

Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (recast) (Text with EEA relevance)

CHAPTER III

INTEROPERABILITY CONSTITUENTS

Article 8

Conditions for the placing on the market of interoperability constituents

- 1 Member States shall take all necessary steps to ensure that interoperability constituents are:
- a placed on the market only if they enable interoperability to be achieved within the Union rail system while at the same time meeting the essential requirements;
 - b used in their area of use as intended and suitably installed and maintained.

This paragraph shall not prevent the placing on the market of those constituents for other applications.

- 2 Member States shall not, in their territory and on the basis of this Directive, prohibit, restrict or hinder the placing on the market of interoperability constituents for use in the Union rail system where these constituents comply with this Directive. In particular, they shall not require checks which have already been carried out as part of the procedure for ‘EC’ declaration of conformity or suitability for use as provided for in Article 10.

Article 9

Conformity or suitability for use

- 1 Member States and the Agency shall consider that an interoperability constituent meets the essential requirements if it complies with the conditions laid down in the corresponding TSI or the corresponding European specifications developed to comply with those conditions. The ‘EC’ declaration of conformity or suitability for use shall attest that the interoperability constituents have been subject to the procedures laid down in the corresponding TSI for assessing conformity or suitability for use.

- 2 Where the TSI so requires, the ‘EC’ declaration shall be accompanied by:
- a a certificate, issued by a notified body or bodies, of the intrinsic conformity of an interoperability constituent considered in isolation, to the technical specifications to be met;
 - b a certificate, issued by a notified body or bodies, of the suitability for use of an interoperability constituent considered within its railway environment, particularly in the case of functional requirements concerned.

- 3 The ‘EC’ declaration shall be dated and signed by the manufacturer or its authorised representative.

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4 The Commission shall establish, by means of implementing acts, the template of the ‘EC’ declaration of conformity or suitability for use of interoperability constituents and the list of accompanying documents. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(3).

5 Spare parts for subsystems that are already placed in service when the corresponding TSI enters into force may be installed in those subsystems without being subject to paragraph 1.

6 TSIs may provide for a period of transition for rail products identified by those TSIs as interoperability constituents which have already been placed on the market when the TSIs enter into force. Such constituents shall comply with Article 8(1).

Article 10

Procedure for ‘EC’ declaration of conformity or suitability for use

1 In order to establish the ‘EC’ declaration of conformity or suitability for use of an interoperability constituent, the manufacturer or his authorised representative shall apply the provisions laid down by the relevant TSIs.

2 Where the corresponding TSI so requires, assessment of the conformity or suitability for use of an interoperability constituent shall be carried out by the notified body with which the manufacturer or his authorised representative has lodged the application.

3 Where interoperability constituents are the subject of other legal acts of the Union covering other matters, the ‘EC’ declaration of conformity or suitability for use shall state that the interoperability constituents also meet the requirements of those other legal acts.

4 Where neither the manufacturer nor his authorised representative has met the obligations laid down in paragraphs 1 and 3, those obligations shall be incumbent on any person who places interoperability constituents on the market. For the purposes of this Directive, the same obligations shall apply to any person who assembles interoperability constituents, or parts of interoperability constituents having diverse origins, or manufactures interoperability constituents for his own use.

5 If a Member State finds that the ‘EC’ declaration has been drawn up improperly, it shall ensure that the interoperability constituent is not placed on the market. In such a case, the manufacturer or his authorised representative shall be required to restore the interoperability constituent to a state of conformity under the conditions laid down by that Member State.

Article 11

Non-compliance of interoperability constituents with essential requirements

1 Where a Member State finds that an interoperability constituent covered by the ‘EC’ declaration of conformity or suitability for use and placed on the market is, when used as intended, unlikely to meet the essential requirements, that Member State shall take all necessary steps to restrict its field of application, prohibit its use, withdraw it from the market or recall it. The Member State shall forthwith inform the Commission, the Agency and the other Member States of the measures taken and give reasons for its decision, stating in particular whether the failure to conform is due to:

- a failure to meet the essential requirements;

- b incorrect application of European specifications where application of such specifications is relied upon;
- c inadequacy of European specifications.

2 The Agency, on a mandate from the Commission, shall start the consultation process with the parties concerned without delay and in any case within 20 days of the date of receipt of that mandate. Where, following that consultation, the Agency establishes that the measure is unjustified, it shall forthwith inform the Commission, the Member State that has taken the initiative as well as other Member States, and the manufacturer or his authorised representative. Where the Agency establishes that the measure is justified, it shall forthwith inform the Member States.

3 Where the decision referred to in paragraph 1 results from an inadequacy of European specifications, the Member States, the Commission or the Agency, as appropriate, shall apply one or more of the following measures:

- a partial or total withdrawal of the specification concerned from the publications containing them;
- b if the relevant specification is a harmonised standard, restriction or withdrawal of that standard in accordance with Article 11 of Regulation (EU) No 1025/2012;
- c review of the TSI in accordance with Article 6.

4 Where an interoperability constituent bearing the 'EC' declaration of conformity fails to comply with the essential requirements, the competent Member State shall take appropriate measures against any entity which has drawn up the declaration and shall inform the Commission and the other Member States thereof.