PROTOCOL E

MUTUAL RECOGNITION OF CONFORMITY ASSESSMENT OF PRODUCTS
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Article 1

Purpose

1. The purpose of this Protocol is to reduce the technical barriers to trade and contribute to the free movement of goods between Turkey and the EFTA States in relation to conformity assessment of industrial products.

Article 2

Definitions

2. The following definitions apply to this Protocol:

**EFTA States:** The Republic of Iceland, the Principality of Liechtenstein, the Kingdom of Norway and the Swiss Confederation.

**EEA EFTA States:** Those EFTA States that are parties to the EEA Agreement, i.e. the Republic of Iceland, the Principality of Liechtenstein, the Kingdom of Norway. When used in the Agreement, without exception, it refers to the three States collectively.

**Conformity Assessment Body:** A body engaged in the performance of procedures to determine whether the relevant requirements in technical regulations or standards are fulfilled.

**Harmonised product sector:** Product sector covered by the EC legislation with a legal basis in Article 95 or equivalent, of the Treaty establishing the European Community.

**EEA Agreement** (for the purpose of this Protocol): the Agreement on the European Economic Area of 1992 and any EC act referred to in Annex II to that Agreement, including amendments before and after the entry into force of this Protocol.

**EC-Swiss MRA** (for the purpose of this Protocol): EC-Swiss Mutual Recognition Agreement of 1999, including amendments before and after the entry into force of this Protocol. That Agreement also applies to Liechtenstein (through the Customs Union Treaty of 1923 concluded between Switzerland and Liechtenstein).

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1 Protocol E was added by Joint Committee Decision No. 3 of 2009 (3 December 2009) and entered into force on 5 July 2011.
EC-Turkey Customs Union (for the purpose of this Protocol): the Ankara Agreement between the EC and Turkey and Decisions adopted by the EC–Turkey Association Council, in particular Decision No 1/95, No 2/97, No 1/2006, and including amendments before and after the entry into force of this Protocol.

Article 3

Scope

1. This Protocol applies in each EFTA State and in Turkey.

2. This Protocol covers all harmonised product sectors in trade between the EEA EFTA States and Turkey.

3. In trade between Turkey and Switzerland, this Protocol applies to the sectors that are covered by the EC-Swiss MRA where the respective legislation under this agreement is deemed equivalent.

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

Article 4

Legislation

1. The product requirements in the EC–Turkey Customs Union apply to products to be placed on the Turkish market.

2. The product requirements in the EEA Agreement apply to products to be placed on the market of the EEA EFTA States.

3. The product requirements in the EC–Swiss MRA apply to products to be placed on the Swiss market.

Article 5

Conformity assessment

1. The Parties agree to mutually accept the results of conformity assessment procedures carried out by conformity assessment bodies notified or accepted under the EEA Agreement, the EC-Swiss MRA or the EC-Turkey Customs Union.2

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2 The list of notified or accepted conformity assessment bodies under this paragraph is to be found under the following address: http://www.efta.int/mra/not-and-ace-conformity.
Article 6

Verification of notified bodies

1. If a Party has grounds for doubts about the quality of the conformity assessment carried out by a body of the other Party concerned, it may request the other Party to verify the technical competence and compliance with the relevant legal provisions applicable to that body. Specific reasons shall be given for such a request in order to allow the Party responsible for the notification to carry out the requested verification and report speedily to the other Party. The Parties shall ensure the full cooperation, take all the appropriate steps and use all available means necessary to resolve any problems which are detected.

2. If the problems cannot be resolved to the satisfaction of both Parties, they may notify the Subcommittee established under Article 9 of their dissent, giving their reasons. The Subcommittee shall decide on appropriate action within a period of two months.

3. Unless decided otherwise by the Subcommittee within the period laid down in paragraph 2, the notification of the body and the recognition of its competence to assess conformity under this Protocol shall be suspended in part or in full at the end of that period by the designating authority.

4. After the expiry of the period laid down in paragraph 2, if new elements emerge, a Party may request the Subcommittee to decide that the suspension provided for in paragraph 3 be reviewed. In that case, experts from both Parties shall jointly examine the conformity assessment body concerned and report their findings to the designating authority and the Subcommittee. On the basis of this report, the Subcommittee may decide if the suspension should be withdrawn.

Article 7

Authorised representatives in the area of medical devices

1. With regard to the designation of an authorised representative according to EC Directives 90/385/EEC, 93/42/EEC and 98/79/EC and their corresponding rules as transposed into national legislation, it shall be sufficient for the purpose of this Protocol to have the manufacturer established or to designate such a representative either in the EC, in an EFTA State or in Turkey.

Article 8

Exchange of information

1. The Parties shall exchange all relevant information regarding the application of this Protocol, including information on the procedure to ensure compliance by notified bodies.
2. Switzerland shall notify Turkey of all changes in the scope of the sectors in the EC-Swiss MRA that are deemed equivalent.

3. Contact points between the Parties are hereby established, allowing for informal contacts by email or telephone in order to deal with matters that require the immediate involvement of experts.

**Article 9**

**Subcommittee on Mutual Recognition of Conformity Assessment of Products**

1. A Subcommittee on Mutual Recognition of Conformity Assessment of Products is hereby established to assist the Joint Committee. The Subcommittee shall consist of representatives from all the Parties to this Agreement and shall meet at the request of a Party, in conjunction with other relevant meetings where possible. The Subcommittee shall act by consensus.

2. The Subcommittee shall adopt its rules of procedure.

3. The Subcommittee shall be responsible for:

   a) preparing amendments to this Protocol;
   b) monitoring the implementation of this Protocol;
   c) the use of the verification of notified bodies in Article 6;
   d) exchanging information in accordance to Article 8; and
   e) improving technical cooperation and exchange experience among Parties in the fields of mutual interest.