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**KTI-TI 01: Information Document.**  
**The conformity assessment of railway subsystems, subsystem parts and the Interoperability Constituents**

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## 1. PURPOSE OF THIS INFORMATION DOCUMENT

This document provides information about the railway conformity assessment services of the **KTI Institute for Transport Sciences Non-profit Ltd. (KTI)**

### 1.1. The Scope of this Document

The scope of this document is to provide useful and basic information for the **manufactures, Railway Undertakings (RU), Infrastructure Managers (IM) wagon Keepers, and the suppliers** about the **EC verification procedure for subsystems and the assessment of conformity and suitability for use of Interoperability constituent (IC)**, requested by the Directive 2008/57/EC and 797/2016/EU and about the railway **conformity assessment activity of the KTI** in this field.

## 2. EC-VERIFICATION, EC-CONFORMITY AND SUITABILITY FOR USE

Interoperability constituents and subsystems must comply with all of the harmonized legal requirements of Technical Specification for Interoperability (TSI) that are in place at the time of its placing on the market or putting into service of the product. A product which has been subject to important changes or overhauls aiming to modify its original performance, purpose or type may be considered as a new product. The person who carries out the changes becomes then the manufacturer with the corresponding obligations.

Conformity assessment is the process carried out by the manufacturer of demonstrating whether specified requirements relating to a product have been fulfilled. A product is subjected to conformity assessment both during the design and production phase. In Union harmonisation legislation, conformity assessment procedures cover both design and production phases. They are composed of one or two modules. Some modules cover both phases. In other cases, distinct modules are used for each phase. Conformity assessment is the responsibility of the manufacturer, whether the legislation provides for the involvement of a notified or in-house accredited conformity assessment body, or not.

Notified Bodies are the bodies which are responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the 'EC' procedure for verification of the subsystems

The manufacturers' responsibility is to check it, whether their products need **EC declaration of conformity or suitability for use** before putting on the market.

If the product is an **IC**, the rolling stock is **new or modernised**; the manufacturer and the applicant have to declare the conformity or suitability for use or the verification that it meets the requirements of the European Union's legal obligations, or fulfils the national requirements on the bases of the certification issued by a **Notified Body (NoBo)** or a **Designated Body (DeBo)**.

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**KTI-TI 01: Information Document.**  
**The conformity assessment of railway subsystems, subsystem parts and the Interoperability Constituents**

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**It is recommended to choose a conformity assessment body at the design period to avoid the conflicts and the expensive reworking costs.**

### **3. THE CONFORMITY ASSESSMENT**

The **KTI** as a **NoBo (NB 2071)** and a **DeBo (VHF/3929-3/2020-ITM)** provides whole range of professional railway assessment services for the **RUs, IM, wagon Keepers**, or the concession holders responsible for carrying out a projects, which orders the design and/or construction or the renewal or upgrading of a subsystem and also for the manufacturers and the suppliers, which produces the subsystem parts and ICs.

#### **3.1. The Conformity Assessment Activity of the KTI as NoBo**

**TSIs** are the specifications adopted in accordance with the Interoperability Directives **TSIs** contains all of the requirement which interoperability constituents and subsystems must conform, and the procedures to be followed in assessing conformity and suitability for use of interoperability constituents and EC verification of subsystems.

The **KTI** examines and tests the interoperability constituents (**IC**) and the subsystems, subsystem parts, examines and audits the manufacturers quality management systems on the requirements of the Annex IV and VI of the 2008/57/EC or Article 9. (2) and Annex IV of the 2016/797/EU Directive under the requirements of the relevant **TSIs**:

##### **Infrastructure**

- Commission Regulation (EU) No 1299/2014 of 18 November 2014 on the technical specifications for interoperability relating to the ‘infrastructure’ subsystem of the rail system in the European Union
- Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 amending Commission Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1303/2014 and (EU) 2016/919 and Commission Implementing Decision 2011/665/EU
- Commission Regulation (EU) No 1300/2014 of 18 November 2014 on the technical specifications for interoperability relating to accessibility of the Union's rail system for persons with disabilities and persons with reduced mobility
- Commission Implementing Regulation (EU) 2019/772 of 16 May 2019 amending Regulation (EU) No 1300/2014 as regards inventory of assets with a view to identifying barriers to accessibility
- Commission Regulation (EU) No 1303/2014 of 18 November 2014 concerning the technical specification for interoperability relating to ‘safety in railway tunnels’ of the rail system of the European Union
- Commission Regulation (EU) 2016/912 of 9 June 2016 correcting Regulation (EU) No 1303/2014 concerning the technical specification for interoperability relating to ‘safety in railway tunnels’ of the rail system of the European Union

**KTI-TI 01: Information Document.**  
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### **Energy**

- Commission Regulation (EU) No 1301/2014 of 18 November 2014 on the technical specifications for interoperability relating to the ‘energy’ subsystem of the rail system in the Union
- Corrigendum to Commission Regulation (EU) No 1301/2014 of 18 November 2014 on the technical specifications for interoperability relating to the ‘energy’ subsystem of the rail system in the Union
- Commission Implementing Regulation (EU) 2018/868 of 13 June 2018 amending Regulation (EU) No 1301/2014 and Regulation (EU) No 1302/2014 as regards provisions on the energy measuring system and data collecting system
- Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 amending Commission Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1303/2014 and (EU) 2016/919 and Commission Implementing Decision 2011/665/EU
- Commission Regulation (EU) 2016/912 of 9 June 2016 correcting Regulation (EU) No 1303/2014 concerning the technical specification for interoperability relating to ‘safety in railway tunnels’ of the rail system of the European Union
- Commission Regulation (EU) No 1303/2014 of 18 November 2014 concerning the technical specification for interoperability relating to ‘safety in railway tunnels’ of the rail system of the European Union

### **Control-Command and Signaling**

- Commission Regulation (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the ‘control-command and signalling’ subsystems of the rail system in the European Union
- Corrigendum to Commission Regulation (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the ‘control-command and signalling’ subsystems of the rail system in the European Union
- Commission Implementing Regulation (EU) 2017/6 of 5 January 2017 on the European Rail Traffic Management System European deployment plan
- Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 amending Commission Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1303/2014 and (EU) 2016/919 and Commission Implementing Decision 2011/665/EU
- Commission implementing Regulation (EU) 2020/387 of 9 March 2020 amending Regulations (EU) No 321/2013, (EU) No 1302/2014 and (EU) 2016/919 as regards the extension of the area of use and transition phases
- Commission Regulation (EU) 2016/912 of 9 June 2016 correcting Regulation (EU) No 1303/2014 concerning the technical specification for interoperability relating to ‘safety in railway tunnels’ of the rail system of the European Union
- Commission Regulation (EU) No 1303/2014 of 18 November 2014 concerning the technical specification for interoperability relating to ‘safety in railway tunnels’ of the rail system of the European Union

**KTI-TI 01: Information Document.**  
**The conformity assessment of railway subsystems, subsystem parts and the Interoperability Constituents**

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**Rolling stock**

- Commission Regulation (EU) No 1302/2014 of 18 November 2014 concerning a technical specification for interoperability relating to the ‘rolling stock — locomotives and passenger rolling stock’ subsystem of the rail system in the European Union
- Commission Regulation (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the ‘control-command and signalling’ subsystems of the rail system in the European Union
- Corrigendum to Commission Regulation (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the ‘control-command and signalling’ subsystems of the rail system in the European Union
- Commission Implementing Regulation (EU) 2018/868 of 13 June 2018 amending Regulation (EU) No 1301/2014 and Regulation (EU) No 1302/2014 as regards provisions on the energy measuring system and data collecting system
- Commission Regulation (EU) No 321/2013 of 13 March 2013 concerning the technical specification for interoperability relating to the subsystem rolling stock — freight wagons of the rail system in the European Union and repealing Decision 2006/861/EC
- Commission Regulation (EU) No 1304/2014 of 26 November 2014 on the technical specification for interoperability relating to the subsystem ‘rolling stock — noise’ amending Decision 2008/232/EC and repealing Decision 2011/229/EU
- Commission Implementing Regulation (EU) 2019/774 of 16 May 2019 amending Regulation (EU) No 1304/2014 as regards application of the technical specification for interoperability relating to the subsystem ‘rolling stock noise’ to the existing freight wagons
- Commission Regulation (EU) No 1303/2014 of 18 November 2014 concerning the technical specification for interoperability relating to ‘safety in railway tunnels’ of the rail system of the European Union
- Commission Regulation (EU) 2016/912 of 9 June 2016 correcting Regulation (EU) No 1303/2014 concerning the technical specification for interoperability relating to ‘safety in railway tunnels’ of the rail system of the European Union
- Commission Regulation (EU) No 1300/2014 of 18 November 2014 on the technical specifications for interoperability relating to accessibility of the Union's rail system for persons with disabilities and persons with reduced mobility
- Commission Implementing Regulation (EU) 2019/772 of 16 May 2019 amending Regulation (EU) No 1300/2014 as regards inventory of assets with a view to identifying barriers to accessibility
- Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 amending Commission Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1303/2014 and (EU) 2016/919 and Commission Implementing Decision 2011/665/EU
- Commission Implementing Regulation (EU) 2020/387 of 9 March 2020 amending Regulations (EU) No 321/2013, (EU) No 1302/2014 and (EU) 2016/919 as regards the extension of the area of use and transition phases

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On the results of the successful examinations, tests and audits of subsystems, subsystem parts and ICs **KTI** issues:

- EC Type Examination Certificate (module CB, SB)
- EC Design Examination Certificate (module CH1, SH1,)
- Quality Management System Approval (module CD, CH, CH1, SD, SH1)
- EC Certificate of Conformity (module CA1, CA2, CF)
- EC Certificate of Verification (module SB+SD, SB+SF, SG, SH1)
- EC Certificate of Suitability for Use (module CV)
- Intermediate Statement of Verification – EC Type Examination (module SB)
- Intermediate Statement of Verification - EC Design Examination (module SH1)
- Intermediate Statement of Verification – Quality Management System Approval (module SD, SH1)
- Intermediate Statement of Verification (module SD, SF, SG, SH1)

according to requirements of the relevant **TSIs**.

### **3.2. The Conformity Assessment Activity of the KTI as Designated Body - DeBo**

The conformity with the national rules shall be assessed and certified: in case of the Open points of section 4.2, the Specific cases listed in section 7.3 of the **TSIs**, if there is not any **TSI** requirements for the parts of the European railway system, or the Member state excluded from the measures they adopt in implementation of the Directive 2016/797/EU, such as the:

- metros, trams and other light rail systems
- networks that are functionally separate from the rest of the railway system and intended only for the operation of local, urban or suburban passenger services, as well as railway undertakings operating solely on these networks
- privately owned railway infrastructure and vehicles exclusively used on such infrastructure that exist solely for use by the owner for its own freight operations;
- infrastructure and vehicles reserved for a strictly local, historical or touristic use.

The **KTI** as a **DeBo** provides railway assessment services for the applicants: in case of the Infrastructure, Energy, Control Command Signalling and Rolling Stock checking against the national rules:

- **NATIONAL REFERENCE DOCUMENT HUNGARY** – Notified National Technical Requirements in case of the conformity assessment of railway rolling stock referred to the point 3. annex IV of Directive 2016/797/EU ,
- **103/2003. (XII. 27.) GKM** - National Railway Regulation OVSz I.,
- **18/1998. (VII. 3.) KHVM** - National Railway Regulation OVSZ II.

KTI performs the DeBo conformity assessment processes according to the procedure of the Nobos.

**KTI-TI 01: Information Document.**  
**The conformity assessment of railway subsystems, subsystem parts and the Interoperability Constituents**

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#### 4. CONTACTS

If you have any question about conformity assessment procedure please contacts us:

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