STATUTORY INSTRUMENTS

# 2019 No. 392

# HEALTH AND SAFETY CONSUMER PROTECTION

## The Conformity Assessment (Mutual Recognition Agreements) Regulations 2019

| | |
|---|---|
| *Made - - - -* | *28th February 2019* |
| *Laid before Parliament* | *28th February 2019* |
| *Coming into force - -* | *22nd March 2019* |

The Secretary of State has been designated for the purposes of making Regulations under section 2(2) of the European Communities Act 1972(**1**) in relation to the matters specified in the Schedule.

The Secretary of State, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972, makes the following Regulations.

### Citation and commencement

**1.** These Regulations may be cited as the Conformity Assessment (Mutual Recognition Agreements) Regulations 2019 and come into force on 22nd March 2019.

### Interpretation

**2.** In these Regulations—

(a) "attestation of conformity" means, in relation to a product, process or service, any of the following—

(i) the results of any conformity assessment carried out in respect of the product, process or service;

(ii) a report, certificate, authorisation, decision or a mark of conformity relating to such an assessment;

(iii) a declaration of conformity;

(iv) the confirmation (within the meaning given by Article 1(1)(f) of the Japanese agreement) of manufacturing facilities;

(**1**) 1972 c. 68; section 2(2) was amended by section 27(1) of the Legislative and Regulatory Reform Act 2006 (c. 51) and by Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c. 7). It is prospectively repealed by section 1 of the European Union (Withdrawal) Act 2018 (c. 16), with effect from exit day (see section 20 of that Act).

(b) "conformity assessment" means systematic examination to determine the extent to which a product, process or service fulfils specified requirements;

(c) "Israeli agreement" means the agreement mentioned in sub-paragraph (e)(xi);

(d) "Japanese agreement" means the agreement mentioned in sub-paragraph (e)(vi);

(e) "mutual recognition agreement" means—

(i) the Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia(**2**);

(ii) the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand(**3**);

(iii) the Protocol on the mutual acceptance of the results of conformity assessment, which is part of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part(**4**);

(iv) the Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products, which is part of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part(**5**);

(v) the Agreement on mutual recognition between the European Community and the United States of America(**6**);

(vi) the Agreement on mutual recognition between the European Community and Japan(**7**);

(vii) the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment(**8**);

---

(**2**) OJ No. L 229, 17.8.1998, p. 3. This agreement was amended by the Agreement between the European Union and Australia amending the Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia (OJ No. L 359, 29.12.2012, p. 2). There are other amendments but they are not relevant.

(**3**) OJ No. L 229, 17.8.1998, p. 62. This agreement was amended by the Agreement between the European Union and New Zealand amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand (OJ No. L 356, 22.12.2012, p. 2).

(**4**) OJ No. L 11, 14.1.2017, p. 567. There are no relevant amendments to this protocol.

(**5**) OJ No. L 11, 14.1.2017, p. 581. There are no relevant amendments to this protocol.

(**6**) OJ No. L 31, 4.2.1999, p. 3. This agreement was amended by: (i) Decision No. 16/2002 of 16 April 2002 of the Joint Committee established under the Agreement on mutual recognition between the European Community and the United States of America on amending the Sectoral Annex on Medical Devices (OJ No. L 302, 6.11.2002, p. 30); and (ii) Decision No. 1/2017 of 1 March 2017 of the Joint Committee established under Article 14 of the Agreement on Mutual Recognition between the European Community and the United States of America, amending the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs) [2017/382] (OJ No. L 58, 4.3.2017, p. 36). There are other amendments but they are not relevant.

(**7**) OJ No. L 284, 29.10.2001, p. 3. There are no relevant amendments to this agreement.

(**8**) OJ No. L 114, 30.4.2002, p. 369. This agreement was amended by: (i) Decision No. 2/2002 of 8 January 2003 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment on the modification of the Annex 1 of the Agreement (OJ No. L 68, 12.3.2003, p. 1); (ii) Decision No. 2/2005 of 30 March 2005 of the Committee established under the Agreement on Mutual Recognition between the EC and the Swiss Confederation on amending Chapter 3 of Annex 1 (OJ No. L 110, 30.4.2005, p. 78); (iii) the Agreement revising the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment (OJ No. L 386, 29.12.2006, p. 51); (iv) Decision No. 1/2006 of 29 September 2006 of the Committee established under the Agreement on Mutual Recognition between the European Community and the Swiss Confederation on amending Chapter 11 of Annex 1 (OJ No. L 325, 24.11.2006, p. 22); (v) Decision No. 1/2008 of 12 March 2008 of the Committee established under the Agreement between the European Community and the Swiss Confederation on Mutual Recognition in relation to Conformity Assessment on the inclusion in Annex 1 of a new Chapter 16 on construction products (OJ No. L 282, 25.10.2008, p. 22); (vi) Decision No. 1/2009 of 21 December 2009 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment on the inclusion in Annex 1 of a new Chapter 17 on lifts and on the amendment of Chapter 1 on Machinery (OJ No. L 147, 12.6.2010, p. 11); (vii) Decision No. 1/2010 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 18 October 2010 on the amendment of Chapter 12 on Motor vehicles of Annex 1 and on the inclusion in Annex 1 of a new Chapter 18

(viii) the Agreement between the European Community and the United States of America on the Mutual Recognition of Certificates of Conformity for Marine Equipment(**9**);

(ix) Decision No. 1/2006 of the EC-Turkey Association Council of 15 May 2006 on the implementation of Article 9 of Decision No. 1/95 of the EC-Turkey Association Council on implementing the final phase of the Customs Union(**10**);

(x) Annex 2-B to the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part(**11**); or

(xi) the Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, on Conformity Assessment and Acceptance of Industrial Products (CAA)(**12**);

(f) "Swiss agreement" means the agreement mentioned in sub-paragraph (e)(vii);

(g) "Turkish agreement" means the decision mentioned in sub-paragraph (e)(ix).

**Recognition of conformity assessments etc.**

**3.**—(1) Subject to paragraph (10), paragraph (2) applies where, pursuant to a mutual recognition agreement, member States are required to recognise or accept an attestation of conformity with the relevant European Union law in respect of a product, process or service (a "mutually recognised attestation of conformity").

(2) Where this paragraph applies, the mutually recognised attestation of conformity is to be treated as if it were an attestation of conformity issued under the updated relevant European Union law by a person authorised or required to issue such attestations in respect of the product, process or service.

on Biocidal products (OJ No. L 46, 19.2.2011, p. 51); (viii) Decision No. 1/2011 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 20 December 2011 on the inclusion in Annex 1 of a new Chapter 19 on cableway installations and the update of legal references listed in Annex 1 (OJ No. L 80, 20.3.2012, p. 31); (ix) Decision No. 1/2012 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 17 December 2012 on the inclusion in Annex 1 of a new Chapter 20 on explosives for civil use, the amendment of Chapter 3 on toys and the update of legal references listed in Annex 1 (OJ No. L 136, 23.5.2013, p. 17); (x) Decision No. 1/2014 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 1 April 2014 on the amendment of Chapter 6 on pressure vessels, Chapter 16 on construction products and the update of legal references listed in Annex 1 (OJ No. L 182, 21.6.2014, p. 61); (xi) Decision No. 1/2015 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 14 April 2015 on the amendment of Chapter 16 on construction products, Chapter 18 on biocidal products and the update of legal references listed in Annex 1 [2015/1058] (OJ No. L 171, 2.7.2015, p. 25); (xii) Decision No. 1/2017 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 28 July 2017 on the amendment of Chapter 4 on medical devices, Chapter 6 on pressure vessels, Chapter 7 on radio equipment and telecommunication terminal equipment, Chapter 8 on equipment and protective systems intended for use in potentially explosive atmosphere, Chapter 9 on electrical equipment and electromagnetic compatibility, Chapter 11 on measuring instruments, Chapter 15 on medicinal products, GMP inspection and batch certification, Chapter 17 on lifts, and Chapter 20 on explosives for civil use, and the update of legal references listed in Annex 1 [2017/2118] (OJ No. L 323, 7.12.2017, p. 51); and (xiii) 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] (OJ No. L 72, 15.3.2018, p. 24). There are other amendments but they are not relevant.

(**9**) OJ No. L 150, 30.4.2004, p. 46. This agreement was amended by Decision No. 1/2018 of 18 February 2019 of the Joint Committee established by the Agreement between the European Community and the United States of America on the mutual recognition of certificates of conformity for marine equipment amending Annexes 1, 2 and 3.

(**10**) OJ No. L 271, 30.9.2006, p. 58.

(**11**) OJ No. L 127, 14.5.2011, p. 1134. There are no relevant amendments.

(**12**) OJ No. L 1, 4.1.2013, p. 2.

(3) Subject to paragraph (10), paragraph (4) applies where, pursuant to Article 1(2) of the Swiss agreement, member States are required to accept an attestation of conformity with the relevant Swiss law in respect of a product, process or service (a "Swiss enhanced attestation of conformity").

(4) Where this paragraph applies—

(a) compliance with requirements of the updated relevant Swiss law in respect of the product, process or service is to be treated as compliance with the equivalent requirements of the updated relevant European Union law; and

(b) the Swiss enhanced attestation of conformity is to be treated as if it were an attestation of conformity issued under the updated relevant European Union law by a person authorised or required to issue such attestations in respect of the product, process or service.

(5) Subject to paragraph (10), paragraph (6) applies where, pursuant to Article 2(3) of the Turkish agreement, member States are required to accept an attestation of conformity with the relevant Turkish law in respect of a product (a "Turkish enhanced attestation of conformity").

(6) Where this paragraph applies—

(a) compliance with requirements of the updated relevant Turkish law in respect of the product is to be treated as compliance with the equivalent requirements of the updated relevant European Union law; and

(b) the Turkish enhanced attestation of conformity is to be treated as if it were an attestation of conformity issued under the updated relevant European Union law by a person authorised or required to issue such attestations in respect of the product.

(7) Subject to paragraph (10), paragraph (8) applies where, pursuant to Article 5(3) of the Israeli agreement, member States are required to accept an attestation of conformity with the relevant Israeli law in respect of a product (an "Israeli enhanced attestation of conformity").

(8) Where this paragraph applies—

(a) compliance with requirements of the relevant Israeli law in respect of the product is to be treated as compliance with the equivalent requirements of the relevant European Union law; and

(b) the Israeli enhanced attestation of conformity is to be treated as if it were an attestation of conformity issued under the relevant European Union law by a person authorised or required to issue such attestations in respect of the product.

(9) In this regulation—

(a) "relevant European Union law", in respect of a mutual recognition agreement as it relates to a product, process or service, means the European Union law in respect of that product, process or service which is specified, or otherwise referred to, in or under the mutual recognition agreement;

(b) "relevant Israeli law", in respect of a product, means any provision of Israeli law in respect of that product which is specified in a notification under the Annex to the Israeli agreement;

(c) "relevant Swiss law", in respect of a product, process or service, means the Swiss law in respect of that product, process or service which is specified in the Swiss agreement;

(d) "relevant Turkish law", in respect of a product, means any provision of Turkish law that reproduces the effect of any provision of relevant European Union law in respect of that product (as specified in a statement adopted as mentioned in Article 1(1) of the Turkish agreement);

(e) "updated relevant European Union law", in respect of a mutual recognition agreement as it relates to a product, process or service, means the relevant European Union law as amended or re-enacted (with or without modifications) before the day on which these Regulations are made (whether or not those amendments or re-enactments are specified,

or otherwise referred to, in or under the mutual recognition agreement as it had effect immediately before that day);

(f) "updated relevant Swiss law", in respect of a product, process or service, means the relevant Swiss law as amended or re-enacted (with or without modifications) before the day on which these Regulations are made (whether or not those amendments or re-enactments are specified in the Swiss agreement as it had effect immediately before that day);

(g) "updated relevant Turkish law", in respect of a product, means any provision of Turkish law that reproduces the effect of any updated relevant European Union law in respect of that product.

(10) Any provision made by paragraph (2), (4), (6) or (8) (a "default provision") does not apply in respect of a product, process or service at any time if, at that time, there is sector specific provision in force.

(11) In paragraph (10), "sector specific provision", means provision in respect of the product, process or service, which is of similar effect to the default provision in question.

**Recognition of authorised representatives established in Switzerland**

**4.**—(1) This regulation applies in respect of the product sectors listed in Chapters 2, 4 to 9, 11, 16, 17, 19 and 20 of Annex 1 to the Swiss agreement ("the specified product sectors").

(2) Any person established in Switzerland is to be treated as established in a member State for the purpose of determining whether that person is, or is eligible to be appointed as, the authorised representative of a manufacturer.

(3) In paragraph (2), "authorised representative" means a person who has received a written mandate from a manufacturer to perform specified tasks on the manufacturer's behalf pursuant to the updated relevant European Union law or the updated relevant Swiss law in respect of the specified product sector concerned.

(4) In paragraph (3), "updated relevant European Union law" and "updated relevant Swiss law" have the meanings given in regulation 3(9).

**Recognition of authorised representatives established in Turkey**

**5.**—(1) This regulation applies where a statement, adopted as mentioned in Article 1(1) of the Turkish agreement, recommends implementation of the principle of mutual recognition of the rights of authorised representatives in respect of any product to which the statement relates ("the relevant product").

(2) Any person established in Turkey is to be treated as established in a member State for the purpose of determining whether that person is, or is eligible to be appointed as, the authorised representative of a manufacturer.

(3) In this regulation, "authorised representative" means a person who has received a written mandate from a manufacturer to perform specified tasks on the manufacturer's behalf in accordance with the updated relevant European Union law or the updated relevant Turkish law in respect of the relevant product concerned.

(4) In paragraph (3), "updated relevant European Union law" and "updated relevant Turkish law" have the meanings given in regulation 3(9).

*Kelly Tolhurst*
Parliamentary Under Secretary of State
Department for Business, Energy and Industrial Strategy

28th February 2019

## SCHEDULE

Preamble

Matters in relation to which the Secretary of State has been designated

**1.** Regulation of the type, description, construction or equipment of vehicles, and of components of vehicles, and in particular any vehicle type approval scheme(**13**).

**2.** Measures for safety as respects electrical equipment(**14**).

**3.** Medicinal products(**15**).

**4.** The regulation of specifications, construction, placing on the market and use of articles, instruments, containers or other equipment intended for weighing, measuring or testing or for purposes ancillary thereto, including, in particular—

(a) approval of patterns and the verification of conformity with patterns or other requirements;

(b) authentication and proof of such approval or verification or of exemption from the need for approval or verification;

(c) supervision and enforcement of compliance with requirements(**16**).

**5.** Units of measurement to be used for economic, health, safety or administrative purposes and the prefixes to be used with such units(**17**).

**6.** Measures relating to safety as regards simple pressure vessels(**18**).

**7.** Measures relating to the approval of telecommunications terminal equipment(**19**).

**8.** Measures relating to construction products(**20**).

**9.** Measures relating to apparatus which is liable to cause electromagnetic disturbance and to apparatus the performance of which is liable to be affected by such disturbance(**21**).

**10.** Measures relating to safety as regards personal protective equipment(**22**).

**11.** Measures relating to safety as regards appliances burning gaseous fuels(**23**).

**12.** Measures relating to active implantable medical devices(**24**).

**13.** Measures relating to efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels(**25**).

**14.** Regulation of the type, description, construction or equipment of agricultural or forestry tractors and of their components, and in particular any type approval scheme for such tractors(**26**).

**15.** Measures relating to the safety of ships and the health and safety of persons on them(**27**).

**16.** Measures relating to medical devices other than active implantable medical devices(**28**).

---

(**13**) S.I. 1972/1811.
(**14**) S.I. 1972/1811, superseded in relation to measures relating to consumer protection by S.I. 1993/2661.
(**15**) S.I. 1972/1811.
(**16**) S.I. 1975/427.
(**17**) S.I. 1976/897.
(**18**) S.I. 1989/1327.
(**19**) S.I. 1989/1327.
(**20**) S.I. 1989/2393.
(**21**) S.I. 1989/2393.
(**22**) S.I. 1990/1304.
(**23**) S.I. 1991/755.
(**24**) S.I. 1991/2289.
(**25**) S.I. 1992/1711.
(**26**) S.I. 1992/1711.
(**27**) S.I. 1993/595.
(**28**) S.I. 1993/2661.

**17.** Measures relating to the placing on the market, transfer and safety of explosives for civil use(**29**).

**18.** Measures relating to consumer protection(**30**).

**19.** Measures relating to maritime transport(**31**).

**20.** Measures relating to equipment and protective systems intended for use in potentially explosive atmospheres(**32**).

**21.** Measures relating to craft intended for recreational purposes(**33**).

**22.** Measures relating to the transport of dangerous or environmentally hazardous goods by road or rail(**34**).

**23.** Measures relating to lifts and the safety components for use in lifts(**35**).

**24.** Measures relating to pressure equipment and assemblies of pressure equipment(**36**).

**25.** Measures in the veterinary and phytosanitary fields for the protection of public health(**37**).

**26.** Measures relating to biocides(**38**).

**27.** Measures relating to wireless telegraphy including radio equipment(**39**).

**28.** Matters in respect of noise emission in the environment by equipment for use outdoors(**40**).

**29.** Cableway installations designed to carry people and components of such installations(**41**).

**30.** The restriction of the use of hazardous substances in electrical and electronic equipment(**42**).

**31.** Health protection measures regulating the use of material of human origin(**43**).

**32.** The regulation, labelling and control of packages and products made up to a pre-determined constant nominal quantity, whether that be weight, volume, number, area, length or any other measurement(**44**).

**33.** Machinery, including—

(a) component parts of machines;

(b) components or equipment to be attached to or used with machines; and

(c) sub-assemblies to be incorporated into or assembled with machines(**45**).

**34.** The packaging of products(**46**).

**35.** Pyrotechnic articles(**47**).

---

(**29**) S.I. 1993/2661.
(**30**) S.I. 1993/2661.
(**31**) S.I. 1994/757.
(**32**) S.I. 1995/751.
(**33**) S.I. 1995/2983.
(**34**) S.I. 1996/266.
(**35**) S.I. 1996/1912.
(**36**) S.I. 1998/2793.
(**37**) S.I. 1999/2027.
(**38**) S.I. 1999/2788.
(**39**) S.I. 1999/2788.
(**40**) S.I. 2000/3238.
(**41**) S.I. 2001/2555.
(**42**) S.I. 2004/706.
(**43**) S.I. 2004/3037.
(**44**) S.I. 2005/2766.
(**45**) S.I. 2007/1679.
(**46**) S.I. 2009/221.
(**47**) S.I. 2009/2743.

**36.** Market surveillance and marking which indicates that a product is in conformity with requirements of EU legislation(**48**).

**37.** The environmental aspects of product design(**49**).

---

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations implement the following agreements between the European Union and third countries ("the mutual recognition agreements")—

(a) the Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia;

(b) the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand;

(c) the Protocol on the mutual acceptance of the results of conformity assessment, which is part of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part;

(d) the Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products, which is part of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part;

(e) the Agreement on mutual recognition between the European Community and the United States of America;

(f) the Agreement on mutual recognition between the European Community and Japan;

(g) the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment ("the Swiss agreement");

(h) the Agreement between the European Community and the United States of America on the Mutual Recognition of Certificates of Conformity for Marine Equipment;

(i) Decision No. 1/2006 of the EC-Turkey Association Council of 15 May 2006 on the implementation of Article 9 of Decision No. 1/95 of the EC-Turkey Association Council on implementing the final phase of the Customs Union ("the Turkish agreement");

(j) Annex 2-B to the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part;

(k) the Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, on Conformity Assessment and Acceptance of Industrial Products (CAA) ("the Israeli agreement").

The mutual recognition agreements require member States to accept attestations of conformity issued by third countries in respect of certain products, processes or services. A third country's attestation of conformity confirms that the product, process or service concerned complies with the requirements

(**48**) S.I. 2009/3214.
(**49**) S.I. 2010/1552.

of European Union law which apply to that product, process or service and which are referred to in the mutual recognition agreement concerned. Regulation 3(2) of these Regulations requires the United Kingdom to accept such attestations of conformity.

Article 1(2) of the Swiss agreement also requires member States to accept an attestation of conformity issued by Switzerland, where the attestation confirms that Switzerland has complied with the requirements of Swiss law which are equivalent to the requirements of European Union law in respect of a product, process or service. Regulation 3(4) of these Regulations provides that the United Kingdom must accept such attestations of conformity.

Article 2(3) of the Turkish agreement requires member States to accept an attestation of conformity issued by Turkey in respect of a product, in cases where the Customs Union Joint Committee has adopted a statement confirming that Turkey has put into force the European Union law in respect of that product. Regulation 3(6) of these Regulations implements that requirement.

Article 5(3) of the Israeli agreement requires member States to accept an attestation of conformity issued by Israel in respect of a product, in cases where Israel has complied with provisions of Israeli law which align with any provision of European Union law in respect of that product which has been specified in a notification under the Annex to the Israeli agreement. Regulation 3(8) of these Regulations implements that requirement.

Regulation 4 of these Regulations implements the provisions in the Swiss agreement that allow a Swiss manufacturer to appoint an authorised representative who is established in the European Union or in Switzerland.

Regulation 5 of these Regulations makes similar provision in relation to authorised representatives who are established in Turkey.

An impact assessment has not been published for this instrument as it has no or no significant impact on the private, public and voluntary sectors.