

MANUFACTURER'S INITIAL ASSESSMENT



Successfully Reaching Your First Type Approval: Step-by-Step Guide to the Initial Assessment

As a Technical Service designated by the German Type Approval Authority Kraftfahrt-Bundesamt (KBA), ALEE supports manufacturers on their path to type approval – especially with the initial assessment at KBA.

Before a manufacturer can participate in a type approval procedure, they must demonstrate their long-term ability to produce compliant products. This is done through the so-called initial assessment, conducted by the German Type Approval Authority Kraftfahrt-Bundesamt (KBA). The aim is to ensure that the manufacturer has an effective quality assurance in place and complies with legal requirements throughout the product lifecycle.

The KBA has published a detailed information sheet outlining both the requirements for the quality management system and the necessary forms to be completed. It is available online via the KBA website: [Information Sheet on Initial Assessment \(MAB\)](#)

Application Process – ALEE Helps You Stay on Track

A key document during the application process is Form 5.1 (Application details). Here, the applicant must indicate, among other things, the types of approval objects to be included in future type approval procedures and whether production will take place in their own or third-party facilities.

Important: The approval holder does not necessarily need their own production site. However, legal responsibility for placing the product on the market always remains with the approval holder. The production site, for the purposes of approval, is considered the location where the approval object is fully completed – including the final production step (e.g., final assembly after which the product is roadworthy). Companies that only supply components are not considered production sites.

In the case of third-party manufacturing, either Form 6.1 (“Declaration on the establishment of manufacturer’s capacity for vehicles/ vehicle components in cases of external manufacture”) or Form 6.2 (“Contract on the establishment of manufacturer’s capacity for vehicles/ vehicle components in cases of external manufacture”) is also required. In practice, the declaration using Form 6.1 is often the more pragmatic option, as it does not require a signature from the production site.

Tip: ALEE helps you select the correct forms and provides templates upon request – saving time and preventing KBA follow-up questions.

Who Can Be an Approval Holder?

Type approvals for systems, components, or separate technical units under EU or UNECE regulations can only be granted to the manufacturer of the approval object, regardless of where the manufacturer is based. For whole vehicle type approvals, the manufacturer must additionally appoint an EU-based representative (Form 8.1).

For national approvals under StVZO, stricter rules apply: the applicant must be based within the European Union. In exceptional cases, approval can be granted to another company – such as an exclusive distributor based in Germany or an EU-based authorized representative, if the product is manufactured outside the EU.

Important: For products manufactured in Germany, only the producer themselves can act as the approval holder.



If the manufacturer does not apply for national approval themselves, Form 7.1 ("Authorisation to apply for a national type approval") must be submitted. The designated distributor must also provide Form 7.2 ("Confirmation of application for a national type approval").

What is Assessed During the Initial Assessment?

The initial assessment focuses on three key areas:

1. **Quality Assurance in Manufacturing**

The manufacturer must have a documented quality assurance system to ensure all relevant production steps are performed according to defined standards.

2. **Internal Conformity of Production (CoP)**

Manufacturers must demonstrate that regular checks are conducted to ensure conformity with the approved type – documented in a systematic and traceable way.

3. **Knowledge of Legal Requirements**

The assessment verifies whether the manufacturer has access to the relevant regulations and is familiar with the type approval process. This includes understanding the content of applicable UN and EU regulations as well as national requirements.

Practical Tip: While many manufacturers already have established quality assurance systems, companies new to type approval often face challenges with CoP implementation and proving regulatory compliance. A procedural instruction outlining the type approval process with all responsibilities and workflows can help. It should also document which legal acts are assessed, by whom, how often, and by what means. A customized quality assurance concept and support from experienced partners such as ALEE help prevent common mistakes. Targeted training on approval requirements is also helpful. **ALEE's homologation training** courses have been recognized by the KBA as equivalent to the KBA's own training on approval relevant requirements.

How Can Compliance Be Demonstrated?

Compliance with initial assessment requirements can be demonstrated in the following ways:

1. Through an on-site audit by the KBA
2. By presenting a valid quality management certificate – e.g., ISO 9001, if the certification body is designated by the KBA as a Category C Technical Service





3. Through an audit conducted by a KBA-designated Category C Technical Service
4. By submitting a confirmation from another European type-approval authority (Certificate of Compliance) stating that an initial assessment has already been carried out

If an audit is necessary, the result is documented in an audit report known as the Report on CoP. A template for this report is also available online: [Report on CoP \(audit report\)](#)

Support from ALEE

As a Technical Service designated by the KBA, **ALEE – Alliance des laboratoires d'essai européenne GmbH** – has extensive experience in type approval testing. In cooperation with a KBA-designated certification body for quality management systems, ALEE supports not only technical testing and inspection but also assists manufacturers with the preparation and execution of the initial assessment – from selecting the appropriate method to conducting the audit and preparing the required documentation. We are happy to advise you individually and support your approval project.

Do You Have Questions About the Initial Assessment or Type Approval in General?

Write to us or visit us at www.lab-alliance.eu – we look forward to your project.

KBA Inspection of Conformity of Production (CoP)

Report on Procedures guaranteeing Conformity of Production

1 Application Reason

☐ For the purpose of Initial assessment

☐ Re-assessment (After Initial assessment)

Occasion

☐ Certification

☐ Other assessment

Kind of audit

☐ Initial audit

☐ Re-audit

☐ Surveillance audit

☐ Additional reports on CoP will be submitted for this approval holder

Date of assessment

2 Organisation

KBA-Register-No. (e.g. A 00123 or internal KBA-No.)

Name of the organisation (e.g. certification body)

Address of the organisation

Lead inspector

Name, Function

Phone

E-Mail

Co-inspector

3 Approval holder and contact person for the KBA

Company/name¹

Address¹

Person in charge of approval relevant requirements (ARR)

Name, function

Phone, e-mail

ALEE – Alliance des laboratoires d'essais européenne GmbH

Technical Service for type approval of vehicles and components
Designated by the German Type Approval Authority (KBA)

www.lab-alliance.eu
info@lab-alliance.eu
+49 6071 496 74 82

Commercial Register: Amtsgericht Darmstadt/HRB 105486
VAT-ID: DE 363845517

KBA
Benannter TD
KBA-P 00125

