AGREEMENT

between the European Union and the United States of America on the mutual acceptance of results of conformity assessment

THE EUROPEAN UNION

and

THE UNITED STATES OF AMERICA

hereinafter “the Parties”,

Having regard

to the Joint Statement agreed by Presidents Juncker and Trump on 25 July 2018,
to the benefits of improved conformity assessment practices both for companies, regulators but also consumers,
to each Party’s right to choose the appropriate levels of protection for their citizens,
to the need of upholding domestic legislation and procedures,

HAVE AGREED AS FOLLOWS

SECTION 1 – GENERAL PROVISIONS

Article 1

Definitions

Annex 1 of the WTO Agreement on Technical Barriers to Trade (“TBT Agreement”) is incorporated into and made part of this Agreement, mutatis mutandis. For the purposes of this Agreement, the following additional definitions also apply:

(a) “economic operators” means manufacturer, importer, authorised representative and distributor.

(b) "EU accreditation body" means an accreditation body appointed by a Member State of the European Union to accredit conformity assessment bodies as competent to assess the conformity with the European Union’s technical regulations for the relevant scope, and which is a member of European co-operation for Accreditation.
(c) “European co-operation for Accreditation” means the body appointed by the European Commission in accordance with Article 14 of Regulation (EC) 765/2008.

(d) “recognized US conformity assessment body” means a US conformity assessment body recognized by the European Union as competent to assess conformity to the EU regulations in accordance with the rules, schemes and programmes on conformity assessment applicable in European Union in accordance with the provisions of Article 6 of this Agreement.

(e) “recognized EU conformity assessment body” means an EU conformity assessment body recognized by the United States as competent to assess conformity to the US technical regulations in accordance with the rules, schemes and programmes on conformity assessment applicable in the territory of the United States.

(f) “US accreditation body” means an accreditation body established in the territory of the United States which has signed the IAAC Multi-lateral Recognition Arrangement, and are signatory members of ILAC and IAF Arrangements.

(g) "US conformity assessment body" means a conformity assessment body established in the territory of the United States.


(i) “first-party conformity assessment” means a procedure under which the manufacturer on his/her sole responsibility declares conformity of a product as assurance of conformity to technical regulations based on the results of an appropriate type of conformity assessment activity which excludes the mandatory use of third party conformity assessment bodies”

Article 2

Context and objectives

1. The objective of this Agreement is to facilitate trade in goods between the Parties with regard to conformity assessment for all products covered under this Agreement.

2. This Agreement specifies the conditions by which each Party will accept results of conformity assessment procedures, produced by the other Party's conformity assessment bodies, when assessing conformity to the importing Party's mandatory requirements, for products covered by this Agreement as a positive assurance that a product or process conforms with a technical regulation of that Party.
3. This Agreement shall not entail mutual acceptance of the standards or technical regulations of the Parties or mutual recognition of the equivalence of such standards or technical regulations.

4. This Agreement shall not limit the ability of a Party to prepare, adopt, apply or amend technical regulations, and conformity assessment procedures in accordance with Articles 2 and 5 of the TBT Agreement.

5. This Agreement shall fully respect the domestic law and regulatory procedures of the Parties, and applicable levels of protection shall be maintained by the Parties.

**Article 3**

**Scope and exceptions**

1. This Agreement shall apply to the following areas:

   (a) categories listed in Annex 1 and as defined by each Party’s respective legislation in accordance with the modalities set out in Articles 4-10.
   
   (b) categories listed in Annex 2 and as defined by each Party’s respective legislation in accordance with the modalities set out in Article 14.

2. Without prejudice to Article 3(3), the Parties shall give positive consideration to applying this Agreement to categories other than those listed in Annex 1 and 2 to this Agreement subject to third-party conformity assessment pursuant to technical regulations by a Party. The Joint Committee shall have the power to amend, through a decision, the Annexes to this Agreement, including such additional categories.

3. This Agreement does not apply:

   (a) to sanitary and phytosanitary measures as defined in Annex A of the WTO Agreement on Sanitary and Phytosanitary Measures;
   
   (b) to agricultural goods; as defined in Annex 1 of the WTO Agreement of Agriculture,
   
   (c) to the assessment of aviation safety, whether or not it is covered under the Agreement on Civil Aviation Safety between the United States and the European Community done in Brussels on 30th June 2008;
   
   (d) to the statutory inspection and certification of vessels other than recreational craft;
   
   (e) to marine equipment as covered by the Agreement between the European Community and the United States of America on the Mutual Recognition of
Certificates of Conformity for Marine Equipment signed on 27th February 2004;

(f) to motor vehicles and their components,

(g) to purchasing specifications prepared by a governmental body for production or consumption requirements of governmental bodies; and

(h) rail systems, subsystems and interoperability constituents.

4. This Agreement does not apply to areas where no harmonized legislation of the European Union exists.

5. Whenever a Party’s domestic legislation refers to a requirement of the existence of a mutual recognition agreement or an equivalent formulation, including a reciprocity requirement, as a precondition for participation in a conformity assessment scheme, this Agreement shall be deemed as fulfilling this requirement for such purposes for the areas covered in its scope.

SECTION 2 – PROVISIONS RELATED TO CONFORMITY ASSESSMENT BODIES

Article 4

Participation of conformity assessment bodies of a Party in conformity assessment procedures of the other Party

1. In the areas defined in Article 3(1)(a), each Party shall accord to conformity assessment bodies located in the territory of the other Party treatment no less favourable than that it accords to conformity assessment bodies located in its own territory. Treatment under this paragraph includes procedures, criteria, fees and other conditions relating to accrediting, approving, licensing, or otherwise recognizing conformity assessment bodies.

2. The treatment accorded by the European Union under paragraph 1 shall be implemented through the procedures set out in Articles 5, 6, 8 and 9.

Article 5

Accreditation of conformity assessment bodies established in the territory of the other Party

4
1. A US conformity assessment body may apply to be accredited by an EU accreditation body for the purposes of assessing conformity to EU technical regulations.

2. For each specific technical regulation covered by this Agreement, the European Commission may establish a list of EU accreditation bodies from which US conformity assessment bodies shall exclusively seek accreditation for the purposes of paragraph 1.

3. In the absence of such a list for a specific technical regulation covered by this Agreement, US conformity assessment bodies may seek accreditation by any EU accreditation body. A US conformity assessment body which has sought accreditation from a specific EU accreditation body for the purposes of assessing conformity to EU technical regulations, shall not be permitted to seek accreditation to assess conformity to the same EU technical regulations through a new procedure with a different EU accreditation body.

4. Notwithstanding paragraph 1, a US conformity assessment body shall seek accreditation by a US accreditation body to assess conformity to EU technical regulations where for the relevant area a US accreditation body has been recognised by the European Union in accordance with paragraph (5).

5. For the purposes of paragraph 4, the European Union may recognise a US accreditation body to accredit US conformity assessment bodies for a particular scope subject to the following conditions:

   (a) The United States requested the recognition by providing the European Commission with a written notification demonstrating the compliance by the nominated US accreditation body of equivalent requirements to those laid down for EU accreditation bodies in accordance with Articles 4(7), 4(8), 6, 8 and 9(4) of Regulation (EC) 765/2008 or the corresponding requirements in successor instruments. The requirement to operate on a not-for-profit basis shall be required only for the activity of the US accreditation body pertaining to the scopes of the application.

   (b) The nominated US accreditation body is a signatory member to the International Laboratory Accreditation Cooperation ("ILAC") or International Accreditation Forum ("IAF") Multilateral Recognition Arrangements.

   (c) The nominated US accreditation body is technically competent to accredit US conformity assessment bodies to assess conformity to EU technical regulations within the scope for which its recognition is requested.

   (d) The US accepts the accreditation of EU conformity assessment bodies by EU accreditation bodies to assess conformity to US technical regulations for the same areas (reciprocity).
6. The fulfilment of the conditions listed in (a) and (c) shall be assessed by the European co-operation for Accreditation, or its successor institution assisted by the relevant sectoral body as appropriate, on the basis of a cooperation agreement concluded with the nominated US accreditation body. The costs of the assessment shall be borne by the applicant accreditation body. The European Commission will notify the United States of the recognition of a US accreditation body for the purpose of paragraph 5, based on the result of the assessment of the European co-operation for Accreditation.

7. The conditions under paragraph (5) shall continue to apply to the recognized US accreditation body after its recognition by the European Union. To this end, the recognized US accreditation body shall undergo periodic peer evaluation by European co-operation for Accreditation, or its successor institution, equivalent to those applied to EU accreditation bodies.

8. The European Union may challenge the competence of a recognized US accreditation body on the grounds that any of the conditions required under paragraph 5 is no longer met by that US accreditation body. In such cases, the European Commission shall immediately notify the United States. The Parties shall cooperate to promptly resolve the challenge.

9. If the challenge is not resolved within 120 days after the United States received the notification referred to in paragraph 8, the European Union shall cease the recognition of the US accreditation body. In the cases in which a US accreditation body ceases to be recognised, the European Union may also cease the recognition of any US conformity assessment bodies recognised on the basis of an accreditation certificate issued from the ceased accreditation body.

Article 6
Designation and recognition of US conformity assessment bodies

1. In cases where the relevant legislation of the European Union requires the notification of conformity assessment bodies to carry out third-party conformity assessment tasks under that legislation, the United States shall designate the US conformity assessment bodies that are duly accredited for a particular scope by an EU accreditation body or an US accreditation body recognised by the European Union. The accreditation shall attest that the US conformity assessment bodies fulfil the requirements set out in the relevant legislation of the European Union. For these purposes, the specific requirement of “establishment under national law” set out in the relevant legislation of the European Union shall be understood to mean “establishment under the law of the United States”.
2. The United States shall notify the information described in Annex 3 to the European Union. The European Union’s electronic notification system\(^1\) shall be used for the purposes of notification of designation.

3. A US conformity assessment body duly designated by the United States in accordance with paragraph 1, shall be deemed to be recognized by the European Union provided the European Commission raises no objection within 60 days following the notification of the designation on the grounds that:

   (a) the US failed to provide information relating to the fulfilment of the requirements set out in Annex 3; or

   (b) that the conformity assessment body designated by the US does not meet the conditions described in Articles 5(2) or 5(3) or 6(1).

4. Following the recognition of a US conformity assessment body by the European Commission, the United States shall ensure that the information described in Annex 3 is kept updated and shall re-notify such information to the European Union in due time and before the expiry of the accreditation certificate of the recognized US conformity assessment body.

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**Article 7**

*Oversight of the conformity assessment bodies of the Parties*

Upon receipt of a written complaint by a Party that products assessed by a conformity assessment body which the Party has recognised do not comply with applicable technical regulations, the other Party shall:

   (a) promptly seek additional information from the recognised conformity assessment body, the accreditation body that provided the respective accreditation of the recognised conformity assessment body and, when necessary, market surveillance authorities and economic operators;

   (b) investigate the complaint; and

   (c) provide the other Party with a written reply to the complaint.

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**Article 8**

*Challenges to recognised US conformity assessment bodies*

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\(^1\) The New Approach Notified and Designated Organisations (“NANDO”) or a successor system
1. The European Union may challenge the competence of a conformity assessment body recognised in accordance with Article 6(3) if:

   (a) the US failed to take the actions provided for by Article 7; or
   
   (b) the European Union has reasons to believe that the results of conformity assessments performed by that conformity assessment body do not provide sufficient assurances that the products assessed by that body as conforming with applicable technical regulations are in fact in conformity with these technical regulations.

2. The European Commission shall immediately notify the United States on the challenge referred to in paragraph 1 and shall provide the reasons for the challenge. The European Union may suspend the conformity assessment body pending the procedure of paragraph 4.

3. The Parties shall cooperate and endeavour to resolve the challenge promptly.

4. The European Union may cease to recognise the US conformity assessment body whose competence is challenged and may remove it from the list referred in Article 25(2) if:

   (a) the Parties resolve the challenge by concluding that the European Union’s concerns as to the competence of the conformity assessment body are valid; or
   
   (b) the United States failed to take up and complete within 60 days following the notification referred to in paragraph 2 the actions required by Article 7; or
   
   (c) the challenge has not been resolved within 120 days after the United States received the notification referred to in paragraph 2.

5. Without prejudice to paragraph 4, the European Union may immediately cease to recognise a conformity assessment body and remove it from the list referred to in Article 25(2) if:

   (a) the conformity assessment body’s accreditation lapses;
   
   (b) the designation of the conformity assessment body is withdrawn pursuant to Article 9; or
   
   (c) the conformity assessment body ceases to qualify as US conformity assessment body because it is no longer established in the territory of the United States.

Article 9

Withdrawals and modifications to reduce the scope of designations of US conformity assessment bodies
1. The United States shall withdraw the designation of a conformity assessment body it has designated, or modify it with a view to reduce its scope, as appropriate, if it becomes aware that the conformity assessment body no longer fulfills the conditions for designation.

2. The United States shall, through the information system referred to in Article 6(2), notify the European Union of a withdrawal or modification of a designation, stating the reasons for its decision and indicating the date as of which the withdrawal or modification applies.

**Article 10**

**Acceptance of the results of conformity assessment by recognised conformity assessment bodies of the Parties**

Each Party shall ensure that the results of conformity assessments performed by recognized EU or US conformity assessment bodies established in the other Party’s territory are accepted, regardless of the nationality or place of establishment of the supplier or manufacturer, or of the country of origin of the product for which the conformity assessment activities are performed.

**SECTION 3 – PROVISIONS RELATED TO CONFORMITY ASSESSMENT PROCEDURES AND MARKET SURVEILLANCE**

**Article 11**

**First-Party Conformity Assessment**

1. Without prejudice to Article 14, a Party shall, whenever it is developing new conformity assessment procedures or reviewing existing conformity assessment procedures, consider introducing first-party conformity assessment as an assurance of conformity in a category:

   (a) that is covered by Annex 1 or 2; and

   (b) for which the other Party allows the application of first-party conformity assessment.

2. When introducing first-party conformity assessment as an assurance of conformity in an area referred to in paragraph 1, neither Party shall require any of the following:

   (a) the intervention of any third or independent conformity assessment body; or

   (b) the testing of the product by a third or independent testing laboratory.
Article 12

Market surveillance

Except for customs procedures, a Party shall ensure that market surveillance or enforcement authorities perform inspections or verifications of conformity with applicable technical regulations for products assessed by a recognised conformity assessment body established in the territory of the other Party or an in-house body, under conditions no less favourable than those applying to products assessed by conformity assessment bodies in the territory of the recognising Party.

SECTION 4 – SPECIAL PROVISIONS RELATED TO CERTAIN SECTORS

Article 13

Special provisions related to the Nationally Recognized Testing Laboratories (NRTL) scheme by the US Occupational Safety and Health Administration (OSHA)

1. The United States shall ensure that any components and parts of a finished equipment are not required to be certified by an NRTL as an individual product when they are subject, together with the finished equipment as a single product, to NRTL certification.

2. The United States shall ensure that any NRTL reports and certificates relating to the assessment, testing and conformity of any products, components and parts are mutually recognised by all other NRTLs.

3. The United States shall ensure that, when a conformity assessment body established in the EU applies to be recognised as an NRTL by OSHA, any certificate issued by a national accreditation body of a Member State of the European Union is recognised as an attestation of the competency of that body and with respect to the scope and products covered by that certificate.

4. For conformity assessment bodies established in the EU, the United States hereby waives the reciprocity requirement foreseen under NRTL scheme governed by OSHA for non-US established conformity assessment bodies.

5. The United States shall not, after the entry into force of this Agreement, maintain or introduce in technical regulations provisions that promote or require the affixing of
multiple certification marks or labels on a single finished product and its components or parts.

6. The United States shall ensure that OSHA or any NRTL use a single uniform certification mark.

**Article 14**

**Use of the results of conformity assessment by the authorities of a Party with respect to categories listed in Annex 2**

1. Each Party shall take into account quality system evaluation reports prepared by conformity assessment bodies (auditing organisations) established in the other Party’s territory which are recognised under the Medical Device Single Audit Programme (MDSAP) developed in the context of IMDRF (International Medical Devices Regulators Forum), in a manner that is compatible with each Party’s respective legislative requirements and provided the report satisfies the requirements of this Party, except under the cases defined in paragraph 4 of this Article.

2. Such conformity assessment bodies established in the European Union shall provide the US Food and Drug Administration (FDA) with MDSAP quality system evaluation reports elaborated against US requirements.

3. Such conformity assessment bodies established in the United States shall provide the conformity assessment body of the manufacturer's choice designated by the European Union with quality system evaluation reports elaborated against EU requirements.

4. Circumstances which could justify that a report is not taken into account 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.
SECTION 5 – INSTITUTIONAL PROVISIONS

Article 15
Contact Points
1. Each Party shall designate a contact point responsible for communications with the other Party related to any matter arising under this Agreement.
2. The contact points may communicate by electronic mail, video-conferencing or any other agreed means.

Article 16
Joint Committee
1. A Joint Committee is hereby set up. It shall be co-chaired by a representative of the United States and a representative of the European Commission. The Joint Committee shall adopt its decisions by consensus. The Joint Committee shall determine its own rules and procedures.
2. The Joint Committee shall:
   (a) monitor and review the implementation and operation of the present Agreement;
   (b) adopt decisions, in particular, to amend the categories referred to in Article 3(1) and (2); and amend the Agreement as referred in Article 22 (2).
   (c) adopt, where necessary, appropriate complementary technical and administrative arrangements for the effective implementation of this Agreement.
3. The Joint Committee shall meet at the request of either Party with respect to issues relating to this Agreement. The Joint Committee may meet in person or by other means.
SECTION 6 – FINAL PROVISIONS

Article 17

Territorial application

This Agreement shall apply:

(a) for the European Union, to the territories in which the Treaty on European Union and the Treaty on the Functioning of the European Union are applied, and under the conditions laid down in those Treaties; and

(b) for the United States, to the territory of the United States.

Article 18

Fulfilment of obligations

1. Each Party is fully responsible for the observance of all provisions of this Agreement.

2. Each Party shall ensure that all necessary measures are taken to give effect to the provisions of this Agreement, including their observance by central, regional or local governments and authorities as well as by non-governmental bodies in the exercise of powers delegated by central, regional or local governments or authorities. Each Party shall act in good faith to ensure that the objectives set out in this Agreement are attained.

Article 19

Safeguard clause

1. A Party may unilaterally suspend the application of this Agreement in its entirety or with regard to certain areas if the participation of the conformity assessment bodies located in its territory in the conformity assessment procedures of the other Party is no longer ensured in accordance with Article 4 by the other Party.

2. A Party may also unilaterally suspend the application of this Agreement with respect to any of the categories listed in the Annexes to this Agreement in case of serious and repeated findings which put into question the validity of results of conformity assessment produced by the conformity assessment bodies recognized by that Party for that specific category.
3. A Party that has challenged the competence of a recognised conformity assessment body under this Agreement or ceased to recognise a conformity assessment body in accordance with Article 8(5) may refuse to accept the results of that body’s conformity assessment activities until the challenge is resolved.

4. If a Party has ceased to recognise a conformity assessment body established in the territory of the other Party, it may cease to accept the results of conformity assessment activities performed by that conformity assessment body from the date when it ceased to recognise that conformity assessment body. Unless the Party has reasons to believe that the conformity assessment body established in the territory of the other Party was not competent to assess conformity of products with the technical regulations of the Party prior to the date when the Party ceased to recognize that conformity assessment body, the Party shall continue to accept the results of conformity assessment activities performed by that conformity assessment body prior to the date when the Party ceased to recognise the conformity assessment body, even though the products may have been placed on the market of the Party after that date.

Article 20

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 third party shall have no force or effect with regard to the other Party in terms of acceptance of the results of conformity assessment procedures by the third party.

Article 21

Entry into force

1. This Agreement shall enter into force on the first day of the second month following the date on which the Parties have notified each other of the completion of their respective procedures for that purpose.

2. The acceptance of results of conformity assessments in accordance with Article 10 and the relevant procedures according to Article 13 shall be implemented by the Parties no later than [two] years after the entry into force of the Agreement.
**Article 22**

**Amendments**

1. The Parties may agree, in writing, to amend this Agreement. Such amendments shall enter into force in accordance with the provisions of Article 21.

2. The Joint Committee may adopt decisions to amend the Agreement in the cases referred to under Article 16.

**Article 23**

**Transition from the 1998 Mutual Recognition Agreement**

1. Annexes on [Telecommunication Equipment and Electromagnetic Compatibility] Electrical Safety, Recreational Craft, and Medical Devices of the 1998 Mutual Recognition Agreement shall be terminated upon entry into force of this Agreement.

2. The Annex on Pharmaceutical Good Manufacturing Practices (GMPs), of the 1998 Mutual Recognition Agreement shall be preserved and shall not be terminated upon entry into force of this Agreement.

3. A conformity assessment body which was designated under the 1998 Mutual Recognition Agreement (MRA) for a sector, product or process that is covered by a category listed in Annex 1 or 2 of this Agreement shall continue to constitute a recognised conformity assessment body for the purposes of this Agreement. Conformity assessment results by such bodies falling under the scope of the MRA shall remain valid in accordance with the applicable legislation.

**Article 24**

**Private rights**

1. Nothing in this Agreement shall be construed as conferring rights or imposing obligations on persons other than those created between the Parties under public international law, nor as permitting this Agreement to be directly invoked in the domestic legal systems of the Parties.

2. A Party shall not provide for a right of action under its domestic law against the other Party on the ground that a measure of the other Party is inconsistent with this Agreement.
Article 25

Transparency

1. Each Party shall publish and keep updated in a single website:
   (a) a list of the relevant domestic legislation for the purposes of Annex 1 and Annex 2 or any additional Annex adopted by the Joint Committee in accordance with Article 3(2); and
   (b) if not included in the relevant domestic legislation published in accordance with subparagraph (a), an overview of the requirements to recognise conformity assessment bodies of the other Party in the areas under the scope of this Agreement.

2. Each Party shall publish and keep updated a single list of recognised conformity assessment bodies specifying the scope of the recognition. The European Commission will assign an identification number to conformity assessment bodies established in the United States that are recognised under this Agreement, and list those conformity assessment bodies in the European Union’s electronic information system.

3. In the cases in which a recognized EU conformity assessment body is ceased to be recognized by the United States on the basis of concerns regarding its technical competence and removed from the list to be published by the United States in accordance with paragraph 2, the United States shall immediately notify the European Union and shall provide the reasons for such a decision. The Parties shall cooperate to resolve any questions or concerns from the European Union regarding cessation of recognition of the EU conformity assessment body.

Article 26

Duration

This Agreement is concluded for an unlimited period.
Article 27

Termination

1. This Agreement shall be terminated on [3 years after the conclusion of the Agreement] if the United States have not completed the necessary rule-making processes to effectively implement Article 13.

2. Either Party may notify the other Party of its intention to terminate this Agreement in its entirety or in respect of an individual category listed in the Annexes. The termination shall take effect six months after the date of the notification.

3. Following termination of the Agreement in its entirety or any individual category 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 under this Agreement.

Article 28

Annexes, appendices, protocols and notes, footnotes and joint declarations

The Annexes, Appendices, Protocols and Notes, Footnotes and Joint Declarations to this Agreement constitute integral parts thereof.

Article 29

Authentic texts

This Agreement is drawn up in duplicate in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages, each text being equally authentic.
ANNEX 1

Coverage in accordance with Article 3 (1)(a)
for which a Party recognizes non-governmental bodies for the purpose of assessing conformity of products with that Party’s technical regulations

(a) Electrical and electronic equipment, including electrical installations and appliances, and related components;
(b) Radio and telecommunications terminal equipment;
(c) Electromagnetic compatibility (EMC);
(d) Toys;
(e) Construction products;
(f) Machinery, including parts, components, including safety components, interchangeable equipment, and assemblies of machines;
(g) Measuring instruments, including non-automatic weighing instruments;
(h) Hot-water boilers, including related appliances;
(i) Equipment, machines, apparatus, devices, control components, protection systems, safety devices, controlling devices and regulating devices, and related instrumentation and prevention and detection systems for use in potentially explosive atmospheres (ATEX equipment);
(j) Equipment for use outdoors as it relates to noise emission in the environment;
(k) Recreational craft, including their components, and personal watercraft;
(l) Pressure equipment, including vessels, piping, accessories and assemblies;
(m) Appliances burning gaseous fuels, including related fittings;
(n) Personal protective equipment;
   (po) Equipment placed on board a ship.
(qp) Restriction of hazardous substances in electrical and electronic equipment.
(q) Pyrotechnic articles
(r) Explosives for civil uses
(s) Simple pressure vessels
(t) Lifts
(u) Cableway installations
ANNEX 2

Coverage in accordance with Article 3 (1)(b)

Areas where a Party requires market authorization by a governmental body, while the other Party requires third-party conformity assessment

Medical devices, including accessories
ANNEX 3

INFORMATION TO BE INCLUDED AS PART OF A DESIGNATION

The information that a Party must provide when designating a conformity assessment body is as follows:

(i) the scope of designation (not to exceed that body’s scope of accreditation);

(ii) the accreditation certificate and the related scope of accreditation;

(iii) the body’s address and contact information.