

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 2/2017 OF THE COMMITTEE ESTABLISHED UNDER THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

of 22 December 2017

**on the amendment of Chapter 2 on Personal protective equipment, Chapter 4 on medical devices,
Chapter 5 on gas appliances and boilers and Chapter 19 on Cableway installations [2018/403]**

THE COMMITTEE,

Having regard to the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment ('the Agreement') and in particular Articles 10(4), 10(5) and 18(2) thereof;

Whereas:

- (1) The European Union has adopted a new Regulation on personal protective equipment ⁽¹⁾ and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the above mentioned European Union legislation.
- (2) Chapter 2, Personal protective equipment, of Annex 1 should be amended to reflect these developments.
- (3) The European Union has adopted a new Regulation on medical devices ⁽²⁾ whose Chapter IV applies mandatorily from 26 November 2017 and a new Regulation on in vitro diagnostic medical devices ⁽³⁾ whose Chapter IV applies mandatorily from 26 November 2017. Furthermore, manufacturers have the possibility to apply these Regulations on a voluntary basis as from this date. Switzerland has amended its regulatory provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned provisions of European Union legislation mandatorily applicable from 26 November 2017.
- (4) Chapter 4, Medical devices, of Annex 1 should be amended to reflect these developments.
- (5) The European Union has adopted a new Regulation on appliances burning gaseous fuels ⁽⁴⁾ and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the above mentioned European Union legislation.
- (6) Chapter 5, Gas appliances and boilers, of Annex 1 should be amended to reflect these developments.
- (7) The European Union has adopted a new Regulation on Cableway installations ⁽⁵⁾ and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the above-mentioned European Union legislation.
- (8) Chapter 19, Cableway installations, of Annex 1 should be amended to reflect these developments.
- (9) Article 10(5) of the Agreement provides that the Committee may, on a proposal from one of the Parties, modify the Annexes to the Agreement,

⁽¹⁾ Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

⁽²⁾ 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).

⁽³⁾ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

⁽⁴⁾ 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).

⁽⁵⁾ Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1).

HAS DECIDED AS FOLLOWS:

1. Chapter 2, Personal protective equipment, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment A annexed to this Decision.
2. Chapter 4, Medical devices, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment B annexed to this Decision.
3. Chapter 5, Gas appliances and boilers, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment C annexed to this Decision.
4. Chapter 19, Cableway installations, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment D to this Decision.
5. This Decision, done in duplicate, shall be signed by representatives of the Committee who are authorised to act on behalf of the Parties. This Decision shall be effective from the date of the later of these signatures.

On behalf of the Swiss Confederation

Christophe PERRITAZ

Signed in Bern on 22 December 2017

On behalf of the European Union

Ignacio IRUARRIZAGA

Signed in Brussels on 21 December 2017

ATTACHMENT A

In Annex 1, Product Sectors, Chapter 2, Personal protective equipment should be deleted and replaced by the following one, which shall be effective from 21 April 2018, when Regulation (EU) 2016/425 and the corresponding Swiss legislation become applicable, except for Section IV, which becomes effective on the same day as the Decision:

‘CHAPTER 2

PERSONAL PROTECTIVE EQUIPMENT

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1.	Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).
Switzerland	100.	Federal Law of 12 June 2009 on product safety (RO 2010 2573)
	101.	Ordinance of 19 May 2010 on product safety (RO 2010 2583) as last amended on 25 October 2017 (RO 2017 5865)
	102.	Ordinance of 25 October 2017 on the safety of personal protective equipment (RO 2017 5859)
	103.	Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Chapter V of Regulation (EU) 2016/425.

SECTION V

Supplementary provisions**1. Economic operators***1.1. Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

- (a) for the purpose of the obligations in Articles 8(6) and 10(3) of Regulation (EU) 2016/425 and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;
- (b) for the purpose of the obligations in Article 8(3) and 10(8) of Regulation (EU) 2016/425 and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keeps the technical documentation and the EU declaration of conformity for 10 years after the PPE has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keeps a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensures that the technical documentation can be made available to those authorities upon request for 10 years after the PPE has been placed on the market in either the European Union or Switzerland;
- (c) for the purpose of the obligations in Article 8(4), second subparagraph, and 10(6) of Regulation (EU) 2016/425 and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. Authorised representative

For the purpose of the obligation in Article 9(2) of Regulation (EU) 2016/425 and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 9(1) of Regulation (EU) 2016/425 or the corresponding Swiss provisions.

1.3. Cooperation with market surveillance authorities

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of a PPE with the legislation in section I.

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 manufacturers or, where applicable, authorised representatives and importers 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 PPE.

2. Exchange of experience

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 35 of Regulation (EU) 2016/425.

3. Coordination of conformity assessment bodies

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 36 of Regulation (EU) 2016/425, directly or by means of designated representatives.

4. Mutual assistance of market surveillance authorities

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. Procedure for dealing with PPE presenting a risk not restricted to the national territory

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reason to believe that a PPE covered by this Chapter presents a risk to the health or safety of persons covered by the legislation in Section I of this Chapter, and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

- the results of the evaluation and of the actions which they have required the economic operator to take;
- where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the PPE being made available on their national market, to withdraw the PPE from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant PPE, their origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

- failure of the PPE to meet requirements relating to the health or safety of persons referred to in the legislation in section I, or
- shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland or Member States shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the PPE concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the PPE concerned, such as withdrawal of the PPE from their market, without delay.

6. Safeguard procedure in case of objections against national measures

Should Switzerland or a Member State disagree with the national measure in paragraph 5, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure is considered:

- justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant PPE is withdrawn from their markets, and shall inform the Commission accordingly;
- unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. Compliant PPE which nevertheless present a risk

Where a Member State or Switzerland finds that, although a PPE that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk for the health or safety of persons, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the PPE concerned, the origin and the supply chain of the PPE, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and, where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. Safeguard clause in case of remaining disagreement between the Parties

In case of a disagreement between the Parties on measures at stake in paragraphs 6 and 7 above, the issue will be forwarded to the Committee established under Article 10 of this Agreement, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is:

- (a) justified, the Parties shall take the measures necessary to ensure that the PPE is withdrawn from their market;
 - (b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.'
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ATTACHMENT B

In Annex 1, Product Sectors, Chapter 4, Medical Devices should be deleted and replaced by the following one:

‘CHAPTER 4

MEDICAL DEVICES

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1). 2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as last amended by Regulation (EC) No 1882/2003 of the European Parliament and the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) 3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1), as last amended by Regulation (EC) No 1882/2003 of the European Parliament and the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) and corrected by Corrigenda (OJ L 22, 29.1.1999, p. 75 and OJ L 6, 10.1.2002, p. 70). 4. Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices (OJ L 131, 16.5.2002, p. 17). 5. Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p. 43). 6. Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 22, 9.8.2012, p. 3). 7. Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12.8.2005, p. 41). 8. Commission Regulation (EC) No 2007/2006 of 22 December 2006 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the importation and transit of certain intermediate products derived from Category 3 material intended for technical uses in medical devices, in vitro diagnostics and laboratory reagents and amending that Regulation (OJ L 379, 28.12.2006, p. 98). 9. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ L 247, 21.9.2007, p. 21). 10. Commission Decision 2011/869/EU of 20 December 2011 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 63). 11. Commission Directive 2011/100/EU of 20 December 2011 amending Directive 98/79/EC of the European Parliament and the Council on in-vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 50).
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12. Directive 2011/65/EU of the European Parliament and the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).
 13. Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed) (OJ L 102, 23.4.2010, p. 45).
 14. Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28).
 15. Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (OJ L 253, 25.9.2013, p. 8).
 16. Chapter IV and Annex VII of 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).
 17. Chapter IV and Annex VII of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).
- Switzerland
100. Federal Law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended 1 January 2014 (RO 2013 4137)
 101. Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 et RS 4 798), as last amended on 20 March 2008 (RO 2008 3437)
 102. Federal Law of 9 June 1977 on metrology (RO 1977 2394), as last amended on 17 June 2011 (RO 2012 6235)
 103. Federal law of 22 March 1991 on radiation protection (RO 1994 1933), as last amended on 10 December 2004 (RO 2004 5391)
 104. Ordinance of 17 October 2001 on medical devices (RO 2001 3487), as last amended on 25 October 2017 (RO 2017 5935)
 105. Ordinance of 18 April 2007 on import, transit and export of animals and animal products (RO 2007 1847), as last amended on 4 September 2013 (RO 2013 3041)
 106. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)
 107. Federal Act on Data Protection of 19 June 1992 (RO 1992 1945), as last amended on 30 September 2011 (RO 2013 3215)

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies under this Chapter, the designating authorities shall:

- comply with the general principles contained in Annex 2 to this Agreement,
- as laid down in Regulation (EU) No 920/2013, comply with the assessment criteria set out in Annex XI to Directive 93/42/EEC, in Annex 8 to Directive 90/385/EEC and in Annex IX to Directive 98/79/EC, and
- comply with the assessment criteria set out in Chapter IV and Annex VII of Regulation (EU) 2017/745 and of Regulation (EU) 2017/746.

The Parties shall make available assessors for the pool established under Regulation (EC) No 920/2013, Article 40 of Regulation (EU) 2017/745 and Article 36 of Regulation (EU) 2017/746. The designating authorities of the Parties shall cooperate for the assessment of notified bodies in line with Article 39 of Regulation (EU) 2017/745 and Article 35 of Regulation (EU) 2017/746. They shall participate in peer reviews pursuant to Article 48 of Regulation (EU) 2017/745 and Article 44 of Regulation (EU) 2017/746.

SECTION V

Supplementary provisions**1. Registration of the person responsible for placing devices on the market**

Any manufacturer or his authorised representative who places on the market of one of the Parties the medical devices referred to in Article 14 of Directive 93/42/EEC or Article 10 of Directive 98/79/EC shall inform the competent authorities of the Party in which he has his registered place of business of the particulars referred to in those Articles. The Parties shall reciprocally recognise that registration. The manufacturer shall not be obliged to designate a person responsible for placing devices on the market established in the territory of the other Party.

2. Labelling of medical devices

Manufacturers of both Parties shall indicate their name or trade name and address on the label of medical devices specified in Annex 1, point 13.3(a) to Directive 93/42/EEC and in vitro diagnostic medical devices specified in Annex 1, point 8.4(a), to Directive 98/79/EC. They shall not be obliged to indicate the name and address of the person responsible for placing the device on the market, of the representative or of the importer established within the territory of the other Party on the label, outer packaging or instructions for use.

For devices imported from third countries, in view of their distribution in the Union and Switzerland, the label, or the outer packaging, or instructions for use, shall contain the name and address of the single authorised representative of the manufacturer established within the Union or Switzerland, as appropriate.

3. Information exchange and cooperation

In accordance with Article 9 of the Agreement,

- the Parties shall in particular exchange the information referred to in Article 8 of Directive 90/385/EEC, Article 10 of Directive 93/42/EEC, Article 11 of Directive 98/79/EC and Article 3 of Regulation (EU) No 920/2013,
- the Parties shall in particular cooperate according to Articles 102 and 103 of Regulation (EC) No 2017/745 and Articles 97 and 98 of Regulation (EU) 2017/746.
- Switzerland may submit the application of expert laboratories for designation by the Commission in accordance with Article 106 of Regulation (EU) 2017/745 or the application of reference laboratories for designation by the Commission in accordance with Article 100 of Regulation (EU) 2017/746.

4. European databases

The competent Swiss authorities shall have access to the European databases established under Article 12 of Directive 98/79/EC, Article 14a of Directive 93/42/EEC, Article 3 of Regulation (EU) No 920/2013, Article 33 of Regulation (EU) 2017/745 and Article 30 of Regulation (EU) 2017/746. They shall transmit to the Commission and/or body responsible for managing the databases the data provided for in those Articles collected in Switzerland for entry into the European databases.

5. Transitional provisions

By way of derogation to the legislation in Section I, devices which comply with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 may be placed on the market of both Parties respectively.

By way of derogation to the legislation in Section I, notified bodies which are designated and notified in accordance with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 may carry out assessment procedures laid down in these regulations and issue certificates in accordance with these Regulations. Such certificates shall be recognized by the Parties.'

ATTACHMENT C

In Annex 1, Product Sectors, Chapter 5, Gas appliances and boilers, should be deleted and replaced by the following one, which shall be effective from 21 April 2018, when Regulation (EU) 2016/426 and the corresponding Swiss legislation become applicable, except for Section IV which becomes effective on the same day as this Decision:

'CHAPTER 5

GAS APPLIANCES AND BOILERS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(1)

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| European Union | 1. | 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 subsequently amended |
| Switzerland | 100. | Ordinance of 16 December 1985 on Air Pollution Control (OAPC) (Annex 3 and 4) (RS 814.318.142.1, as subsequently amended) |

Provisions covered by Article 1(2)

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|----------------|------|--|
| European Union | 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). |
| Switzerland | 100. | Federal Law of 12 June 2009 on product safety (RO 2010 2573) |
| | 101. | Ordinance of 19 May 2010 on product safety (RO 2010 2583), as last amended on 25 October 2017 (RO 2017 5865) |
| | 102. | Ordinance of 25 October 2017 on gas appliances (RO 2017 5865) |
| | 103. | Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261) |

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Chapter IV of Regulation (EU) 2016/426.

SECTION V

Supplementary provisions**1. Economic operators***1.1. Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

- (a) for the purpose of the obligations in Articles 7(6) and 9(3) of Regulation (EU) 2016/426 and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark, and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;
- (b) for the purpose of the obligations in Article 7(3) and 9(8) of Regulation (EU) 2016/426 and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keeps the technical documentation and the EU declaration of conformity for 10 years after the appliance or the fitting has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keeps a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensures that the technical documentation can be made available to those authorities upon request for 10 years after the appliance or the fitting has been placed on the market in either the European Union or Switzerland;
- (c) for the purpose of the obligations in Article 7(4), second subparagraph, and 9(6) of Regulation (EU) 2016/426 and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. Authorised representative

For the purpose of the obligation in Article 8(2) of Regulation (EU) 2016/426 and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 8(1) of Regulation (EU) 2016/426 or the corresponding Swiss provisions.

1.3. Cooperation with market surveillance authorities

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of an appliance or fitting with the legislation in section I.

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 manufacturers or, where applicable, authorised representatives and importers 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 appliance or the fitting.

2. Exchange of experience

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 34 of Regulation (EU) 2016/426.

3. Coordination of conformity assessment bodies

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 35 of Regulation (EU) 2016/426, directly or by means of designated representatives.

4. Mutual assistance of market surveillance authorities

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. Procedure for dealing with appliances or fittings presenting a risk not restricted to the national territory

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reason to believe that an appliance or fitting covered by this Chapter presents a risk to the health or safety of persons or to domestic animals or property covered by the legislation in Section I of this Chapter, and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

- the results of the evaluation and of the actions which they have required the economic operator to take;
- where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the appliances or fittings being made available on their national market, to withdraw the appliance or fitting from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant appliance or fitting, their origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

- failure of the appliance or fitting to meet requirements relating to the health or safety of persons or to domestic animals or property referred to in the legislation in section I, or
- shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland or Member States shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the appliance or fitting concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the appliance or fitting concerned, such as withdrawal of appliance or fitting from their market, without delay.

6. Safeguard procedure in case of objections against national measures

Should Switzerland or a Member State disagree with the national measure in paragraph 5, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure relating to an appliance or fitting is considered:

- justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant appliance or fitting is withdrawn from their markets, and shall inform the Commission accordingly;
- unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. Compliant appliances or fittings which nevertheless present a risk

Where a Member State or Switzerland finds that, although an appliance or fitting that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk for the health or safety of persons or to domestic animals or property, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the appliance or fitting concerned, the origin and the supply chain of the appliance or fitting, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and, where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. Safeguard clause in case of remaining disagreement between the Parties

In case of a disagreement between the Parties on measures at stake in paragraphs 6 and 7 above, the issue will be forwarded to the Committee established under Article 10 of this Agreement, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is:

- (a) justified, the Parties shall take the measures necessary to ensure that the appliance or fitting is withdrawn from their market;
- (b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.

9. Information exchange

In accordance with Article 12 of this Agreement, the Parties shall exchange information on the types of gas and the corresponding supply pressures of gaseous fuels used on their territory referred to in Annex II of Regulation (EU) 2016/426. Further Switzerland shall inform about the changes thereof within six months after the announcement of the envisaged changes. The European Union shall inform about the changes thereof within six months after it received the notification by a Member State.'

ATTACHMENT D

In Annex 1, Product Sectors, Chapter 19, Cableway installations should be deleted and replaced by the following one, which shall be effective from 21 April 2018, when Regulation (EU) 2016/424 and the corresponding Swiss legislation become applicable, except for Section IV which becomes effective as the same day as this Decision:

CHAPTER 19

CABLEWAY INSTALLATIONS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1.	Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1).
Switzerland	100.	Federal Law of 23 June 2006 on cableway installations transporting people (RO 2006 5753) as last amended on 20 March 2009 (RO 2009 5597)
	101.	Ordinance of 21 December 2006 on cableway installations transporting people (RO 2007 39) as last amended on 11 October 2017 (RO 2017 5831)
	102.	Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Chapter IV of Regulation (EU) 2016/424.

SECTION V

Supplementary provisions**1. Economic operators***1.1. Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

- (a) for the purpose of the obligations in Articles 11(6) and 13(3) of Regulation (EU) 2016/424 and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;
- (b) for the purpose of the obligations in Article 11(3) and 13(8) of Regulation (EU) 2016/424 and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keeps the technical documentation and the EU declaration of conformity for 30 years after the subsystem or the safety component has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keeps a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensures that the technical documentation can be made available to those authorities upon request for 30 years after the subsystem or the safety component has been placed on the market in either the European Union or Switzerland;
- (c) for the purpose of the obligations in Article 11(4), second subparagraph, and 13(6) of Regulation (EU) 2016/424 and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 12(2) of Regulation (EU) 2016/424 and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 12(1) of Regulation (EU) 2016/424 or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of a subsystem or safety component with the legislation in section I.

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 manufacturers or, where applicable, authorised representatives and importers 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 subsystem or safety component.

2. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 37 of Regulation (EU) 2016/424.

3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 38 of Regulation (EU) 2016/424, directly or by means of designated representatives.

4. Mutual assistance of market surveillance authorities

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. Procedure for dealing with subsystems or safety components presenting a risk not restricted to the national territory

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reason to believe that a subsystem or safety component covered by this Chapter presents a risk to the health or safety of persons or to property covered by the legislation in Section I of this Chapter, and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

- the results of the evaluation and of the actions which they have required the economic operator to take;
- where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the subsystem or safety component being made available on their national market, to withdraw the subsystem or safety component from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant subsystem or safety component, its origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

- failure of the subsystem or safety component to meet requirements relating to the health or safety of persons or to property referred to in the legislation in section I, or
- shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland or Member States shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the subsystem or safety component concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the subsystem or safety component concerned, such as withdrawal of subsystems or safety components from their market, without delay.

6. Safeguard procedure in case of objections against national measures

Should Switzerland or a Member State disagree with the national measure in paragraph 5, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure relating to a subsystem or safety component is considered:

- justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant subsystem or safety component is withdrawn from their markets, and shall inform the Commission accordingly;
- unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. Compliant subsystems or safety components which nevertheless present a risk

Where a Member State or Switzerland finds that, although a subsystem or safety component that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk to the health or safety of persons or to property, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the subsystem or safety component concerned, the origin and the supply chain of the subsystem or safety component, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and, where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. Safeguard clause in case of remaining disagreement between the Parties

In case of a disagreement between the Parties on measures at stake in paragraphs 6 and 7 above, the issue will be forwarded to the Committee established under Article 10 of this Agreement, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is:

- (a) justified, the Parties shall take the measures necessary to ensure that the subsystem or safety component is withdrawn from their market;
 - (b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.'
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