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European Union

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#### **LEGISLATIVE ACTS AND OTHER INSTRUMENTS**

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Subject: Amending Protocol to the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to Conformity Assessment

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AMENDING PROTOCOL  
TO THE AGREEMENT  
BETWEEN THE EUROPEAN COMMUNITY  
AND THE SWISS CONFEDERATION  
ON MUTUAL RECOGNITION  
IN RELATION TO CONFORMITY ASSESSMENT

THE EUROPEAN UNION, hereinafter referred to as the "Union",

and

THE SWISS CONFEDERATION, hereinafter referred to as "Switzerland",

hereinafter referred to as the "Contracting Parties",

HAVING REGARD to the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment, done in Luxembourg on 21 June 1999, which entered into force on 1 June 2002 (hereinafter referred to as the "Agreement");

WHEREAS a broad bilateral package, including the Institutional Protocol to this Agreement, has been agreed between the Contracting Parties in order to stabilise and develop mutual relations in the fields related to the internal market in which Switzerland participates;

WHEREAS, in the framework of that broad bilateral package, it is necessary to update certain provisions of the Agreement,

HAVE AGREED AS FOLLOWS:

## ARTICLE 1

### Amendments to the Agreement

The Agreement is amended as follows:

- (1) Article 1 is replaced by the following:

#### "ARTICLE 1

##### Purpose

1. The Community and Switzerland hereby grant mutual acceptance of reports, certificates, authorisations and conformity marks issued by the bodies recognised in accordance with the procedures of this Agreement (hereinafter "recognised conformity assessment bodies") and of the manufacturer's declarations of conformity certifying conformity to the requirements of the other Party with regard to products under Chapter 11, Section I, point A, of Annex 1 at the time of entry into force of the amending Protocol to this Agreement.
2. In order to avoid duplication of procedures, the Community and Switzerland shall mutually accept reports, certificates and authorisations issued by recognised conformity assessment bodies and manufacturer's declarations of conformity certifying conformity to their respective requirements in the areas covered by Article 3.

Reports, certificates, authorisations and manufacturer's declarations of conformity shall indicate conformity with the Community legislation and may refer to the corresponding Swiss provisions adopted or maintained pursuant to Article 5(2) of the Institutional Protocol. Conformity marks required by the legislation of one of the Parties shall be affixed to products placed on the market of that Party.";

(2) Article 3 is replaced by the following:

"ARTICLE 3

Scope

1. This Agreement covers the obligatory conformity assessment procedures ensuing from the legislative, regulatory and administrative provisions listed in Annex 1 to this Agreement and, as regards provisions covered by Article 1(2), the corresponding Swiss provisions adopted or maintained in accordance with Article 5(2) of the Institutional Protocol.

2. Annex 1 defines the product sectors covered by this Agreement. Annex 1 is divided up into sectoral chapters and these are subdivided in principle as follows:

Section I: Legislative, regulatory and administrative provisions;

Section II: Conformity assessment bodies;

Section III: Designating authorities;

Section IV: Special rules relating to the designation of conformity assessment bodies;

Section V: Any additional provisions.

3. Annex 2 sets out general rules applicable to the designation of conformity assessment bodies.";

(3) Article 9 is replaced by the following:

"ARTICLE 9

Implementation of the Agreement

1. The Parties shall cooperate with a view to ensuring the satisfactory application of the legislative, regulatory and administrative provisions listed in Annex 1 to this Agreement and, as regards provisions covered by Article 1(2), the corresponding Swiss provisions adopted or maintained in accordance with Article 5(2) of the Institutional Protocol to this Agreement.

2. The designating authorities shall ascertain by appropriate means whether the recognised conformity assessment bodies under their jurisdiction are observing the general principles of designation listed in Annex 2, subject to the provisions listed in the respective section IV in Annex 1.

3. The recognised conformity assessment bodies shall cooperate in an appropriate way in the framework of the coordination and comparison work conducted by each of the Parties in respect of the sectors covered by Annex 1 in order to ensure that the conformity assessment procedures provided for in the laws and regulations of the Parties covered by this Agreement are applied in a consistent manner. The designating authorities shall use their best endeavours to ensure that recognised conformity assessment bodies cooperate in an appropriate way.";

(4) Article 10 is replaced by the following:

"ARTICLE 10

Joint Committee

1. A Joint Committee (hereinafter referred to as "the Committee") is hereby established.

The Committee shall be composed of representatives of the Parties.

2. The Committee shall be co-chaired by a representative of the Union and a representative of Switzerland.

3. The Committee shall:

(a) ensure the proper functioning and the effective administration and application of this Agreement;

- (b) provide a forum for mutual consultation and a continuous exchange of information between the Parties, in particular with a view to finding a solution to any difficulty of interpretation or application of this Agreement or of a legal act of the Union to which reference is made in this Agreement in accordance with Article 10 of the Institutional Protocol to this Agreement;
- (c) make recommendations to the Parties in matters pertaining to this Agreement;
- (d) adopt decisions where provided for in this Agreement and adopt, on the proposal by one of the Parties, a decision to add chapters to Annex 1 to this Agreement; and
- (e) be responsible for:
  - (i) drawing up the procedure for carrying out the verifications provided for in Article 7;
  - (ii) drawing up the procedure for carrying out the verifications provided for in Article 8;
  - (iii) deciding on the recognition of conformity assessment bodies contested under Article 8;
  - (iv) deciding on the withdrawal of recognition of recognised conformity assessment bodies contested under Article 8; and
  - (v) where necessary to ensure coherence, upon proposal by one of the Parties, adopt a decision to modify Annex 2.

4. The Committee shall act by consensus.

Decisions shall be binding on the Parties, which shall take all necessary measures to implement them.

5. The Committee shall meet at least once a year, in Brussels and Bern alternately, unless the co-chairs decide otherwise. It shall also meet at the request of either Party.

The co-chairs may agree that a meeting of the Committee be held by videoconference or teleconference.

6. The Committee shall adopt its rules of procedure and update them as necessary.

7. The Committee may decide to set up any working party or group of experts that can assist it in carrying out its duties.";

(5) Article 11 is replaced by the following:

"ARTICLE 11

Recognition, withdrawal of recognition, modification of the scope, and suspension of conformity assessment bodies

1. The following procedure shall apply for the recognition of conformity assessment bodies in relation to the requirements set out in the relevant Chapters of Annex 1 to this Agreement and, as regards provisions covered by Article 1(2), the corresponding Swiss provisions adopted or maintained in accordance with Article 5(2) of the Institutional Protocol to this Agreement:

- (a) A Party wishing to have recognised any conformity assessment body shall notify the other Party in writing of its proposal, to that effect, adding the appropriate information to its request.
- (b) If the other Party agrees to the proposal or raises no objection within 60 days of the notification of the proposal, the conformity assessment body shall be considered to be a recognised conformity assessment body under the terms of Article 5.
- (c) If the other Party raises objections in writing within that 60-day period referred to in point (b), Article 8 shall apply.

2. A Party can withdraw or suspend the recognition or remove the suspension of recognition of a conformity assessment body under its jurisdiction. The Party concerned shall immediately notify the other Party of its decision in writing, together with the date of such decision. The withdrawal, suspension, or removal of suspension shall take effect at that date. Such withdrawal or suspension shall be indicated in the common list of recognised conformity assessment bodies referred to in Annex 1.

3. A Party can propose that the scope of activity of a recognised conformity assessment body under its jurisdiction be amended. For scope extensions and scope reductions, the procedures provided for in Article 11(1) and (2), respectively, shall apply.

4. A Party can, in exceptional circumstances, contest the technical competence of a recognised conformity assessment body under the jurisdiction of the other Party. In this case Article 8 shall apply.

5. Reports, certificates, authorisations and conformity marks issued by a conformity assessment body after the date at which its recognition has been withdrawn or suspended need not be recognised by the Parties. Reports, certificates, authorisations and conformity marks issued by a conformity assessment body before the date its recognition has been withdrawn shall continue to be recognised by the Parties, unless the responsible designating authority has limited or cancelled their validity. The Party under whose jurisdiction the responsible designating authority is operating shall notify the other Party in writing of any such changes relating to a limitation or cancellation of validity.";

(6) Article 12 is repealed;

(7) Article 13 is replaced by the following:

"ARTICLE 13

Professional Secrecy

1. Representatives, experts and other agents of the Parties shall be required, even after their duties have ceased, not to disclose information acquired under this Agreement which is of the kind covered by the obligation of professional secrecy. This information may not be used for purposes other than those envisaged by this Agreement.

2. Technical adaptations of the relevant chapters of Annex 1 may set out specific provisions for the protection of information as referred to in paragraph 1 of this Article.";

(8) the following Article is inserted:

"ARTICLE 13bis

Classified information and sensitive non-classified information

1. Nothing in this Agreement shall be construed as requiring a Party to make available classified information.

2. Classified information or material provided by, or exchanged between, the Parties under this Agreement shall be handled and protected in compliance with the Agreement between the Swiss Confederation and the European Union on the security procedures for the exchange of classified information, done at Brussels on 28 April 2008, and any security arrangement implementing it.

3. The Committee shall adopt, by means of a decision, handling instructions to ensure the protection of sensitive non-classified information exchanged between the Parties.";

(9) Article 17 is replaced by the following:

"ARTICLE 17

Territorial application

This Agreement shall apply, of the one part, to the territory in which the Treaty on European Union and the Treaty on the Functioning of the European Union apply and under the conditions laid down in those Treaties, and, of the other part, to the territory of Switzerland."

## ARTICLE 2

### Amendments to Annex 1

Annex 1 is amended as follows:

- (1) the following text is inserted after the list of chapters:

"GENERAL PROVISIONS

#### ARTICLE 1

Unless otherwise provided for in technical adaptations, rights and obligations provided for in the legal acts of the Union integrated into this Annex for Member States of the Union shall be understood to be provided for for Switzerland. This shall be applied in full compliance with the Institutional Protocol to this Agreement. For the purposes of clarity, given the specificities of this Agreement, the foregoing shall only apply where those rights and obligations fall under the scope of this Agreement.

#### ARTICLE 2

1. Where a Member State of the Union is to submit information to the European Commission (hereinafter referred to as the 'Commission'), Switzerland shall submit such information to the Commission via the Committee. Where the Commission is to submit information to one or more Member States of the Union, where Switzerland is concerned, the Commission shall submit such information to Switzerland via the Committee, unless otherwise provided for in technical adaptations to the relevant chapters of this Annex.

2. Where the competent authorities of the Member States of the Union are to submit information to the competent authorities of another Member State of the Union, they shall also submit that information to the competent authorities of Switzerland while informing the Commission, unless otherwise provided for in technical adaptations to the relevant chapters of this Annex. The competent authorities of Switzerland shall submit information to the competent authorities of the Member States of the Union and inform the Commission thereof.
3. The Committee can, by means of technical adaptations to the relevant chapters of this Annex, agree on appropriate solutions providing for the direct exchange of information in areas where the rapid transfer of information is necessary.
4. Paragraphs 1 and 2 are without prejudice to the sector-specific rules and arrangements applicable to the exchange of information by means of information systems.

### ARTICLE 3

Where a legal act of the Union set out in this Annex requires the competent authorities of the Member States of the Union or the economic operators in the Member States of the Union to provide information or data by means of digital tools, and where it is relevant for the implementation of this Agreement, each relevant chapter of this Annex shall establish whether the Swiss competent authorities and the economic operators in Switzerland may provide such information and/or data by using the relevant Swiss interface. Where a chapter in this Annex allows for the use of such interface, the extent and conditions of such use shall be agreed and established in the same chapter.

## ARTICLE 4

1. Whenever the legal acts of the Union set out in this Annex, or the corresponding Swiss provisions adopted or maintained in accordance with Article 5(2) of the Institutional Protocol to this Agreement, assign obligations to economic operators, persons or entities established in the Union or Switzerland, respectively, the obligations can, when it is relevant for the purposes of the implementation of this Agreement, also be fulfilled by economic operators, persons or entities established in Switzerland or in the Union, respectively, unless otherwise provided for in technical adaptations to the relevant chapters of this Annex.

2. Whenever the legal acts of the Union set out in this Annex or the corresponding Swiss provisions adopted or maintained in accordance with Article 5(2) of the Institutional Protocol to this Agreement, provide that an item of information is to be made available to the competent authorities of a Party by an economic operator, person or entity as referred to in paragraph 1 of this Article, those authorities may contact the competent authorities of the other Party or enter into direct contact with the economic operators, persons or entities in the territory of the other Party, in order to obtain that information.";

- (2) in Chapter 4, the following sentence will be inserted in a position to be determined when the technical work is carried out by the Contracting Parties:

"For the purpose of clarity, Switzerland will participate as an observer in the Committee on Medical Devices and in the Medical Device Coordination Group (MDCG) established by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p.1), in accordance with the relevant rules of procedure.";

(3) Chapter 5 is amended as follows:

(i) the following paragraph is inserted after the title:

"This Chapter covers the appliances burning gaseous fuels as defined in Regulation (EU) 2016/426, which is listed under point 1 of Section I of this Chapter, as well as the energy efficiency and emissions requirements relating to hot-water boilers fired with liquid or gaseous fuels as defined in Directive 92/42 CEE, which is listed under point 2 of Section I of this Chapter.";

(ii) Section I is replaced by the following:

"Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

- |                |  |
|----------------|--|
| European Union | <ol style="list-style-type: none"><li>1. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99).</li><li>2. Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (OJ L 167, 22.6.1992, p. 17), as last amended by Commission Regulation (EU) No 813/2013 of 2 August 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for space heaters and combination heaters (OJ L 239, 6.9.2013, p. 136).";</li></ol> |
|----------------|--|

(4) in Chapter 11, Section I is replaced by the following:

"Section I

Legislative, regulatory and administrative provisions

A. Provisions covered by Article 1(1)

- |                |      |   |
|----------------|------|---|
| European Union | 1.   | Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC (OJ L 247, 21.9.2007, p. 17) applicable as from 11 April 2009. |
| Switzerland    | 100. | Ordinance of 5 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RS 941.204), as subsequently amended.   |
|                | 101. | Ordinance of the Federal Ministry of Justice and Police of 10 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RS 941.204.1), as subsequently amended.  |

## B. Provisions covered by Article 1(2)

- European Union
1. Directive 2009/34/EC of the European Parliament and of the Council of 23 April 2009 relating to common provisions for both measuring instruments and methods of metrological control (OJ L 106, 28.04.2009, p. 7).
  2. Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers (OJ L 42, 15.2.1975, p. 14).
  3. Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making up by weight or by volume of certain prepackaged products (OJ L 46, 21.2.1976, p. 1).
  4. Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40) as last amended by Directive 2009/3/EC of the European Parliament and of the Council of 11 March 2009 (OJ L 114, 7.5.2009, p. 10).
  5. Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.3.2014, p. 107).
  6. Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96, 29.3.2014, p. 149).
  7. Directive 2011/17/EU of the European Parliament and of the Council of 9 March 2011 repealing Council Directives 71/317/EEC, 71/347/EEC, 71/349/EEC, 74/148/EEC, 75/33/EEC, 76/765/EEC, 76/766/EEC and 86/217/EEC regarding metrology (OJ L 71, 18.3.2011, p. 1).";

- (5) in Chapter 15, the following sentence will be inserted in a position to be determined when the technical work is carried out by the Contracting Parties:

"Notwithstanding Article 4 of the Institutional Protocol to this Agreement, Switzerland shall not participate in, and Switzerland's experts shall not be consulted on, the preparation of the proposals and drafts referred to therein relating to the development, manufacture, placing on the market and use of medicinal products including, in the context of procedures related to medicinal products. The application by Switzerland of the relevant provisions of the legal acts of the Union listed in this Section, pursuant to Article 1 of Annex 1 to this Agreement, shall not give the right to Switzerland to participate in the European Medicines Agency with the exception of participation as an observer in the meetings of GMDP Inspectors Working Group, in accordance with relevant rules of procedure."

### ARTICLE 3

#### Entry into force

1. This Protocol shall be ratified or approved by the Contracting Parties in accordance with their own procedures. The Contracting Parties shall notify each other of the completion of the internal procedures necessary to the entry into force of this Protocol.
2. This Protocol shall enter into force on the first day of the second month following the last notification regarding the following instruments:
  - (a) Institutional Protocol to the Agreement between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons;

- (b) Amending Protocol to the Agreement between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons;
- (c) Institutional Protocol to the Agreement between the European Community and the Swiss Confederation on air transport;
- (d) Amending Protocol to the Agreement between the European Community and the Swiss Confederation on air transport;
- (e) State Aid Protocol to the Agreement between the European Community and the Swiss Confederation on air transport;
- (f) Institutional Protocol to the Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road;
- (g) Amending Protocol to the Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road;
- (h) State Aid Protocol to the Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road;
- (i) Amending Protocol to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products;
- (j) Institutional Protocol to the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment;

- (k) Agreement between the European Union and the Swiss Confederation on Switzerland's regular financial contribution towards reducing economic and social disparities in the European Union;
- (l) Agreement between the European Union and the European Atomic Energy Community, of the one part, and the Swiss Confederation, of the other part, on the participation of the Swiss Confederation in Union programmes;
- (m) Agreement between the European Union and the Swiss Confederation on the terms and conditions for the participation of the Swiss Confederation in the European Union Agency for the Space Programme.

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

IN WITNESS WHEREOF, the undersigned, duly authorised thereto, have signed this Protocol.

Done at ... this day of ... in the year ...

For the European Union

For the Swiss Confederation