



## 99159014006001

## Anerkennung als BS, BSt, UBS, ECMZ Genehmigung als BS

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Modul	Sachverhalt
Leistungsschlüssel	99159014006001
Leistungsbezeichnung l	Anerkennung als BS, BSt, UBS, ECMZ Genehmigung als BS
Leistungsbezeichnung II	Apply for recognition as a Notified Body (NB)
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Genehmigung (6)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400), Prüfung





Modul	Sachverhalt
	und Nachweise für Sachkunde und Sicherheit (2120300)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	22.10.2024
Fachlich freigegen durch	Federal Ministry for Digital and Transport Affairs (BMDV)
Handlungsgrundlage	https://www.gesetze-im-internet.de/eigv/35.html https://www.gesetze-im-internet.de/eigv/35a.html https://www.gesetze-im-internet.de/aeg_1994/5.html
Teaser	If your company is active in the rail sector and is a so-called conformity assessment body it needs to be recognized as a Notified Body (NB) by the German Federal Railway Authority (EBA).
Volltext	You want to become a conformity assessment body in the railroad sector? Then you must from the Federal Railway Authority (EBA) as a Notified Body (NB). Notified bodies (NBs) test technical specifications for interoperability (TSIs) and can operate within the European Union (EU). Certain bodies (BSt), on the other hand, test according to the notified national technical (NNTV) regulations in Germany. In your application, you can also limit yourself to a selection of the areas of activity and expertise listed below. Notified Body (NB) Notified bodies (NB) are Conformity assessment bodies designated by the state. These bodies check compliance with the European Technical Specifications for Interoperability (TSI) and issue EC certificates of verification (EC = European Community).
	For example, NBs test products and processes on request to determine whether the legal requirements for interoperability and suitability for use are met. Interoperability means that all components of a





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	railroad system are designed in such a way that safe and continuous rail traffic is guaranteed in Germany and Europe.
	The tasks of a conformity assessment include testing, inspection, evaluation and certification decisions. The tests include components and component groups on which the interoperability of the railroad system depends and which are required in the following areas, for example:
	<ul> <li>Infrastructure, for example, tracks, switches, level crossings, bridges, tunnels, stations, safety and protective equipment</li> <li>Energy: For example, railroad power supply, catenary systems such as overhead lines and power consumption measuring and charging equipment</li> <li>Trackside and on-board train control or train protection and signaling</li> <li>Railroad vehicles, for example wagon body structure, current collection devices, traction and energy conversion devices, braking systems, couplings, bogies, axles, doors</li> </ul>
	Recognition as a NB
	Recognition as a NB is valid for a maximum of 5 years. It can be extended for a further 5 years. The EBA reports this to the European Commission for publication in the New Approach Notified and Designated Organizations (NANDO) databaseas the basis for EU-wide NB action. Recognition is also published on the EBA website.
	The EBA regularly monitors recognized NBs.
Erforderliche Unterlagen	<ul> <li>a description of your conformity assessment activities your procedures as part of the conformity assessment procedures and the structural areas (infrastructure, energy supply, control-command and signalling (CCS), rolling stock) that you cover</li> <li>completed form "F10c" checklist according to EN ISO/IEC 17065 and ERA assessment scheme</li> <li>depending on the field of activity for which you wish to be recognized, in addition to application form F09c:</li> </ul>





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	Form "F09c1" - Appendix Professional competence infrastructure Form "F09c2" - Appendix for energy expertise (BS only) Form "F09c3" - Appendix ZZS expertise Form "F09c4" - Appendix: Rail vehicle expertise • If applicable, current certificate of accreditation according to DIN EN ISO/IEC 17065 • If applicable, current certificate of certification according to ISO 9001 • Proof of EBA-approved expert status, if applicable • Other proof of competence
Voraussetzungen	To be recognized as a BS, you must
	<ul> <li>be based in the Federal Republic of Germany.</li> <li>have the number of employees with specialist knowledge and sufficient relevant experience specified in European law.</li> <li>have the relevant descriptions of procedures according to which conformity assessment is carried out to ensure transparency and the possibility of applying these procedures.</li> <li>have appropriate policies and procedures in place that distinguish between the tasks you carry out as a conformity assessment body and other activities.</li> <li>have appropriate procedures for carrying out your activities. The procedures take into account the size of your business, the sector in which you operate, your company structure and the degree of complexity of the product technology in question.</li> <li>Have the necessary resources to adequately perform the technical and administrative tasks associated with conformity assessment. In addition, you must have access to all necessary equipment or facilities.</li> <li>have liability insurance for personal injury, property damage and financial loss with a minimum sum insured of EUR 2.5 million for each insured event and at least 2 times the cover for the entire year</li> <li>be impartial, which means you must have no connection whatsoever with the organization or the manufacturer of the product you are evaluating if you and the organization or manufacturer belong to the same trade or professional association: there must be no conflicts of interest. The requirements for independence in accordance with DIN EN ISO/IEC</li> </ul>



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	17065 Chapter 4.2 apply to NBs.
Kosten	The fees you have to pay are based on the time required to process your application: • Hourly rate: EUR 120.00
	• for every quarter of an hour or part thereof: EUR 30.00.
Verfahrensablauf	You can apply for recognition as a Notified Body (NB) online. If required, you can arrange a free information meeting with the EBA before submitting your application.
	If you wish to apply for recognition as an NB, the following steps are necessary:
	<ul> <li>Download the application forms F09c, F09cx and F10c from the website of the Federal Railway Authority (EBA) and complete them in full.</li> <li>Call up the EBA's e-Service portal.</li> <li>Log in with your user data. If you do not yet have a user account for the e-Service portal, you must register once.</li> <li>Select the procedure and the type of job.</li> <li>The application wizard will guide you step by step through the required information.</li> <li>Upload the required documents as a file and submit the application. Supported file formats: PDF, DOCX, DOC, XLSX, XLS, maximum 30 megabytes per file.</li> <li>You will receive an automated confirmation of receipt by e-mail when the application has been received.</li> <li>If necessary, you will receive an additional request for documents still to be submitted by e-mail.</li> <li>The EBA will confirm the completeness and verifiability of your application for recognition and put together an assessment team.</li> <li>Once the content has been checked, you will receive a list of assessment questions to answer.</li> <li>Submit the answered assessment questionnaire as a follow-up submission via the e-Service.</li> <li>The EBA will check the content of the documents you have submitted.</li> </ul>
	<ul> <li>If the results of the review are insufficient, the EBA will carry out an on-site assessment with you.</li> </ul>





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	<ul> <li>Once the assessment has been completed, the assessment team submits an assessment report to the recognition committee and makes a proposal regarding recognition.</li> <li>The recognition body at the EBA decides on recognition. If recognition is granted, the EBA will send you the draft certificate of recognition, including the annex, and ask you to submit a statement on it within 2 weeks.</li> <li>If you do not submit a statement or if the certificate of recognition has been agreed between the EBA and you as a result of the statement, the EBA will finalize the notice of recognition and the certificate and send them to you by post together with the assessment report.</li> <li>You will also receive a notification of costs, which will also be sent to you by post. Pay the fees.</li> </ul>
Bearbeitungsdauer	6 - 24 Monat(e)
Frist	5 Jahr(e) Recognition is valid for a maximum of 5 years and can be extended for a further 5 years.
weiterführende Informationen	https://www.eba.bund.de/DE/Themen/Benannte_Stelle n_Bestimmte_Stellen/benannte_stellen_bestimmte_stel len_node.html https://www.eba.bund.de/SharedDocs/Downloads/DE/ Benannte_Stellen_Bestimmte_Stellen/D02_Handbuch.p df
Hinweise	There are no indications or special features.
Rechtsbehelf	<ul> <li>Contradiction Detailed information on how to lodge an objection can be found in the notification.</li> <li>Appeal to the administrative court</li> </ul>
Kurztext	<ul> <li>Recognition as NB, BSt, UBS, ECMZ Approval as NB</li> <li>Notified bodies (NBs) are conformity assessment bodies: they assess the conformity or suitability for use of the interoperability constituents In the rail sector, they carry out the EC (European Community) verification procedure for subsystems in accordance with the applicable Technical Specifications for Interoperability (TSI).</li> <li>Notified bodies (NBs) examine TSIs and can operate</li> </ul>





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	<ul> <li>within the European Union (EU), Certain bodies</li> <li>(Bodies), on the other hand according to the notified national technical regulations (NNTV) in Germany.</li> <li>Recognition as a Notified Body (NB) is necessary in order to be able to act as a conformity assessment body within the European Union (EU).</li> <li>Fees are calculated according to time spent: Hourly rate 120.00 EUR, EUR 30.00 per quarter of an hour or part thereof.</li> <li>Application: online</li> <li>Deadlines: none</li> <li>Processing timeusually between 6 months and 2 years.</li> <li>Responsible: Federal Railway Authority (EBA)</li> </ul>
Ansprechpunkt	
Zuständige Stelle	
Formulare	Forms available: Yes Written form required: No Informal application possible: No Personal appearance necessary: No Online services available: Yes
Ursprungsportal	Anerkennung als BS, BSt, UBS, ECMZ Genehmigung als BS, Anerkennung als BS, BSt, UBS, ECMZ Genehmigung als BS