Commission Decision of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council (notified under document C(2010) 7582) (Text with EEA relevance) (2010/713/EU) (revoked)

Article 1 Subject matter
Article 2 Scope
Article 3 Definitions
Article 4 Conformity assessment procedures
Article 5 Procedure for assessment of suitability for use
Article 6 EC verification procedures
Article 7 Subsidiaries of and subcontracting by notified bodies
Article 8 Application
Article 9 Addressees
Signature

ANNEX I

Modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability

MODULES FOR CONFORMITY ASSESSMENT OF INTEROPERABILITY CONSTITUENTS

Module CA: Internal production control

1. Internal production control is the conformity assessment procedure whereby the...
2. Technical documentation
3. Manufacturing
4. EC declaration of conformity
   - 4.1. The manufacturer shall draw up a written EC declaration of...
   - 4.2. The EC declaration of conformity shall meet the requirements of...
5. Authorised representative

Module CA1: Internal production control plus product verification by individual examination

1. Internal production control plus product verification by individual examination is...
2. Technical documentation
3. Manufacturing
4. Product checks
5. EC certificate of conformity
6. EC declaration of conformity
   - 6.1. The manufacturer shall draw up a written EC declaration of...
   - 6.2. The EC declaration of conformity shall meet the requirements of...
7. Authorised representative

Module CA2: Internal production control plus product verification at random intervals

1. Internal production control plus product verification at random intervals is...
2. Technical documentation
3. Manufacturing
4. Product checks
   - 4.1. At the choice of the manufacturer, either an accredited in-house...
   - 4.2. The manufacturer shall present his products in the form of...
   - 4.3. All interoperability constituents shall be available for verification in the...
5. EC certificate of conformity
6. EC declaration of conformity
   - 6.1. The manufacturer shall draw up a written EC declaration of...
   - 6.2. The EC declaration of conformity shall meet the requirements of...
7. Authorised representative

Module EC-type examination

1. EC-type examination is the part of a conformity assessment procedure...
2. EC-type examination may be carried out in either of the...
3. The manufacturer shall lodge an application for EC-type examination with...
4. The notified body shall:
5. The notified body shall draw up an evaluation report that...
6. Where the type meets the requirements of the TSI that...
7. The manufacturer shall inform the notified body that holds the...
8. Each notified body shall inform its notifying authorities concerning the...
9. The manufacturer shall keep a copy of the EC-type examination...
10. The manufacturer's authorised representative may lodge the application referred to...

Module C Conformity to type based on internal production control

1. Conformity to type based on internal production control is the...
2. Manufacturing
3. EC declaration of conformity
   - 3.1. The manufacturer shall draw up a written EC declaration of...
   - 3.2. The EC declaration of conformity shall meet the requirements of...
4. Authorised representative

Module CD Conformity to type based on quality management system of the...

1. Conformity to type based on quality management system of the...
2. Manufacturing
3. Quality management system
   - 3.1. The manufacturer shall lodge an application for assessment of his...
   - 3.2. The quality management system shall ensure that the interoperability constituents...
   - 3.3. The notified body shall assess the quality management system to...
   - 3.4. The manufacturer shall undertake to fulfil the obligations arising out...
   - 3.5. The manufacturer shall keep the notified body that has approved...

4. Surveillance under the responsibility of the notified body
4.1. The purpose of surveillance is to make sure that the...
4.2. The manufacturer shall, for periodic audits purposes, allow the notified...
4.3. The notified body shall carry out periodic audits to make...
4.4. In addition, the notified body may pay unexpected visits to...
5. EC declaration of conformity
5.1. The manufacturer shall draw up a written EC declaration of...
5.2. The EC declaration of conformity shall meet the requirements of...
6. The manufacturer shall, for the period defined in the relevant...
7. Each notified body shall inform its notifying authorities of quality...
8. Authorised representative

Module C1 Conformity to type based on product verification
1. Conformity to type based on product verification is the part...
2. Manufacturing
3. Verification
4. Verification of conformity by examination and testing of every interoperability...
4.1. All interoperability constituents shall be individually examined and appropriate tests...
4.2. The notified body shall issue an EC certificate of conformity...
5. Statistical verification of conformity
5.1. The manufacturer shall take all measures necessary so that the...
5.2. A random sample shall be taken from each lot according...
5.3. If a lot is accepted, all interoperability constituents of the...
5.4. If a lot is rejected, the notified body or the...
6. EC declaration of conformity
6.1. The manufacturer shall draw up a written EC declaration of...
6.2. The EC declaration of conformity shall meet the requirements of...
7. Authorised representative

Module H Conformity based on full quality management system
1. Conformity based on full quality management system is the conformity...
2. Manufacturing
3. Quality management system
3.1. The manufacturer shall lodge an application for assessment of his...
3.2. The quality management system shall ensure compliance of the interoperability...
3.3. The notified body shall assess the quality management system to...
3.4. The manufacturer shall undertake to fulfil the obligations arising out...
3.5. The manufacturer shall keep the notified body that has approved...
4. Surveillance under the responsibility of the notified body
4.1. The purpose of surveillance is to make sure that the...
4.2. The manufacturer shall, for periodic audits purposes, allow the notified...
4.3. The notified body shall carry out periodic audits to make...

4.4. In addition, the notified body may pay unexpected visits to...
5. EC declaration of conformity
5.1. The manufacturer shall draw up a written EC declaration of...
5.2. The EC declaration of conformity shall meet the requirements of...
6. The manufacturer shall, for the period defined in the relevant...
7. Each notified body shall inform its notifying authorities of quality...
8. Authorised representative
Module CH1 Conformity based on full quality management system plus design examination...
1. Conformity based on full quality management system plus design examination...
2. Manufacturing
3. Quality management system
3.1. The manufacturer shall lodge an application for assessment of his...
3.2. The quality management system shall ensure compliance of the interoperability...
3.3. The notified body shall assess the quality management system to...
3.4. The manufacturer shall undertake to fulfil the obligations arising out...
3.5. The manufacturer shall keep the notified body that has approved...
3.6. Each notified body shall inform its notifying authorities of quality...
4. Design examination
4.1. The manufacturer shall lodge an application for examination of the...
4.2. The application shall make it possible to understand the design,...
4.3. The notified body shall examine the application, and where the...
4.4. The manufacturer shall keep the notified body that has issued...
4.5. Each notified body shall inform its notifying authorities of the...
4.6. The manufacturer shall keep a copy of the EC design...
5. Surveillance under the responsibility of the notified body
5.1. The purpose of surveillance is to make sure that the...
5.2. The manufacturer shall, for periodic audits purposes, allow the notified...
5.3. The notified body shall carry out periodic audits to make...
5.4. In addition, the notified body may pay unexpected visits to...
6. EC declaration of conformity
6.1. The manufacturer shall draw up a written EC declaration of...
6.2. The EC declaration of conformity shall meet the requirements of...
7. The manufacturer shall, for the period defined in the relevant...
8. Authorised representative

MODULES FOR SUITABILITY FOR USE OF INTEROPERABILITY CONSTITUENTS
Module CV Type validation by in-service experience (suitability for use)

1. Type validation by in-service experience is the part of assessment...
2. The manufacturer shall lodge an application for type validation by...
3. The technical documentation shall make it possible to assess the...
4. The programme for the validation by in-service experience shall include:...
5. Type validation by in-service experience
6. Where the type meets the requirements of the TSI that...
7. The manufacturer shall inform the notified body that holds the...
8. Each notified body shall inform its notifying authorities concerning the...
9. Each notified body shall inform the other notified bodies concerning...
10. The Commission, the Member States and the other notified bodies...
11. EC declaration of suitability for use
    - 11.1. The manufacturer shall draw up a written EC declaration of...
    - 11.2. The EC declaration of suitability for use shall meet the...
    - 11.3. The interoperability constituent may be placed on the market only...
12. Authorised representative

MODULES FOR EC VERIFICATION OF SUBSYSTEMS

Module SB. EC-type examination

1. EC-type examination is the part of an EC verification procedure...
2. EC-type examination shall be carried out by:
3. The applicant shall lodge an application for EC-type examination with...
4. The notified body shall
5. When the subsystem referred to in point 3 is subject...
6. The notified body shall draw up an evaluation report that...
7. Where the type meets the requirements of the relevant TSI(s)...
8. The applicant shall inform the notified body that holds the...
9. Each notified body shall inform its notifying authorities concerning the...
10. The applicant shall keep a copy of the EC-type examination...
11. The applicant's authorised representative may lodge the application referred to...

Module SD. EC verification based on quality management system of the production...

1. EC verification based on quality management system of the production...
2. Manufacturing
3. Quality management system
    - 3.1. The applicant shall lodge an application for assessment of the...
    - 3.2. The quality management system shall ensure that the subsystem is...
    - 3.3. The notified body shall assess the quality management system to...
    - 3.4. The applicant shall undertake to fulfil the obligations arising out...
    - 3.5. The applicant shall keep the notified body that has approved...
4. Each notified body shall inform its notifying authorities of quality...
5. EC verification
    - 5.1. The applicant shall lodge an application for the EC verification...
    - 5.2. The notified body chosen by the applicant shall first examine...

6. When the subsystem referred to in point 5.1 is subject...
7. Surveillance under the responsibility of the notified body
   - 7.1. The purpose of surveillance is to make sure that the...
   - 7.2. The applicant shall, for periodic audits purposes, allow the notified...
   - 7.3. The notified body shall carry out periodic audits to make...
   - 7.4. In addition, the notified body may pay unexpected visits to...
   - 7.5. The notified body responsible for the EC verification of the...
8. EC certificate of verification and EC declaration of verification
   - 8.1. Where the subsystem meets the requirements of the relevant TSI(s),...
   - 8.2. The applicant shall draw up a written EC declaration of...
   - 8.3. The notified body shall be responsible for compiling the technical...
9. The applicant shall, throughout the service life of the subsystem,...
10. Each notified body shall inform its notifying authorities of EC...
11. Authorised representative

Module SE. verification based on product verification

1. EC verification based on product verification is the part of...
2. Manufacturing
3. The applicant shall lodge an application for the EC verification...
4. EC verification
   - 4.1. The notified body chosen by the applicant shall first examine...
   - 4.2. All subsystems shall be individually examined and appropriate tests set...
   - 4.3. The notified body shall agree with the applicant the locations...
   - 4.4. When the subsystem referred to in point 3 is subject...
   - 4.5. The notified body shall issue an EC certificate of verification...
5. EC declaration of verification
   - 5.1. The applicant shall draw up a written EC declaration of...
   - 5.2. The notified body shall be responsible for compiling the technical...
6. Each notified body shall inform its notifying authorities of EC...
7. Authorised representative

Module SG. verification based on unit verification

1. EC verification based on unit verification is the EC verification...
2. The applicant shall lodge an application for the EC verification...
3. Technical documentation
4. Manufacturing
5. EC verification
   - 5.1. A notified body chosen by the applicant shall carry out...
   - 5.2. The notified body shall examine:
   - 5.3. The notified body shall agree with the applicant the locations...
   - 5.4. When the subsystem referred to in point 2 is subject...
6. EC declaration of verification
   - 6.1. Where the subsystem meets the requirements of the relevant TSI(s),...
   - 6.2. The applicant shall draw up a written EC declaration of...
   - 6.3. The notified body shall be responsible for compiling the technical...
   - 6.4. The technical file accompanying the EC certificate of verification shall...
7. Each notified body shall inform its notifying authorities of EC...

8. Authorised representative
Module SH1 verification based on full quality management system plus design...
1. EC verification based on full quality management system plus design...
2. Manufacturing
3. Quality management system
3.1. The applicant shall lodge an application for assessment of the...
3.2. The quality management system shall ensure compliance of the subsystem...
3.3. The notified body shall assess the quality management system to...
3.4. The applicant shall undertake to fulfil the obligations arising out...
3.5. The applicant shall keep the notified body that has approved...
3.6. Each notified body shall inform its notifying authorities of quality...
4. EC verification
4.1. The applicant shall lodge an application for EC verification of...
4.2. The application shall make it possible to understand the design,...
4.3. When the subsystem referred to in point 4.1 is subject...
4.4. The notified body shall examine the application, and where the...
4.5. The applicant shall keep the notified body that has issued...
4.6. Each notified body shall inform its notifying authorities of the...
4.7. The applicant shall keep a copy of the EC design...
5. Surveillance under the responsibility of the notified body
5.1. The purpose of surveillance is to make sure that the...
5.2. The applicant shall, for periodic audits purposes, allow the notified...
5.3. The notified body shall carry out periodic audits to make...
5.4. In addition, the notified body may pay unexpected visits to...
5.5. The notified body responsible for the EC verification of the...
6. EC certificate of verification and EC declaration of verification
6.1. Where the subsystem meets the requirements of the relevant TSI(s),...
6.2. The applicant shall draw up a written EC declaration of...
6.3. The notified body shall be responsible for compiling the technical...
7. The applicant shall, throughout the service life of the subsystem,...
8. Each notified body shall inform its notifying authorities of EC...
9. Authorised representative

ANNEX II

ANNEX III

Changes to legislation:
There are currently no known outstanding effects for the Commission Decision of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council (notified under document C(2010) 7582) (Text with EEA relevance) (2010/713/EU) (revoked).