(RS 0.946.536.71) (Consolidated unofficial version)

## Agreement

### between the Swiss Confederation and the United Kingdom of Great Britain and Northern Ireland on mutual recognition in relation to conformity assessment

Text as of 17 November 2022

The Swiss Confederation («Switzerland») and the United Kingdom of Great Britain and Northern Ireland («the United Kingdom»),

together referred to as «the Parties».

Considering the close ties that exist between the Parties;

Considering the Trade Agreement between the Swiss Confederation and the United Kingdom of Great Britain and Northern Ireland of 11 February 2019;

Desiring to conclude an additional more ambitious agreement providing for the mutual recognition of the results of conformity assessment procedures required for access to the respective markets of the Parties for certain product sectors;

Considering that mutual recognition in relation to conformity assessment will facilitate trade between the Parties and ensure protection for health, safety, the environment and consumers; in full respect of regulatory procedures of the Parties as well as of the applicable levels of protection;

Considering that comparable legal frameworks facilitate mutual recognition;

Considering their obligations as Contracting Parties to the Agreement establishing the World Trade Organization and, in particular, to the Agreement on Technical Barriers to Trade, which encourages the negotiation of mutual recognition agreements;

Considering that mutual recognition agreements can contribute to harmonisation at international level of standards and technical regulations;

Considering that the close ties between the Parties make the conclusion of further agreements between the Parties appropriate;

have agreed as follows:

### Art. 1 Purpose

<sup>1</sup> The Parties hereby grant mutual acceptance of reports, certificates and other results of conformity assessment procedures issued by the bodies recognised in accordance with the procedures of this Agreement certifying conformity to the requirements of the other Party in the areas covered by Article 3.

<sup>2</sup> Conformity marks required by the legislation of one of the Parties must be affixed to products placed on the market of that Party.

<sup>3</sup> This Agreement may provide in Annex I for facilitations regarding the obligations of economic operators set out in the relevant legislative, regulatory and administrative provisions of the relevant Section I in Annex I.

<sup>4</sup> This Agreement shall not entail mutual acceptance of the standards or technical regulations of the Parties or mutual recognition of the equivalence of standards or technical regulations.

<sup>5</sup> 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 WTO Agreement of 15 April 1994 on Technical Barriers to Trade.

## Art. 2 Definitions

<sup>1</sup> For the purposes of this Agreement:

«Economic operator» shall mean the manufacturer, the authorised representative, the importer, the distributor, the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant legislative, regulatory and administrative provisions in the relevant Section I in Annex I.

«National accreditation body» shall mean the sole body in a Party that performs accreditation with authority derived from the Party where it is established to verify and confirm the technical competence of bodies to assess the conformity with the other Party's designated standards and technical regulations for the relevant product sector laid down in the legislative, regulatory and administrative provisions referred to in the relevant Section I in Annex I.

«Accreditation» shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by international standards and, where applicable, any additional requirements including those set out in the legislative, regulatory and administrative provisions referred to in the relevant Sections I and II in Annex I, to carry out a specific conformity assessment activity.

«European co-operation for Accreditation» shall mean the body who supports and enables National Accreditation Body Members to share and build within Europe and among the Mediterranean States a common body of knowledge to develop a sound and harmonised approach to accreditation which is required to ensure that conformity assessment bodies have the technical capacity to perform their task.

«Conformity assessment» shall mean systematic examination to determine the extent to which a product, process or service fulfils specified requirements.

«Conformity assessment body» shall mean a body established in the territory of either Party that independently performs conformity assessment activities, including calibration, testing, certification or inspection.

«Joint Committee» (hereinafter referred to as the « Committee») shall mean the Committee composed of representatives of the Parties and responsible for the management and monitoring of the smooth functioning of this Agreement. «Designating authority» shall mean an authority responsible for the designation, suspension and withdrawal of conformity assessment bodies under its jurisdiction in accordance with Annex II.

«Market surveillance authority» shall mean an authority responsible for carrying out market surveillance in the Parties.

«Notifying authority» shall mean the single authority of a Party responsible for the notification of designated conformity assessment bodies to be recognised under this Agreement by the other Party.

«Technical regulation» shall mean a document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

 $^2$  The definitions laid down by ISO and IEC may be used to establish the meaning of the general terms relating to conformity assessment contained in this Agreement. In the event of an inconsistency between the definitions laid down by ISO and IEC, and definitions in this Agreement, the definitions in this Agreement shall prevail.

## Art. 3 Scope, structure and exceptions

<sup>1</sup> This Agreement covers the mandatory conformity assessment procedures ensuing from the legislative, regulatory and administrative provisions listed in Annex I.

<sup>2</sup> Annex I defines the product sectors covered by this Agreement. The Annex is divided up into sectoral chapters and these are subdivided as follows:

Section I:	legislative, regulatory and administrative provisions;
Section II:	conformity assessment bodies;
Section III:	designating authorities and authorities responsible for market surveillance information sharing;
Section IV:	special rules relating to the designation of conformity assessment bodies;
Section V:	supplementary provisions.

<sup>3</sup> Annex II sets out general rules applicable to the designation and the notification of conformity assessment bodies.

<sup>4</sup> Annex III sets out general rules applicable to accreditation bodies.

<sup>5</sup> This Agreement does not apply to motor vehicles and their components, to Good Laboratory Practice (GLP) and to Good Manufacturing Practice (GMP) inspection for medicinal products and batch certification as covered by the Trade Agreement between the Swiss Confederation and the United Kingdom of Great Britain and Northern Ireland of 11 February 2019.

## Art. 4 Origin

The provisions of this Agreement shall apply to products covered by this Agreement irrespective of their origin.

## Art. 5 Recognised conformity assessment bodies

The Parties hereby agree that conformity assessment bodies recognised in accordance with Article 6 fulfil the conditions of eligibility to assess conformity.

### Art. 6 Recognition of conformity assessment bodies

<sup>1</sup> 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 I:

- a. A Party wishing to have a designated conformity assessment body recognised shall notify the other Party in writing of its proposal to that effect, adding the information according to Annex II to its request.
- b. If the other Party agrees to the proposal or does not contest it within 60 days following the notification of the proposal, the conformity assessment body shall be considered a recognised conformity assessment body.
- c. If the other Party contests the proposal within 60 days following the notification of the proposal, or the designated conformity assessment body does not meet the conditions described in Annex II, the conformity assessment body shall not be considered a recognised conformity assessment body and the procedure set out in paragraphs 2 to 6 of Article 7 shall be followed. After the completion of verification, the proposal to list the conformity assessment body may be resubmitted to the other Party.

 $^{2}$  A Party can propose that the scope of activity of a recognised conformity assessment body under its jurisdiction be amended. The procedure provided for in paragraph 1 shall apply.

## Art. 7 Challenge and suspension of conformity assessment bodies

<sup>1</sup> Each Party shall have the right to contest the technical competence of a recognised conformity assessment body under the jurisdiction of the other Party.

<sup>2</sup> Any contestation shall be exercised in an objective and reasoned manner in writing to the other Party.

<sup>3</sup> Upon receipt of a written complaint by the contesting Party pursuant to paragraph 2, the other Party shall promptly:

- seek additional information from the conformity assessment body, market surveillance authorities, national accreditation body and economic operators, as relevant;
- b. investigate the complaint; and
- c. provide the other Party with a written reply to the complaint in order to refute the challenge or to correct the deficiencies which form the basis of the contestation.

<sup>4</sup> In the event of the challenge not being resolved following the procedure in paragraph 3, the disagreement shall be referred by the contesting Party to the Committee. Where the Committee decides that a verification of the technical competence of the conformity assessment body in question is required, this shall be undertaken jointly by the Parties in accordance with Annex II paragraph 6. <sup>5</sup> Each Party shall ensure that conformity assessment bodies under its jurisdiction are available for verification of their technical competence as required.

<sup>6</sup> The result of that verification shall be discussed in the Committee with a view to resolving the issue as soon as possible.

<sup>7</sup> Unless otherwise decided by the Committee, the disputed recognised conformity assessment body shall be suspended by the competent designating authority from the time disagreement has been established until agreement has been reached in the Committee. Suspension shall be indicated in the list of recognised conformity assessment bodies referred to in Article 14 paragraph 5.

<sup>8</sup> The suspension shall remain in effect until agreement has been reached by the Committee with respect to the future status of that conformity assessment body.

### Art. 8 Withdrawal of recognised conformity assessment bodies

<sup>1</sup> The designating authority of a Party shall withdraw designation of a recognised conformity assessment body where:

- a. the Committee, pursuant to Article 7 paragraph 8, agrees that the disputed body should be withdrawn;
- b. the challenge has not been resolved within 120 days after suspension under Article 7 paragraph 7;
- c. the conformity assessment body's accreditation lapses;
- d. the conformity assessment body ceases to qualify as a conformity assessment body because it is no longer established in the territory of the Party; or
- e. a Party has established that a conformity assessment body under its jurisdiction no longer meets the requirements laid down in Annex II, or that it is failing to fulfil its obligations according to the legislation in the relevant Section I in Annex I.

<sup>2</sup> The designating authority shall notify the other Party of the withdrawal immediately.

# Art. 9 Recognition of conformity assessment as well as treatment of files of a suspended or withdrawn conformity assessment body

<sup>1</sup> Reports, certificates and other results of conformity assessment procedures issued by a conformity assessment body after the date at which its designation has been withdrawn or suspended need not be recognised by the Parties. Reports, certificates and other results of conformity assessment procedures issued by a conformity assessment body before the date its designation has been suspended or 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 changes relating to a limitation or cancellation of validity.

 $^2$  In the event of suspension or withdrawal of a conformity assessment body, or where the conformity assessment body has ceased its activity, the designating Party shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible designating and market surveillance authorities at their request.

### Art. 10 Information exchange

<sup>1</sup> The Parties shall exchange all relevant information regarding implementation and application of the legislative, regulatory and administrative provisions listed in Annex I.

<sup>2</sup> Each Party shall notify changes to its designating, notifying and market surveillance authorities to the other Party in writing within 60 days after their implementation.

## Art. 11 Notification of regulatory change

<sup>1</sup> The Parties shall notify each other of any change to the legislative, regulatory and administrative provisions listed in Annex I at least 60 days before its entry into force. Any change shall be indicated and the Party making the change shall provide additional information identifying the reasons for the change. The Party making the change shall provide reasonable assistance to the other Party's designating authorities in identifying differences with its own legislative, regulatory and administrative provisions.

<sup>2</sup> The designating authorities of the Parties shall assess where necessary the impact of the differences on the functioning of this Agreement, taking into account, in particular, product safety and compliance, obligations of economic operators, conformity assessment bodies, as well as accreditation bodies and designating authorities.

<sup>3</sup> If a Party requires additional information beyond that provided under paragraphs 1 and 2 to understand the differences, it may submit the matter to the Committee in writing within a 30-day period from the notification described in paragraph 1.

<sup>4</sup> The Committee, where necessary, shall:

- a. update the legislative, regulatory and administrative provisions listed in Annex I following the notification referred to in paragraph 1;
- b. keep a list of any differences identified during the procedure referred to in paragraph 1.
- c. decide on the appropriate course of action to ensure the good functioning of the Agreement.

<sup>5</sup> The Parties shall review this Article in view of the inclusion of new sectors or in case the legislation in the relevant Section I in Annex I changes substantially; in the latter case the review shall take place within a year after the entry into force of the change.

### Art. 12 Missing notification of regulatory change

<sup>1</sup> If a Party has reasons to believe that the other Party has failed to notify a change in its legislation, it may request the missing notification from the other Party. The other Party shall promptly provide the missing notification in accordance with Article 11 or indicate the reasons for the absence of notification.

<sup>2</sup> The Committee shall be informed of any missing notifications.

<sup>3</sup> Where the requesting Party considers a notification necessary and notification is not subsequently submitted in accordance with paragraph 1, evidence from the competent authority of the other Party shall be submitted to the Committee within 30 days from the request under paragraph 1 to determine that the notification was not necessary.

The Committee shall decide within 30 days following the notification according to this paragraph 3.

<sup>4</sup> Whenever a Party has failed to notify three times in a product sector – unless the Committee has confirmed that the notification was not necessary – the application of the impacted Chapter of Annex I shall be considered suspended, unless otherwise agreed by the Committee.

## Art. 13 Designating authorities

<sup>1</sup> The Parties shall ensure that designating authorities do not have a conflict of interest with conformity assessment bodies they designate. The Parties shall ensure that their designating authorities have the necessary power, competence and sufficient number of competent personnel to designate conformity assessment bodies or withdraw designation, suspend or remove suspension of designated conformity assessment bodies under their respective jurisdiction.

<sup>2</sup> For the designation of conformity assessment bodies, the designating authorities shall ensure compliance with the requirements for designation set out in Annex II, subject to the provisions of the relevant Section IV in Annex I. These designating authorities shall observe the same principles when withdrawing designation, suspending or removing suspension.

## Art. 14 Notifying authorities

<sup>1</sup> The Parties shall appoint a single authority responsible for notifying designated conformity assessment bodies.

<sup>2</sup> The notifying authorities shall exchange upon request in writing information concerning the procedures used to ensure that recognised conformity assessment bodies under their jurisdiction comply with the general principles of designation outlined in Annex II subject to the provisions of the relevant Section IV in Annex I.

<sup>3</sup> The notifying authorities shall compare methods used to verify conformity of the bodies with the general principles of designation outlined in Annex II, subject to the provisions of the relevant Section IV in Annex I.

<sup>4</sup> Following the recognition of a conformity assessment body by the other Party, the designating Party shall ensure that the information described in Annex II is kept up to date and shall re-notify such information to the other Party in due time and before the expiry of the accreditation certificate of the recognised conformity assessment body.

<sup>5</sup> Each Party shall publish and keep updated in a single website a list of conformity assessment bodies it recognises under this Agreement specifying the scope of the recognition.

## Art. 15 Cooperation of market surveillance authorities with economic operators

<sup>1</sup> If they differ from the designating authority, the competent market surveillance authority shall be listed in Annex I in the relevant Chapter. Amendments shall be notified to the other Party within 60 days.

<sup>2</sup> The competent national market surveillance authority of a Party may, on reasoned request, ask the relevant economic operators in the other Party to provide all information and documentation necessary to demonstrate the conformity of a product with the legislation in Annex I, Section I of the corresponding Chapter.

<sup>3</sup> That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request economic operators to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the product or any non-compliance.

## Art. 16 Mutual assistance of market surveillance authorities

<sup>1</sup> The Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of the Parties shall cooperate. They shall give each other assistance on an adequate scale for the purposes of market surveillance by supplying information or documentation on products, including concerning economic operators based in the United Kingdom or in Switzerland.

<sup>2</sup> Where the market surveillance authorities of a Party have found that a product covered by this Agreement does not comply with requirements laid down in its legislation in Annex I, Section I of the corresponding Chapter, they may take all appropriate measures and if they consider that the product's non-compliance may also extend to or originate from the other Party, they shall inform the market surveillance authority of the other Party without undue delay taking into account the risk presented by the product. Information shall include available details, in particular:

- the data necessary for the identification of the non-compliant product;
- the product's origin;
- the nature of the non-compliance alleged and the risk involved;
- the nature and duration of the national measures taken;
- the arguments put forward by the relevant economic operator;
- the results of the evaluation and of the actions which they have required the economic operator to take; and
- any appropriate measures taken to prohibit or restrict the products being made available on their national market, to withdraw the product from that market or to recall it.

<sup>3</sup> The other Party shall ensure that appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of the product from their market, without delay.

<sup>4</sup> Should either Party disagree with the national measure in paragraph 2, it shall inform the Committee of its objections within three months of the receipt of the information.

Where objections are raised by a Party against a measure taken by the other Party, the Committee shall without delay review the national measure. The Committee shall also consult the relevant market surveillance authorities to facilitate transparency and the finding of mutually acceptable solutions.

If following these discussions the objecting Party still disagrees with the national measure, this disagreement shall be added to the list of differences referred to in Article 11 paragraph 4. This shall not prevent the market surveillance authorities from taking the national measure.

<sup>5</sup> Where the market surveillance authority of the United Kingdom or Switzerland finds that, although a product that an economic operator has made available on the United Kingdom and on the Swiss market is in compliance with the legislation referred to in Annex I, Section I of the corresponding Chapter, it nevertheless presents a risk for the health or safety of persons or animals, property, environment or national security, it may take all appropriate measures and shall immediately inform the Committee and the relevant market surveillance authority of the other Party. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

Where objections are raised by a Party against a measure taken by the other Party, that Party may forward the issue to the Committee pursuant to paragraph 4.

<sup>6</sup>Nothing in this Article shall require the Parties to disclose information regarding sensitive personal data, in particular data in relation to ongoing administrative or criminal proceedings and sanctions.

### Art. 17 Joint Committee

<sup>1</sup>A Joint Committee («Committee») is hereby established. It shall be composed of representatives of the Parties. It shall be responsible for the management and monitoring of the good functioning of this Agreement. To that end, it shall issue recommendations and take decisions in the circumstances provided for in this Agreement. It shall adopt its decision by mutual agreement.

<sup>2</sup> The Committee shall establish its own rules of procedure, which shall include provisions on the convening of meetings, the appointment of the chairman and the chairman's term of office.

<sup>3</sup> The Committee shall meet as and when necessary and at least once a year unless the Parties agree otherwise. Either Party may request the convening of a meeting. The Committee may meet in person or by other means.

<sup>4</sup> The Committee may consider any matter related to this Agreement. In particular, it shall be responsible for:

- a. deciding on verification and the future status of conformity assessment bodies in accordance with Article 7;
- b. taking the necessary action in accordance with Article 11;
- c. verifying and deciding on missing notifications in accordance with Article 12;
- d. consulting with market surveillance authorities on mutual assistance in accordance with Article 16;
- e. considering disputes in accordance with Article 20.

<sup>5</sup> The Committee may modify the Annexes to this Agreement.

### Art. 18 Confidentiality

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. Information exchanged among the Parties may not be used for purposes other than those envisaged by this Agreement.

### Art. 19 Implementation of the Agreement

<sup>1</sup> The Parties shall cooperate with a view to ensuring the satisfactory application of the legislative, regulatory and administrative provisions listed in Annex I.

 $^2$  The designating authorities shall ascertain that recognised conformity assessment bodies under their jurisdiction are observing the general principles of designation listed in Annex II, subject to the provisions listed in the relevant Section IV in Annex I.

<sup>3</sup> The recognised conformity assessment bodies may be requested to cooperate to ensure the good functioning of this Agreement.

### Art. 20 Dispute settlement

Each Party may refer any dispute relating to the interpretation or application of this Agreement to the Committee. The Committee shall endeavour to settle the dispute and must be supplied with any information which may facilitate a thorough examination of the situation with a view to finding an acceptable solution. For that purpose, the Committee shall consider every possible means of maintaining the good functioning of this Agreement.

### Art. 21 Agreements with third countries

<sup>1</sup> The Parties hereby agree that mutual recognition agreements concluded by either Party with a country that is not party to this Agreement shall in no circumstances entail an obligation upon the other Party in terms of the acceptance of reports, certificates or other results of conformity assessments issued by conformity assessment bodies in that third country, unless there is an explicit agreement between the Parties.

<sup>2</sup> Upon request of a Party, the Parties shall without undue delay negotiate an arrangement extending to each other treatment related to this Agreement that each Party has granted to a third Party.

### Art. 22 Annexes

The Annexes to this Agreement constitute integral parts thereof.

### Art. 23 Territorial application

1 This Agreement shall apply to the territory of the United Kingdom, and to the territory of Switzerland, in accordance with international law.

<sup>2</sup> For as long as the Protocol on Ireland/Northern Ireland to the Agreement on the Withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, signed in London and

Brussels on 24 January 2020 (the «Protocol») is in force, nothing in this Agreement shall preclude the United Kingdom from adopting or maintaining measures, or refraining from doing so, further to the Protocol, and amendments thereto and subsequent agreements replacing parts thereof, provided that such measures, or the absence of such measures, are not used as a means of arbitrary or unjustified discrimination against the other Party or as a disguised restriction on trade.

## Art. 24 Review

The Parties shall commence a review of this Agreement no later than one year after its entry into force with a view to considering the addition of further product sectors.

### Art. 25 Amendment and modification

<sup>1</sup> The Parties may agree, in writing, to amend this Agreement. An amendment made under this Article shall enter into force on the first day of the second month following the later of the Parties' notifications that they have completed their respective internal procedures, or on such other date as the Parties may agree.

<sup>2</sup> The Committee may modify the Annexes to this Agreement according to Article 17.

### Art. 26 Suspension

Where a Party establishes that the other Party fails to comply with the conditions of this Agreement, it may, after consulting the Committee, suspend the application of the impacted chapters of Annex I in full or in part. Suspension shall be indicated on the lists referred to in Article 14 paragraph 5.

### Art. 27 Safeguard clause

A Party that has challenged the competence of a recognised conformity assessment body in accordance with Article 7, may refuse to accept the results of that body's conformity assessment activities where there is an urgent risk for the health or safety of persons or to animals or property until the challenge is resolved.

2 Notwithstanding Article 9 paragraph 1, a Party that no longer recognises reports, certificates and other results of conformity assessment procedures issued by a conformity assessment body may refuse to accept the results of that body's conformity assessment activities, before the date its recognition was suspended or withdrawn, where that Party can demonstrate that there is an urgent risk for the health or safety of persons or to animals or property.

### Art. 28 Acquired rights

1 The Parties shall continue to recognise reports, certificates and other results of conformity assessments issued in accordance with, and prior to the expiry of, this Agreement, provided that the request for conformity evaluation was made before the notice of non-renewal or denunciation was given.

2 In the sectors covered by this Agreement, the Parties shall continue to recognise reports, certificates and other results of conformity assessments issued in accordance with the measures in place from 31 December 2020 to 31 December 2022 until their expiry, in line with the provisions of this Agreement.

#### Art. 29 Entry into force and duration

1 This Agreement shall be ratified or approved by the Parties in accordance with their own procedures. It shall enter into force on the 1<sup>st</sup> of January 2023 or on the date of receipt of the later of the Parties' notifications confirming completion of their internal procedures, whichever is the later.

2 This Agreement shall be concluded for an initial period of three years. Either party may request in writing at least 6 months before the expiration of that initial period the extension of this Agreement.

<sup>3</sup> Notwithstanding paragraph 2, the United Kingdom or Switzerland may denounce this Agreement in full or in part by a six months' written notice to the other Party.

#### Art. 30 Provisional application

<sup>1</sup> Pending its entry into force, the United Kingdom and Switzerland may agree to provisionally apply this Agreement by an exchange of notes through diplomatic channels. Provisional application shall take effect on the day following the later of the Parties' notes and terminate on the 28<sup>th</sup> of February 2023 or the date of entry into force of the Agreement further to Article 29 paragraph 1, whichever is the earlier.

2 Where this Agreement is provisionally applied, the term «entry into force of this Agreement» in any provisionally applied provisions shall be deemed to refer to the date that such provisional application takes effect.

In witness whereof the undersigned, duly authorised thereto by their respective Governments, have signed this Agreement.

Done at London, on the 17<sup>th</sup> of November 2022, in two originals, each in the English and French languages, both texts being equally authentic. In the event of inconsistency, the English language text shall prevail.

On behalf of the Swiss Confederation

On behalf of the United Kingdom of Great Britain and Northern Ireland

Markus Leitner

Amanda Brooks

## **Product sectors**

This Annex is divided up into the following Chapters by sector:

- Chapter 1 Electrical equipment and electromagnetic compatibility
- Chapter 2 Measuring instruments
- Chapter 3 Radio equipment
- Chapter 4 Transportable pressure equipment
- Chapter 5 Noise emitting equipment for use outdoors

## Chapter 1 Electrical equipment and electromagnetic compatibility

## Section I Legislative, regulatory and administrative provisions

Switzerland	Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 and RS 4 798), as last amended on 22 March 2019 (RO <b>2020</b> 6159).
	Ordinance of 30 March 1994 on electrical weak current installations (RO <b>1994</b> 1185), as last amended on 20 April 2016 (RO <b>2016</b> 119).
	Ordinance of 30 March 1994 on electrical heavy current installations (RO <b>1994</b> 1199), as last amended on 3 April 2019 (RO <b>2019</b> 1363).
	Ordinance of 25 November 2015 on electrical low voltage equipment (OMBT, RO <b>2016</b> 105), as last amended on 24 November 2021 (RO <b>2021</b> 822).
	Ordinance of 25 November 2015 on electro- magnetic compatibility (OCEM, RO <b>2016</b> 119), as last amended on 18 November 6137).
	Ordinance of 25 November 2015 on Tele- communications Equipment (OIT) (RO <b>2016</b> 179), as last amended on 1 October 2021 (RO <b>2021</b> 589).
United Kingdom	The Electrical Equipment (Safety) Regula- tions 2016 (SI 2016/1101) (as amended).
	The Electromagnetic Compatibility Regula- tions 2016 (SI 2016/1091) (as amended).

## Section II Conformity assessment bodies

Each Party shall maintain an up-to-date list online of recognised conformity assessment bodies for its jurisdiction as well as of recognised conformity assessment bodies designated by the other Party.

UK	SWITZERLAND
Designating authority Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom approvedbodies@beis.gov.uk	Designating authority (Electromag- netic compatibility) Federal Office of Communications Market Access and Conformity (MK) Zukunftstrasse 44 P.O. Box 256 2501 Biel Switzerland Phone: +41 58 460 55 11 e-mail: info@bakom.admin.ch
Authority responsible for market surveillance information sharing UK Product Safety Contact Point Office for Product Safety and Standards Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom +44 121 345 1201 ukproductsafetycp@beis.gov.uk	Authority responsible for market surveillance information sharing (Electromagnetic compatibility) Federal Office of Communications Market Access and Conformity (MK) Zukunftstrasse 44 P.O. Box 256 2501 Biel Switzerland Phone: +41 58 460 55 11 e-mail: faa@bakom.admin.ch
Authority responsible for market surveillance information sharing (Electrical safety) UK Product Safety Contact Point Office for Product Safety and Standards Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street	Authority responsible for market surveillance information sharing (Electrical safety) Federal Inspectorate for Heavy Current Installations Market Surveillance Luppmenstrasse 1 CH-8320 Fehraltorf Switzerland

# Section III Designating authorities and authorities responsible for market surveillance information sharing

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

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex II to this Agreement and any assessment criteria set out in the legislative, regulatory and administrative provisions, as set out in Section I, applicable to the designating authorities.

## Section V Supplementary provisions

## Chapter 2 Measuring instruments

Section I	Legislative, regulatory and administrative provisions	
Switzerland		al Law of 17 June 2011 on metrology <b>012</b> 6235).
	measu	ance of 23 November 1994 on units urement (RO <b>1994</b> 3109), as last ded on 20 May 2019 (RO <b>2019</b> 1133).
	measu last ar	ance of 15 February 2006 concerning uring instruments (RO <b>2006</b> 1453), as nended on 25 November 2015 <b>015</b> 5835).
	and P matic as last	ance of the Federal Ministry of Justice olice of 16 April 2004 on non-auto- weighing instruments (RO <b>2004</b> 2093), amended on 5 December 2015 <b>016</b> 5225).
	and Poinstru	ance of the Federal Ministry of Justice olice of 19 March 2006 on measuring ments of length (RO <b>2006</b> 1433), as nended on 24 August 2020 (RO <b>2020</b>
	and Povolum	ance of the Federal Ministry of Justice olice of 19 March 2006 on measure of ne (RO <b>2006</b> 1525), as last amended on wember 2015 (RO <b>2016</b> 245).
	and P syster (RO <b>2</b>	ance of the Federal Ministry of Justice olice of 19 March 2006 on measuring ns for liquids other than water <b>006</b> 1533) as last amended on 20 Octo- 20 (RO <b>2020</b> 4625).
	and Pe weigh	ance of the federal Ministry of Justice blice of 19 March 2006 on automatic ing instruments (RO <b>2006</b> 1545), as nended on 5 December 2016 (RO <b>2016</b>

Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on instruments for thermal energy (RO **2006** 1569), as last amended on 7 December 2012 (RO **2012** 7183).

Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for gas quantities (RO **2006** 1591), as last amended on 7 December 2012 (RO **2012** 7183).

Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for exhaust gases of combustion engines (RO **2006** 1599), as last amended on 4 March 2021 (RO **2021** 147).

Ordinance of the Federal Ministry of Justice and Police of 26 August 2015 on measuring instruments for the electrical energy and power (RO **2015** 3085), as last amended on 31 October 2017 (RO **2017** 7183).

Ordinance of the Federal Ministry of Justice and Police of 15 August 1986 on weights (RO **1986** 2022), as last amended on 7 December 2012 (RO **2012** 7183).

Ordinance of the Federal Ministry of Justice and Police of 5 November 2013 on taximeters (RO **2013** 4333), as last amended on 19 November 2014 (RO **2014** 4547).

Ordinance of 5 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RO **2012** 7245), as last amended on 30 October 2019 (RO **2019** 3493).

Ordinance of the Federal Ministry of Justice and Police of 10 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RO **2012** 5301), as last amended on 11 November 2019 (RO **2019** 4273). United Kingdom

The Measuring Instrument Regulations 2016 (SI 2016/1153) (as amended).

The Non-automatic Weighing Instruments Regulations 2016 (SI 2016/1152) (as amended).

## Section II Conformity assessment bodies

Each Party shall maintain an up-to-date list online of recognised conformity assessment bodies for its jurisdiction as well as of recognised conformity assessment bodies designated by the other Party.

# Section III Designating authorities and authorities responsible for market surveillance information sharing

UK	SWITZERLAND
Designating authority	Designating authority
Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom approvedbodies@beis.gov.uk	Federal Department of Justice and Police FDJP General Secretariat, Legal Service Federal Palace, West Wing 3003 Berne Switzerland Phone +41 58 462 21 11 e-mail: info@gs-ejpd.admin.ch
Authority responsible for market surveillance information sharing	Authority responsible for market surveillance information sharing
UK Product Safety Contact Point Office for Product Safety and Stand- ards Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom +44 121 345 1201 ukproductsafetycp@beis.gov.uk	Federal Institute of Metrology Surveillance and Metrological Super- vision Lindenweg 50 3003 Berne-Wabern Switzerland Phone +41 58 387 01 11 e-mail: info@metas.ch

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

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex II to this Agreement and any assessment criteria set out in the legislative, regulatory and administrative provisions, as set out in Section I, applicable to the designating authorities.

## Section V Supplementary provisions

- 1. The conformity mark shall indicate the number of the conformity assessment body according to its legislation as well as the country code in which the conformity assessment body is domiciled.
- 2. The conformity mark required by the legislation of Switzerland according to Article 1 paragraph 2 is the Swiss marking as specified in Annex 2 of the Ordinance of the Federal Ministry of Justice and Police of 26 August 2015 on measuring instruments for the electrical energy and power.

## Chapter 3 Radio equipment

Section I	Legislative, regulatory and administrative provisions	
Switzerland	Federal Law of 30 April 1997 on Telecom- munications (LTC) (RO <b>1997</b> 2187), as last amended on 22 March 2019 (RO <b>2020</b> 6159).	
	Ordinance of 25 November 2015 on Tele- communication Equipment (OIT) (RO <b>2016</b> 179), as last amended on 18 November 2020 (RO <b>2020</b> 6213).	
	Ordinance of 9 March 2007 on Telecommu- nication Services (RO <b>2007</b> 945), as last amended on 18 November 2020 (RO <b>2020</b> 6183).	
	Ordinance of 26 May 2016 of the Federal Of- fice of Communications (OFCOM) on Tele- communications Equipment (RO <b>2016</b> 1673), as last amended on 21 November 2017 (RO <b>2017</b> 7137).	
United Kingd	The Radio Equipment Regulations 2017 (SI 2017/1206) (as amended).	

## Section II Conformity assessment bodies

Each Party shall maintain an up-to-date list online of recognised conformity assessment bodies for its jurisdiction as well as of recognised conformity assessment bodies designated by the other Party.

# Section III Designating authorities and authorities responsible for market surveillance information sharing

UK	SWITZERLAND
Designating authority	Designating authority
Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London	Federal Office of Communications Market Access and Conformity (MK) Zukunftstrasse 44 P.O. Box 256

SW1H OET United Kingdom approvedbodies@beis.gov.uk	2501 Biel Switzerland Phone: +41 58 460 55 11 e-mail:
Authority responsible for market surveillance information sharing	Authority responsible for market surveillance information sharing
UK Product Safety Contact Point Office for Product Safety and Standards Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom +44 121 345 1201 ukproductsafetycp@beis.gov.uk	Federal Office of Communications Market Access and Conformity (MK) Zukunftstrasse 44 P.O. Box 256 2501 Biel Switzerland Phone: +41 58 460 55 11 e-mail: faa@bakom.admin.ch

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

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex II to this Agreement and any assessment criteria set out in the legislative, regulatory and administrative provisions, as set out in Section I, applicable to the designating authorities.

## Section V Supplementary provisions

Chapter 4	Transportable pressure equipment	
Section 1	Legislative, regulatory and administrative provisions	
Switzerland		Federal Law of 12 June 2009 on product safety (RO <b>2010</b> 2573).
		Ordinance of 19 May 2010 on product safety (RO <b>2010</b> 2583), as last amended on 1 October 2021 (RO <b>2021</b> 589).
		Ordinance of 31 October 2012 relating to the placing on the market of dangerous goods receptacles and the market surveillance (RO <b>2012</b> 6607), as last amended on 25 May 2016 (RO <b>2016</b> 1859).
		Ordinance of 29 November 2002 on the transport of dangerous goods by road (RO <b>2002</b> 4212), as last amended on 20 September 2022 (RO <b>2022</b> 531).
		Ordinance of 31 October 2012 on the transport of dangerous goods by rail and cableway, as last amended on 4 December 2020(RO <b>2020</b> 6155).
United Kingd	om	The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regu- lations 2009 (SI 2009/1348) (as amended).

## Section II Conformity assessment bodies

Each Party shall maintain an up-to-date list online of recognised conformity assessment bodies for its jurisdiction as well as of recognised conformity assessment bodies designated by the other Party.

# Section III Designating authorities and authorities responsible for market surveillance information sharing

UK	SWITZERLAND
Designating authority	Designating authority
The Vehicle Certification Agency (VCA) The VCA Dangerous Goods Office Cleeve Road Leatherhead Surrey KT22 7NF tanks@vca.gov.uk	Federal Department of the Environ- ment, Transport, Energy and Commu- nications 3003 Berne Switzerland Phone: +41 (0)58 462 57 11 e-mail: info@gs-uvek.admin.ch
Authority responsible for market surveillance information sharing	Authority responsible for market surveillance information sharing
Health and Safety Executive	Federal Office of Transport
Redgrave Court	Safety Division
Merton Road	Environment Section
Bootle	3003 Berne
Merseyside	Switzerland
L20 7HS	Phone: $+41 (0)58 462 57 11$
	e-mail:umwelt@bav.admin.ch

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

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex II to this Agreement and any assessment criteria set out in the legislative, regulatory and administrative provisions, as set out in Section I, applicable to the designating authorities.

## Section V Supplementary provisions

- 1. The conformity mark shall indicate the number of the conformity assessment body according to its legislation as well as the country code in which the conformity assessment body is domiciled.
- 2. In addition to Article 2, owners and operators are also economic operators.

## Chapter 5 Noise emitting equipment for use outdoors

## Section I Legislative, regulatory and administrative provisions

Switzerland	Ordinance of 22 May 2007 on the noise emission in the environment by equipment for use outdoors (RO <b>2007</b> 2827), as last amended on 25 November 2019 (RO <b>2019</b> 4253).
United Kingdom	The Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001 (SI 2001/1701) (as amended).

## Section II Conformity assessment bodies

Each Party shall maintain an up-to-date list online of recognised conformity assessment bodies for its jurisdiction as well as of recognised conformity assessment bodies designated by the other Party.

# Section III Designating authorities and authorities responsible for market surveillance information sharing

UK	SWITZERLAND
Designating authority	Designating authority
Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom approvedbodies@beis.gov.uk	Federal Office for the Environment FOEN Aircraft, Industrial and Shooting Noise Section 3003 Bern Switzerland Phone.: +41 58 462 93 11 e-mail: noise@bafu.admin.ch
Authority responsible for market surveillance information sharing	Authority responsible for market surveillance information sharing
UK Product Safety Contact Point Office for Product Safety and Stand- ards Department for Business, Energy and	Federal Office for the Environment FOEN Aircraft, Industrial and Shooting Noise Section
Industrial Strategy (BEIS) 1 Victoria Street	3003 Bern Switzerland

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

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex II to this Agreement and any assessment criteria set out in the legislative, regulatory and administrative provisions, as set out in Section I, applicable to the designating authorities.

## Section V Supplementary provisions

In addition to the Swiss marking on the guaranteed sound power level or the UK marking, the number of the conformity assessment body according to its legislation as well as the country code in which the conformity assessment body is domiciled shall be indicated.

# General rules regarding the designation of conformity assessment bodies

## A. General terms and conditions

<sup>1</sup> The designating authorities shall remain solely responsible for the competence of the bodies they have designated according to this Agreement. They shall only designate bodies under their jurisdiction.

<sup>2</sup> Designating authorities shall designate conformity assessment bodies able to demonstrate that they understand and have the requisite experience and competence to apply the requirements and certification procedures laid down in the legislative, regulatory and administrative provisions of the other Party referred to in Annex I in the relevant Section I, that are applicable to the specific product, product category or sector for which they are designated.

<sup>3</sup> Demonstration of technical competence shall cover:

- the conformity assessment body's technical knowledge of the relevant products, processes or services which it is willing to treat;
- the understanding of the technical standards and legislative, regulatory and administrative provisions for which designation is sought;
- the physical capability to perform a given conformity assessment activity;
- the adequate management of the activity concerned; and
- any other circumstance necessary to give assurance that the conformity assessment activity will be adequately performed at all times.

<sup>4</sup> The technical competence criteria shall be based as far as possible on internationally accepted documents, such as the ISO 17000 series of standards or equivalents as well as on supplemented interpretative documents as appropriate. These documents need to be interpreted to take account of the requirements laid down in the applicable legislative, regulatory and administrative provisions in Annex I in the relevant Section I.

<sup>5</sup> The Parties shall encourage harmonisation of designation procedures and coordination of conformity assessment procedures through cooperation between designating authorities, national accreditation bodies and conformity assessment bodies. Cooperation may include coordination meetings, participation in mutual recognition arrangements, and ad hoc working party meetings.

## B. System for verification of conformity assessment bodies' competence

<sup>6</sup> In order to verify the technical competence of conformity assessment bodies, the authorities concerned may use various procedures ensuring an appropriate level of trust between the Parties. If necessary, a Party shall indicate to the designating authority possible ways of demonstrating competence.

### a) Accreditation

<sup>7</sup> Accreditation shall constitute a presumption of the technical competence of conformity assessment bodies in relation to the application of the requirements of the other Party provided that the competent accreditation body:

- complies with the relevant international provisions in force (ISO 17000 standards or ISO/IEC guides); and
- is signatory to multilateral arrangements under which it is subject to peer evaluation, in particular International Laboratory Accreditation Cooperation («ILAC») or International Accreditation Forum «IAF») as well as European co-operation for Accreditation («EA»).

<sup>8</sup> Where the criteria applicable to conformity assessment bodies require them to assess the conformity of products, processes or services directly to standards or technical specifications, the designating authorities may use accreditation as a presumption of the conformity assessment body's technical competence provided that it enables assessment of those bodies' ability to apply standards or technical specifications. Designation shall be limited to those accredited activities of the conformity assessment body.

<sup>9</sup> Where the criteria applicable to conformity assessment bodies require them to assess the conformity of products, processes or services not directly to standards or technical specifications, but to general (essential) requirements, the designating authorities may use accreditation as a presumption of the conformity assessment body's technical competence provided that it incorporates elements which will enable assessment of the capacity of the conformity assessment body (technical knowledge of the product, of its use, etc.) to assess the conformity of the product to those essential requirements. Designation shall be limited to those accredited activities of the conformity assessment body.

b) Other means

<sup>10</sup> If there is no accreditation scheme, or the accreditation scheme cannot be used, the authorities concerned shall require the conformity assessment bodies to demonstrate their competence by other means, e.g.:

- participation in regional or international mutual recognition arrangements or certification systems;
- regular peer evaluation, based on clear criteria and conducted with the appropriate expertise;
- aptitude tests; or
- comparison of conformity assessment bodies.
- c) Evaluation of the verification system

<sup>11</sup> The Parties may define a verification system to evaluate the competence of conformity assessment bodies. Once established, each Party will be invited to check that the system ensures the conformity of the designation process to its

own legal requirements. Checks shall focus on the appropriateness and effectiveness of the verification system rather than on the conformity assessment bodies themselves.

d) Notification of a designated conformity assessment body

<sup>12</sup> When the Parties submit their proposals to the Committee for inclusion of conformity assessment bodies in the list under Article 14 paragraph 5, they shall provide the following details in respect of each body:

- a) its name;
- b) its postal address;
- c) its e-mail address;
- d) the scope of designation, i.e. sectoral Chapter, product categories or products, processes and services covered by the designation (not exceed that body's scope of accreditation);
- e) the conformity assessment procedures covered by the designation;
- f) the methods used to establish the body's competence;
- g) the accreditation certificate and the related scope of accreditation where applicable.

## General rules regarding the national accreditation body

<sup>1</sup> The accreditation body shall be technically competent to accredit conformity assessment bodies to assess conformity to the other Party's designated standards and technical regulations within the scope for which recognition is requested.

<sup>2</sup> The Parties encourage their nationally appointed accreditation bodies to create and manage actively a regular cooperative dialogue on accreditation and other relevant conformity assessment issues. This will enable the dissemination of best practices in accredited conformity assessment, including the understanding and use of new technologies where appropriate. It will also support the notification of conformity assessment bodies under this Agreement and the mutual understanding of the regulatory requirements of the Parties.

<sup>3</sup> As members of European co-operation for Accreditation, the national accreditation bodies of the Parties shall undergo periodic peer evaluation by European co-operation for Accreditation, or its successor institution.

<sup>4</sup> One Party may challenge the competence of an accreditation body of the other Party on the grounds that any of the conditions required under paragraph 1 - 3 is no longer met. The Party shall immediately notify the other Party of its challenge and the Parties shall cooperate to promptly resolve the challenge.

<sup>5</sup> If the challenge is not resolved within 120 days after the other Party received the notification referred to in paragraph 4, the party shall cease to recognise any conformity assessment bodies.