Customer information for railway interoperability

TÜV NORD LUXEMBOURG S.à r.l.

TÜV NORD
LUXEMBOURG

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1. INFORMATION FOR APPLICANTS
CONTACT DATA

This customer information provides the necessary basic information required for your application for an EC conformity evaluation (certification) pursuant to Directive 2008/57/EC or (EU) 2016/797. For further information, please contact TÜV NORD LUXEMBOURG S.à r.l. (TNLUX):

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1. INFORMATION FOR APPLICANTS
REQUIRED DOCUMENTATION

- TNLUX requires an order from its customers – generally referred to as application – with the following information:

- Name, address, and company form of the client or his representatives
- Information about product to be certified
  - Sub-system or interoperability component
  - Relevant technical specifications for interoperability (TSI)
  - Module / module combination (we recommend previously coordinating with the notified body)
- Declaration of Consent
  - To provide the required information and documentation corresponding to the check list to be coordinated
  - To provide auditors access to the production site if necessary
  - To recognize the conditions of the EC conformity evaluation pursuant to the Directive 2008/57/EC or (EU) 2016/797
  - To always comply with the certification requirements, including the implementation of corresponding changes
  - To ensure that the certified product meets the production requirements for the entire product life span

1. INFORMATION FOR APPLICANTS
DUTIES OF CERTIFYING BODY / NOBO

The certifying body / NoBo (notified body) must

- grant all providers non-discriminatory and unconditional access to the certification service
- require an application for certification which is signed by an authorized representative of the applicant (concerning application for certification see also No. 2 of this customer information)
- upon request provide the applicant with additional information about the application

1. INFORMATION FOR THE APPLICANT
DUTIES OF PROVIDER

In terms of its customers, TNLUX expects that they

- always comply with the relevant requirements of the certification program
- make the preparations for the implementation of the evaluation (the evaluation is one step in the certification procedure)
- only use the certification in that area (sub-area, interoperability component, scope) for which it was issued
- do not apply the product certification in a form which discredits the certifying body
- use the certification in advertising in a reputable manner

2. APPLICATION FOR EC CONFORMITY EVALUATION (CERTIFICATION) / CONTRACT / ASSIGNMENT

- The EN ISO/IEC 17065 terms the contract concluded between the customer and the certification body / NoBo as application for certification.
- The duration for which NoBo must save documents is specified in Directive 2008/57/EC or (EU) 2016/797 and the appurtenant technical specifications for interoperability (TSI) and other legal regulations (e.g. product liability law). It is generally 10 years.
- The certifications issued by NoBo are published in the overview of NB Rail.
- TNLUX checks the application
  - to ensure that applicants and TNLUX do not have different interpretations,
  - to ensure that it is capable of performing the certification service.
- If TNLUX accepts the assignment, a contract is concluded with the customer

3. ASSIGNMENT OF SUBCONTRACTS

- With the consent of its customers and in compliance with the prescriptions of Directive 2008/57/EC or (EU) 2016/797, the NoBo can assign subcontracts for certain certification steps.
- TNLUX is entitled to hire testing labs or inspection bodies for testing or partial testing of products.
- In connection with the evaluation of the QM system, TNLUX may hire correspondingly accredited bodies within the TÜV NORD Group for the audit.
- Other bodies are always hired / involved in coordination with the client

4. IMPLEMENTATION OF EC CONFORMITY EVALUATION

- The procedure for the EC conformity evaluation depends on the selected module / module combination.
- The TSI relevant for the evaluation lists the permissible modules / module combinations for the respective sub-system and interoperability components, from which the client can select.
- We can generally distinguish between pure product audits (type or individual audit) and pure evaluations of the QM system and a combination of product audit (type) and QM system audit.
- The following table provides an overview.

4. IMPLEMENTATION OF EC CONFORMITY EVALUATION
DESCRIPTION OF THE MODULES

Modules pursuant to 2010/713/EC	Components	Subsystems
Internal production control	CA	
Internal production control with product testing by means of individual inspection	CA 1	
Internal production control with product testing in irregular intervals	CA 2	
EC type audit	CB	SB
Conformity with the type based on an internal production control	CC	
EC audit based on a QM system for the production process	CD	SD
EC audit based on product testing	CF	SF
EC audit based on individual inspection		SG
Conformity based on comprehensive QM system	CH	
EC audit based on comprehensive QM system with design audit	CH 1	SH1
Type validation by operational trial (operational fitness)	CV	

Possible combinations can be found in the respective TSI.

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4. IMPLEMENTATION OF EC CONFORMITY EVALUATION

- According to the specifications in the TSI to be used as basis for the audit, the audit goes through several phases. Which should be evaluated depends on the product to be tested and the selected module combination.
  The main ones are:
  - design audit
  - type audit
  - monitoring of production (product testing or regular audit of QM system)
  - In certain cases: evaluation of operational fitness (validation)

4. IMPLEMENTATION OF EC CONFORMITY EVALUATION

- Before the start of the conformity audit, an audit list is created which specifies the requirements of the TSI to be met, the type of verification management, the type of evidence to be submitted, and the evaluating personnel and auditors.
- The audit plan can also be used for documenting the evaluation results and thus becomes part of the technical file.
- Whether and to what extent audits (e.g. type tests) need to be accompanied by the certifying body must be determined on a case by case basis.
- If the evaluation has a positive result, the certificates are issued by the correspondingly authorized employees of TNLUX and given to the applicant together with the associated documentation. The applicant is not entitled to issue a declaration of conformity for the national start-up procedure.

5. DOCUMENTS REQUIRED FROM CUSTOMER

- Type and extent of the documentation for the conformity evaluation depends on the selected module combination in each case. In general these are drawings, calculations, and test reports for proof of conformity and any documentation on the QM system of the manufacturer.
- If the conformity evaluation contains the evaluation of the QM system for production, then all relevant locations must be included.
- The formats of the documentation (files, texts, graphics etc.) are coordinated with the customer in each case.
- In general, the documentation should be available in German or English.
- Other languages can be agreed in specific cases.

6. ISSUING THE CERTIFICATION

- The issue of the certification / certificate of conformity depends on the agreement of the product attributes with the applicable requirements of the TSI.
- In terms of requirements, evaluation, and certification decision, TNLUX limits itself expressly to the applicable scope.
- After a positive evaluation, a conformity certificate is issued and, if applicable, a type audit certificate and a recognition of the QM system.
- If the application refers only to part of the requirements (e.g. for parts of a partial system or steps), an interim certification can be issued.
- The client is informed of any negative evaluation result in writing with a list of the reasons.
- The certification may only be used in its complete wording.

7. MAINTAINING AND EXPANDING CERTIFICATION

- The validity of the certification is limited in accordance to the prescriptions of the applicable TSI. If necessary, the certification can be extended after completed monitoring and in consideration of new requirements.
- During the term of the certification, the manufacturer is responsible for checking any changes to the product for their impact on the TSI requirements and documenting the result. This also applies if there is a change of supplier of installed components.

  If an effect on the conformity of the certified product to the relevant TSI cannot be ruled out, the manufacturer shall immediately report the changes to the certifying body. It then evaluates the case and makes adjustments to the certification if necessary.

  If the changes lead to non-conformity, the certification is revoked.

8. SUSPENSION OR REVOCATION OF CERTIFICATION

- The certification becomes invalid if
  a) the term of the certification has expired
  b) the certification holder no longer meets the obligations specified in the certification conditions
  c) the requirements for the certified product have changed, taking into account the transition periods, unless monitoring shows that the product meets the changed requirements
  d) the certification is used for products which are not identical to the certified product, unless TNLUX has issued a decision to the contrary after being informed of the changes (see Section 7, Maintaining and expanding certification)
  e) it turns out that the certification holder or his representative has misled or attempted to mislead TNLUX or an inspection body working on behalf of TNLUX
  f) deficiencies were found in the products afterwards which were not recognized during the audit or other facts have become known which counter-indicate the issue of a certification
- TNLUX is obligated to publish the revocation of the certification via NB Rail

8. SUSPENSION OR REVOCATION OF CERTIFICATION

- In cases in which the certification is to be revoked because the certified product does not meet or no longer meets the certified requirements, the procedure is as follows:
  1. TNLUX or a hired evaluator notifies the certification holder of the impending revocation of the certification and asks them to submit a proposal for restoring conformity within a suitable period of at most four weeks.
  2. If conformity is not restored, the certification is suspended and may no longer be used by the manufacturer.
  3. TNLUX evaluates the proposal for restoring the conformity of the product, possibly with consultation of external experts. If the proposal is satisfactory, the manufacturer is given the possibility to restore the conformity of the product within a suitable period and provide corresponding proof. The certification remains suspended until such time. The period may not exceed the usual time span between two monitoring audits.
  4. TNLUX evaluates the submitted evidence, possibly with consultation of external experts. If conformity is demonstrated, the certification is restored again.
     If no such proof is provided, the certification is revoked completely.

9. MONITORING

- If specified in the applicable module combinations, TNLUX regularly monitors compliance with the TSI requirements via the certified product (see Section "Maintaining and expanding certification").
  This may occur through annual or semi-annual audits, reporting duties of the manufacturer, or individual inspections of products.

10. RIGHTS AND DUTIES OF APPLICANTS AND PROVIDERS

- The rights and duties of applicants and providers are described in the previous sections and the section on Complaints.
- We also refer to the Audit and Certification Directive which is also available on the internet.
- Furthermore, for audits pursuant to Directive (EU) 2016/797, we point out the duty of the notified body to provide information for the notifying body, the security agency, and the other bodies which are mentioned in the Directive.

11. COSTS AND FINANCING

Expenses:

- The costs that arise during the EC conformity audit are constituted by costs for
  - initial certification
  - monitoring, if specified in the applied module combination
  - processing of changes
- Fees are collected for the activities of the certifying body. Unless the quote specifies a fixed flat price for the fees, they are billed depending on expenses based on the currently valid hourly rates.
- The client is billed separately for fees that arise in connection with subcontracts to or participation of third parties and which were not already included in the quote. The client shall be informed of the probable fees before the third party is hired.

Financing:

- The TNLUX is financed by the revenue generated by its activities. The prices are calculated so that the budgeted revenue exceeds the budgeted costs. Controlling and subsequent calculations are performed to verify whether the budgeted results were achieved and thus the financial stability of the TNLUX is ensured.

12. COMPLAINTS

We distinguish

- applicant complaints concerning the work of TNLUX
  - complaints which question the effectiveness of the QM system and rules for the implementation of the certification work of TNLUX
  - complaints against a TNLUX decision
- third-party complaints concerning a product certified by TNLUX

12. COMPLAINTS CONCERNING THE WORK OF TNLUX

- Complaints should be submitted in writing, represent the relevant facts and contain an application.
- Complaints which question the effectiveness of the QM system and rules for the implementation of the certification work of TNLUX are passed on to the Advisory Board. If applicable, it shall demand corrections and follow their implementation.
- Complaints against a TNLUX decision are processed by the management. In special cases, the Advisory Board is involved. It shall strive for a mutual agreement and/or mediation decision.

12. COMPLAINTS CONCERNING A PRODUCT CERTIFIED BY TNLUX

- The certification holder shall record all complaints which concern the requirements of the manufactured products and the remedy of these complaints and provide them to TNLUX for inspection upon request.

13. EXPLANATIONS AND INTERPRETATIONS

- Explanations concerning the use of the TSI can be found in the "TSI Application Guide" on the pages of the ERA (European Railway Agency)
- The ERA provides technical supplements to the TSI in form of "technical opinions" and "technical documents"
- Interpretations on the understanding and application of the TSI can be found on the internet under: nb-rail.eu/co/co_docs_en.html in the form "Question / Clarification" (Q/c) and especially in the form of the "Recommendation for use" (RFU), the application of which is mandatory for the NoBos.