNAECOLOGY PANEL

Fetal Monitoring	884.1660	Transcervical endoscope (amnioscope) and accessories	2
	884.1690	Hysteroscope and accessories (for performance standards)	2
	884.2225	Obstetric-gynecologic ultrasonic imager	2
	884.2600	Fetal cardiac monitor	2
	884.2640	Fetal phonocardiographic monitor and accessories	2
	884.2660	Fetal ultrasonic monitor and accessories	2
	884.2675	Fetal scalp circular (spiral) electrode and applicator	1
	884.2700	Intrauterine pressure monitor and accessories	2
	884.2720	External uterine contraction monitor and accessories	2
	884.2740	Perinatal monitoring system and accessories	2
	884.2960	Obstetric ultrasonic transducer and accessories	2

Product Family	Section No	Device Name	Tier
Gynecological Surgery Equipment	884.1720	Gynecologic laparoscope and accessories	2
	884.4160	Unipolar endoscopic coagulator-cutter and accessories	2
	884.4550	Gynecologic surgical laser	2
	884.4120	Gynecologic electrocautery and accessories	2
	884.5300	Condom	2
Ophthalm. Implants	886.3320	Eye sphere implant	2
Contact Lens	886.1385	Polymethylmethacrylate (PMMA) diagnostic contact lens	2
	886.5916	Rigid gas permeable contact lens (daily wear only)	2
Diagnostic Equipment	886.1120	Ophthalmic camera	1
	886.1220	Corneal electrode	1
	886.1250	Euthyscope (AC-powered)	1
	886.1360	Visual field laser instrument	1
	886.1510	Eye movement monitor	1
	886.1570	Ophthalmoscope	1
	886.1630	AC-powered photostimulator	1
	886.1640	Ophthalmic preamplifier	1
	886.1670	Ophthalmic isotope uptake probe	2
	886.1780	Retinoscope (AC-powered device)	1
	886.1850	AC-powered slitlamp biomicroscope	1
	886.1930	Tonometer and accessories	2
	886.1945	Transilluminator (AC-powered device)	1
	886.3130	Ophthalmic conformer	2
(Diagnostic/ Surgery Equipment)	886.4670	Phacofragmentation System	2
Ophthalm. Implants	886.3340	Extraocular orbital implant	2
	886.3800	Scleral shell	2
Surgical Equipment	886.5725	Infusion pump (performance standards)	2
	886.3100	Ophthalmic tantalum clip	2
	886.3300	Absorbable implant (scleral buckling method)	2
	886.4100	Radiofrequency electrosurgical cautery apparatus	2

Product Family	Section No	Device Name	Tier
	886.4115	Thermal cautery unit	2
	886.4150	Vitreous aspiration and cutting instrument	2
	886.4170	Cryophthalmic unit	2
	886.4250	Ophthalmic electrolysis unit (AC-powered device)	1
	886.4335	Operating headlamp (AC-powered device)	1
	886.4390	Ophthalmic laser	2
	886.4392	Nd:YAG laser for posterior capsulotomy	2
	886.4400	Electronic metal locator	1
	886.4440	AC-powered magnet	1
	886.4610	Ocular pressure applicator	2
	886.4690	Ophthalmic photocoagulator	2
	886.4790	Ophthalmic sponge	2
	886.5100	Ophthalmic beta radiation source	2
	none	Ophthalmoscopes, replacement batteries, hand-held	1

ORTHOPEDIC PANEL

Implants	888.3010	Bone fixation cerclage	2
	888.3020	Intramedullary fixation rod	2
	888.3030	Single/multiple component metallic bone fixation appliance and accessories	2
	888.3040	Smooth or threaded metallic bone fixation	2
	888.3050	Spinal interlaminal fixation orthosis	2
	888.3060	Spinal intervertebral body fixation orthosis	2
Surgical Equipment	888.1240	AC-powered dynamometer	2
	888.4580	Sonic surgical instrument and accessories/attachments	2
	none	Accessories, fixation, spinal interlaminal	2
	none	Accessories, fixation, spinal intervertebral body	2
	none	Monitor, pressure, intracompartmental	1
	none	Orthosis, fixation, spinal intervertebral fusion	2
	none	Orthosis, spinal pedicle fixation	
	none	System, cement removal extraction	1

Product Family	Section No	Device Name	Tier
		PHYSICAL MEDICINE PANEL	
Diagnostic Equipement	890.1225	Chronaximeter	2
	890.1375	Diagnostic electromyograph	2
	890.1385	Diagnostic electromyograph needle electrode	2
	890.1450	Powered reflex hammer	2
	890.1850	Diagnostic muscle stimulator	2
or (Therapy)	890.5850	Powered muscle stimulator	2
Therapeutic Equipment	890.5100	Immersion hydrobath	2
	890.5110	Paraffin bath	2
	890.5500	Infrared lamp	2
	890.5720	Water circulating hot or cold pack	2
	890.5740	Powered heating pad	2
		RADIOLOGY PANEL	
MRI	892.1000	Magnetic resonance diagnostic device	2
Ultrasound Diagnostic	884.2660	Fetal ultrasonic monitor and accessories	2
	892.1540	Nonfetal ultrasonic monitor	
	892.1560	Ultrasonic pulsed echo imaging system	2
	892.1570	Diagnostic ultrasonic transducer	2
	892.1550	Ultrasonic pulsed doppler imaging system	
Angiographic	892.1600	Angiographic x-ray system	2
Diagnostic X-Ray	892.1610	Diagnostic x-ray beam-limiting device	2
	892.1620	Cine or spot fluorographic x-ray Camera	2
	892.1630	Electrostatic x-ray imaging system	2
	892.1650	Image-intensified fluoroscopic x-ray system	2
	892.1670	Spot film device	2
	892.1680	Stationary x-ray system	2
	892.1710	Mammographic x-ray system	2
	892.1720	Mobile x-ray system	2
	892.1740	Tomographic x-ray system	1
	892.1820	Pneumoencephalographic chair	2
	892.1850	Radiographic film cassette	1

Product Family	Section No	Device Name	Tier
	892.1860	Radiographic film/cassette changer	1
	892.1870	Radiographic film/cassette changer programmer	2
	892.1900	Automatic radiographic film processor	2
	892.1980	Radiologic table	1
CT Scanner	892.1750	Computed tomography x-ray system	2
Radiation Therapy	892.5050	Medical charged-particle radiation therapy system	2
	892.5300	Medical neutron radiation therapy system	2
	892.5700	Remote controlled radionuclide-applicator system	2
	892.5710	Radiation therapy beam-shaping block	2
	892.5730	Radionuclide brachytherapy source	2
	892.5750	Radionuclide radiation therapy system	2
	892.5770	Powered radiation therapy patient support assembly	2
	892.5840	Radiation therapy stimulation system	2
	892.5930	Therapeutic x-ray tube housing assembly	1
Nuclear Medicine	892.1170	Bone densitometer	2
	892.1200	Emission computed tomography system	2
	892.1310	Nuclear tomography system	1
	892.1390	Radionuclide rebreathing system	2

GENERAL/PLASTIC SURGERY PANEL

Surgical Lamps	878.4630	Ultraviolet lamp for dermatologic disorders	2
	890.5500	Infrared lamp	2
	878.4580	Surgical lamp	2
Electrosurgical Cutting Equipment	878.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology	2
	878.4400	Electrosurgical cutting and coagulation device and accessories	2
Miscellaneous	878.4780	Powered suction pump	2

Appendix 3

Authorities responsible for designating conformity assessment bodies

EC access to the US market	US access to the EC market
— *Belgium* Ministère de la Santé publique, de l'Environnement et de l'Intégration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Inetgratie — *Denmark* Sundhedsministeriet — *Germany* Bundesministerium für Gesundheit — *Greece* Υπουργείο Υγείας Ministry of Health — *Spain* Ministerio de Sanidad y Consumo — *France* Ministère de l'emploi et de la solidarité Ministère de l'économie, des finances et de l'industrie — *Ireland* Department of Health — *Italy* Ministero della Sanitá — *Luxembourg* Ministère de la Santé — *Netherlands* Staat der Nederlanden — *Austria* Bundesministerium für Arbeit, Gesundheit und Soziales — *Portugal* Ministerio da Saude — *Finland* Sosiaali-ja terveysministeriö/Social-och hälsovårdsministeriet — *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *United Kingdom* Department of Health	Food and Drug Administration (FDA)

Appendix 4

Conformity assessment bodies

EC access to the US market	US access to the EC market
Conformity assessment bodies located in the EC shall be designated by the Authorities identified in Appendix 3.	Conformity assessment bodies located in the US shall be designated by the Authorities identified in Appendix 3.
(to be provided by the EC)	(to be provided by the US)

JOINT DECLARATION

to the Agreement on Mutual Recognition between the European Community and the United States of America

The Parties agree that, although in this exceptional case the Agreement on Mutual Recognition between the United States of America and the European Community is being signed while the consistency of the various linguistic versions of the Agreement is being verified, notification of the completion of their respective procedures for the entry into force of the Agreement, as referred to in Article 21(1) of the Agreement, will be made only after the Parties have completed the verification of the texts signed today and, through agreement between the Parties, any discrepancies have been brought into conformity with the English text.

Done at London on the eighteenth day of May in the year one thousand nine hundred and ninety-eight.

For the European Community *For the United States of America*