**Report on**

**Procedures guaranteeing Conformity of Production**

# 1 Application

|  |  |  |
| --- | --- | --- |
| Reason | Occasion | Kind of audit |
| [ ]  For the purpose of Initial assessment[ ]  Re-assessment (After Initial assessment) | [ ]  Certification[ ]  Other assessment | [ ]  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/name[[1]](#footnote-1) |  |
| Address1 |  |
| **Person in charge of approval relevant requirements (ARR)** |
| Name, function |  |
| Contact data (phone, e-mail) |  |
| **Person in charge of Market surveillance (MS)** |
| Name, function |  |
| Contact data (phone, e-mail) |  |
| **Approval holder certified with ARR (if applicable)** |
| Number of certificate |  |
| Certificate valid until |  |

# 4 Inspected representative approval objects

|  | Approval numberor approval mark(current extension, if applicable) | Technical standard [[2]](#footnote-2) | Approval object(Short description [[3]](#footnote-3), type) | Last/Plannedvolumeof production(per year) |
| --- | --- | --- | --- | --- |
| 1 |  |  |  |  |
| 2 |  |  |  |  |

# 5 Production plants according to Information Sheet on Initial Assessment (MAB)

## 5.1 Information on approval objects mentioned in section 4

| Company/Name | Approval object[[4]](#footnote-4) | Certified (with ARR)[[5]](#footnote-5) | Certified (without ARR)5 |
| --- | --- | --- | --- |
| Approval holder is producing in the following own production plants |
|  |  |  |  |
|  |  |  |  |
| Approval holder is producing in the following external production plants[[6]](#footnote-6) |
|  |  |  |  |
|  |  |  |  |

## 5.2 Changes to the production plants reported to the KBA[[7]](#footnote-7)

[ ]  not applicable

| Information on new production plants/names/addresses |
| --- |
| Own production plants |
|  |
|  |
| External production plants6 |
|  |
|  |

# 6 Place of inspection

Please use separate forms if the assessment was performed in several companies.

|  |  |
| --- | --- |
| [ ]  | On the approval holders premises |
|[ ]  In the following production plant |
|  | Company/Name: |  |
|  | Address: |  |
|  | Contact: |  |

# 7 Involved economic operators for Market Surveillance (MS)

|  |
| --- |
| [ ]  **Approval holder located inside the EU**[ ]  Distributor structure is documented by the approval holder/manufacturer and distributorsare informed about their obligations |
|  |
| [ ]  **Approval holder located outside the EU with the following functions** |
| Function | Company/Name | Address/location | Phone/e-mail |
| [ ]  Representative (MS) |  |  |  |
| [ ]  Importer[[8]](#footnote-8) |  |  |  |
| [ ]  Distributor8[ ]  Distributor structure is documented by the approval holder/manufacturer and distributorsare informed about their obligations[ ]  Distributors are informed about their obligations by the importer or the authorised representative of the approval holder |
|  |
| Notes |
|  |

# 8 Arrangements to ensure the conformity of the products with the approved type

## 8.1 Regulations of the manufacturer/approval holder for the production process[[9]](#footnote-9)

**Approval object:** **[[10]](#footnote-10)**

| Stage of production[[11]](#footnote-11) | Characteristic to be tested | Requirement[[12]](#footnote-12) | Test method[[13]](#footnote-13) | Test frequency/Sample size | ok | nok |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |
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## 8.2 Control of type approved characteristics for the approved type (regarding CoP test criteria)

**Approval object:       10**

| Characteristicto be tested | Requirement | Requirement of | Test method13(incl. information on responsible executing unit and location of the test) | Test frequencyand sample | Records | ok | nok |
| --- | --- | --- | --- | --- | --- | --- | --- |
| EU, UNECE, StVZO | Type approval[[14]](#footnote-14)Other |
|  |  |  |  |  |  |  |  |  |
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## 8.3 Supplementary evaluation to ensure product conformity by the approval holder

| No. | Requirements to the approval holder | Arrangements of the approval holder/of the production plant | ok | nok |
| --- | --- | --- | --- | --- |
|  | Availability of test procedures for incoming goods (for critical parts, essential for approved characteristics)* Coordinated test planning between approval holder and supplier
* Check of test records
* Defined procedure if test records are not available
 |  |  |  |
|  | Production process/availability of work and test instructions * Suitable and maintained equipment, planned maintenance is arranged
* Personnel in production is instructed/qualified and sufficiently competent, skills will be increased
* Instructions are clear, appropriate and available
 |  |  |  |
| 1. 3
 | Tests and test records* Testing personnel is defined; competence is guaranteed
* Suitable test environment
* Test equipment is suitable and in good condition
* Test requirements are appropriate and suitable
* Appropriate retention period; further analysis is guaranteed
* Adequate storage conditions
 |  |  |  |
|  | CoP arrangements to ensure production/product conformity* Procedures and responsibilities are defined
* Place of CoP testing
* Test frequency and sample size (CoP-testing program) are adequately defined
* Procedures and arrangements are effective
* Availability of test records for reporting to the KBA is guaranteed
 |  |  |  |
|  | Analysis of test results* Responsibilities are assigned
* Results within the accepted range
* Trend analysis
* Corrective actions if necessary
 |  |  |  |
|  | Non-conformity/Corrective action* Complaint management/analysis
* (market and service data)
* Root cause analysis and risk analysis regarding similar products
* Immediate and adequate implementation/realisation is guaranteed
* Effectiveness is analysed
 |  |  |  |
| 1.
 | Notification of non-conformities to the KBA[[15]](#footnote-15) * Reporting obligations known
* Responsibilities established
 |  |  |  |
|  | Traceability of products * Marking in production (e.g. part, batch, time, VIN)
* Clearly recognisable and attributable
* Appropriate retention period guaranteed [[16]](#footnote-16)
 |  |  |  |
|  | Approval compliant marking of the approval objects* Complete in accordance with the type approval or the regulation on which type approval is based
* Size, readability, durability
 |  |  |  |
|  | CoC-Document, date confirmation according to StVZO, template 2d (StVZO § 20 Abs. 3a) certificate of registration part II (ZB II)* Printout on paper with forgery-proof features
* Signature authorisation according to type approval
* Receipt and processing authorisation for ZB II defined (also recommended for CoC document)
* Secure storage and routing of defective ZB II and CoC document paper specified
 |  |  |  |
| Not applicable |

# 9 Further arrangements to meet the approval relevant and the market surveillance requirements

| No. | Requirements to the approval holder | Arrangements of the approval holder/of the production plant | ok | nok |
| --- | --- | --- | --- | --- |
|  | It is ensured that* The approval holder is familiar with his rights and obligations
* Only approved and up-to-date internal and external documents are in use in the departments
* The approval holder is familiar with the latest version of relevant standards/requirements
* The approval holder is able to react on changes appropriately and in time
 |  |  |  |
|  | Extension of type approvals are appliedat the KBA* Prior to design changes
* In case of administrative changes[[17]](#footnote-17)
* Prior to other alterations regarding the application
* In case of replacement of suppliers (only if specified by the type approval or legally required)
 |  |  |  |
|  | Responsibilities for MS are defined* Representative (for MS and ARR), importer, distributor, interfaces are defined
* Reporting obligations to MS authority is known
* Definition of risks
* Obligations are known
* Chain of commands are defined
 |  |  |  |
|  | Recall of risky products is guaranteed * Sources of information
* Responsibilities are defined
* Control of information and escalation is defined
* Further handling of products is defined
 |  |  |  |
|  | Immediate information to the KBA* Administrative changes[[18]](#footnote-18)
* Suspension/termination of a certification
* In case of definitive cessation of production of approved products[[19]](#footnote-19)
* In case of safety or environmentally relevant deficits (2001/95/EC art. 5 (3) and par. 6 (4) German Product Safety Law (ProdSG))
* Reporting obligations according to framework regulation (EU) 2018/858 (14), (EU) 167/2013 (9) and (EU) 168/2013 (10)
 |  |  |  |
|  | Management of non-conformities* Recording and analysis
* Evaluation/decision on their relevance (safety, environment, function)
* Responsibilities and interfaces defined (risk assessment, processing)
* Decision-maker defined
* Procedures defined (analysis, risk assessment, measures, verification)
* Notifications of non-conformities to the KBA according to section 8.3 No. 7
 |  |  |  |
| 1.
 | Assembly and operating instructions(as required by regulation and/or type approval)* comprehensible design/presentation
* described in the language of the sales target
* shown as available for users/customer
 |  |  |  |
| Not applicable |
|  | Providing digital CoC data (IVI)(applies only to vehicle in accordance with Vehicle Registration Regulation (FZV) § 45a)* Q-assurance agreement with KBA exists
* Data records generated and verified
* Reconciliation of existing CoC data with IVI CoC is ensured
* Process for corrective actions is defined
* Subsequent data is checked (regarding relevance to CoC data changes) and released
* Transfer of CoC data to distributors/sales areas is defined, including control of changes
* Data transfer to KBA (interface and authorised persons defined)
 |  |  |  |
| Not applicable |

# 10 Measures for manufacturing in external production plants

[ ]  Not applicable (no external production plants)

| No. | Requirements to the approval holder | Arrangements of the approval holder/of the production plant | ok | nok |
| --- | --- | --- | --- | --- |
|  | A document on the establishment of manufacturer’s capacity is availableaccording to KBA template (MAB template 6.1 or 6.2) or alternative declaration on the establishment of manufacturer’s capacity in case of external production, approved by the KBA in advance |  |  |  |
|  | Production process and test jobs to be done by the external production site have verifiably been agreed the approval holder* Release of test planning, product audit and test procedure(s)
* Appropriateness of test equipment
* Appropriate sampling
* Form and content of records (test results)
 |  |  |  |
|  | The conformity inspections are performed at the maker on behalf of the approval holder[[20]](#footnote-20)* CoP test planning harmonised (sampling, test criteria)
* Appropriateness of test equipment/environment
* Results are identifiable
* Procedure for nonconforming results is defined
* Test records are available for the approval holder at any time
 |  |  |  |
|  | The approval holder has appropriate information at any time (in particularabout compliance with the approved characteristics) and analyses it * Sufficient level of detail

(number of failures/type of failure)* Analysis of trends
* A competent contact is defined at the maker
* Results of regularly scheduled product audits
 |  |  |  |
|  | Action, if test results are not submittedor if they are not suitable as evidenceof conformity * Stop of distribution
* Procedures for management of non-conformities(incl. root cause analysis)
* Procedure for new release of production is defined
 |  |  |  |
|  | Information to the approval holder in case of* Conformity problems
* Recognition of possible risks regarding the approval object (respective use, application)
* Change of relevant processes (production steps, technology, competence of staff)
* Relocation of production
* Other changes regarding to points 2 and 3 of this table
 |  |  |  |

# 11 Summary

|  |
| --- |
| **Evaluation in case of Initial assessment** |
| Planned arrangements guaranteeing serial production of products which are conform with the type approval are |
| [ ]  Sufficient, the Initial assessment is recommended |
| [ ]  Not sufficient[ ]  The inspector recommends to grant the Initial assessment (comments in section 12)[ ]  The inspector recommends to grant the Initial assessment after closing of corrective actions(KBA must be informed). |

|  |
| --- |
| **Evaluation in case of repetition** |
| Arrangements guaranteeing serial production of products which are conform with the type approval are[ ]  Sufficiently implemented[ ]  Not sufficiently implemented |
| Non-conformities found during the previous inspection in year       [ ]  Sufficiently eliminated[ ]  Not sufficiently eliminated[ ]  Not applicable |

|  |
| --- |
| **Corrective action**In case of Initial inspection (in any case) and in case of major non-conformities as defined by the designation rules, the technical service informs the KBA immediately about settlement or non-settlement of agreed corrective actions. |
| [ ]  Not required[ ]  Required; realisation agreed by:       |
|  |

# 12 Additional comments/list of enclosures/opportunity for improvement

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| --- |
|  |

Lead inspector

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Place |  | Date |  | Name/Signature |

Review by Technical Service

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Place |  | Date |  | Name/Signature |

Please send this document to the KBA, Dresden
(In case of inspection for Initial assessment: with handwritten signature; submission as pdf file with scanned signature is acceptable).

1. Data according to official register document [↑](#footnote-ref-1)
2. Explicit EU legal acts or -Regulations (basic issue), UN-regulations, national standards [↑](#footnote-ref-2)
3. Examples: passenger car, moped, silencing system, special wheel, rear underrun protection, installation of rear underrun protection [↑](#footnote-ref-3)
4. No. from [section 4](#Abschnitt4) [↑](#footnote-ref-4)
5. Certification body, date of validity, standard, number of QM-certificate [↑](#footnote-ref-5)
6. Legally independent production plants (further details in [section 10](#Abschnitt10)) [↑](#footnote-ref-6)
7. Concerns all approval objects [↑](#footnote-ref-7)
8. Has to fulfil the obligations of a manufacturer if he wants to make an approval object available on the market under his own name
or brand. [↑](#footnote-ref-8)
9. Please add further lines if necessary. [↑](#footnote-ref-9)
10. No. as given in [section 4](#Abschnitt4) (please copy this page for further products). [↑](#footnote-ref-10)
11. At least incoming goods (if relevant), manufacturing (please specify the production stage), final inspection, further stages such as warehousing, shipping etc. [↑](#footnote-ref-11)
12. Refer to documents if applicable. [↑](#footnote-ref-12)
13. If applicable, specify name and/or document (e.g. procedure instruction, testing instruction, sample size) [↑](#footnote-ref-13)
14. Type approval = Approval + information document + test report of the designated technical service. [↑](#footnote-ref-14)
15. In accordance to framework regulation (EU) 2018/858 (14), 167/2013 (9) and 168/2013 (10) using e-mail address nonconform@kba.de [↑](#footnote-ref-15)
16. According to the legal requirement, see also KBA recommendation "Retention periods for approvals and relevant quality records". [↑](#footnote-ref-16)
17. This is valid for the Whole Vehicle Type Approval and for nameplates. [↑](#footnote-ref-17)
18. The KBA must immediately be informed about changes of legal status, name and place of the approval holder or of the producer
or of the production sites. [↑](#footnote-ref-18)
19. For approved vehicle parts according to the National Type approval for vehicle parts (ABG) § 22a StVZO (German Road Traffic Law), the KBA must be informed if the production start is not done within more than one year and also if the production is interrupted for a period of more than one year. [↑](#footnote-ref-19)
20. This can be skipped if CoP-tests are performed by the approval holder or on his behalf by a designated laboratory. [↑](#footnote-ref-20)