Report on
Procedures guaranteeing Conformity of Production

1 Application

Information for forwarding to individual departments of the KBA and for better understanding

Reason	Occasion	Kind of audit
☑ For the purpose of Initial assessment	☐ Certification	☐ Initial audit
☐ Re-assessment (After Initial assessment)	☐ Verification	☐ Re-audit
	☑ Other assessment	☐ Surveillance audit

☐ Additional CoP reports will be submitted for this approval holder

If serveral sites of the approval holder are assessed (e.g. production, development), a separate form must be used for each.

Date of assessment	16 October 2017

2 Organisation

Designated Technical Service or KBA employee carrying out the CoP inspection

KBA-Register-No. (e.g. A 00123 or internal KBA-No.)	A 00123
Name of the organisation (e.g. certification body)	Certification body A
Address of the organisation	32 Street, 11111 Template City
Lead inspector[1]	
Name/Function	Ms. Nazar, Lead auditor
Phone/Fax	0815 012158710
E-Mail	info@certificationbody.com
Co-inspector	Mr. Anton, Auditor

3 Approval holder and contact person for KBA

Company/name	ABC Factory Ltd.
Address	56 Template Street, 11222 A-City
Person in charge of approval relevant requirements/Contact for KBA	
Name, function	Mr. A. Müller, QA Manager
Contact data (phone, e-mail)	0819 12598713, a.mueller@abc.com
Person in charge of Market surveillance (MS)	Not to be confused with the authorized representative for market surveillance, who have to named only by companies located outside of the EC. It should be an employee of the approval holder who is in charge for this task.
Name, function	Mr. B. Maier, Head of Marketing Department
Contact data (phone, e-mail)	0819 12598722, b.maier@abc.com

[1] E.g. auditor

4 Inspected representative approval objects

	Approval number or approval mark (current extension, if applicable)	Technical standard[2]	Approval object (Type, short description)[3]	Last/Planned volume of production per year
1	E1 10R-04 1234	UN-Regulation No. 10	FZS-10A, Passenger counting system	800 parts
2				

5 Production plants for approval objects listed in chapter 4

Company/Name	Approval object[4]	Certified (with ARR)/ Verified[5]	Certified[5] (without ARR)
At the approval holder produces in the following own production plants			
ABC Factory, 11222 A-City	1	Certification body A ISO 9001:2015 Valid until 21 Dec. 2018 Certificate No. 0815-0815	
At the approval holder produces in the following external production plants[6]			
Company XYZ, 22222 B-Town	1		Certification body B ISO 9001:2015 Valid until 06 Dec. 2018 Certificate No. 1234734
Company wdv Ltd., 33333 C-Village	1		

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:	Company XYZ
Address:	12 Street, 22222 B-Town
Contact:	Mr. Schmidt, Head of QC

[2] Explicit EU legal acts (basic issue), UN-regulations, national standards. This information is only required if the standard cannot be recognized from the approval number. For initial assessment, the name of the applicable standard is required.

[3] Examples: moped, exhaust silencer, truck tyres.

[4] No. from section 4.

[5] Certification body, date of validity, standard, number of QM-certificate.

[6] Legally independent production plant, bound by contract in accordance with the Information Sheet on Initial Assessment (MAB) (Further details in section 10).

7 Involved economic operators for Market Surveillance (MS)

☐ Approval holder located inside the EU			
☑ Approval holder located outside the EU with the following functions			
Function	Company/Name	Address/location	Phone/e-mail
☑ Representative (MS)	Consulting Ltd.	7 Template Place, 33333 Template Town	0123 458769, info@consult.com
☑ Importer[7]	Dealers Ltd.	1 Template Bld., 44444 Template Hill	0999 99887, info@dealer.com
☑ Distributor[7] ☑ Distributer structure is documented by the approval holder/manufacturer and distributers are informed about their obligations ☑ Distributers are informed about their obligations by the importer			
Notes The information letter to the dealers has been checked. It meets the requirement. The approval holder (AH) delivers only to OEM. Spare parts are also only distributed by OEM.			

The dealer structure shall be also documented by AH inside the EU. The dealers shall be also informed by their duties in this case.

[7] 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.

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

Entries in sections 8.1 and 8.2 (except evaluation) may be prepared by the approval holder.

8.1 Regulations of the manufacturer/approval holder for the production process[8]

Approval object: 1 [9]

In Section 8.1, details on production monitoring and process control should be given. The relevant inspections usually do not relate only to characteristics which are approved/to be approved. However, they provide additional information which can be important for evaluation of measures to ensure conformity. Only inspections which are significant for attaining/maintaining the approved/to be approved characteristics should be entered into the table.

Stage of production[10]	Characteristic to be tested	Requirement[11]	Test method	Test frequency/ Sample size	ok	nok
Incoming Goods Inspection (IGI)	Plausibility (identity, quantity), damage, labelling according to drawing	IG inspection plan, material no., delivery note/order	Visual inspection, measurement inspection according to drawing (measuring room)	10 subjects per delivery (max. 200)		F1
Circuit board mounting	Components, mounting, function test	Circuit board parts list according to contract, electrical test	Optical test Identity and allocation, simulation test	100 % automated test	X	
Component assembly	Assembly quality, A + B cable polarity	Assembly parts list, inspection instruction AA-0815 (Rev. 03/16), assembly instruction AA-0816 (Issue: 27 Febr. 17), drawing No. xy/004	Visual inspection according to drawing, burn-in test	100 %	X	
Final inspection	Function, labelling, quality of processing	Inspection instruction AA-0821 final check (Issue: 03 March 17), drawing No. xy/004,	Final test with function simulation, visual inspection	100 %	X	
Delivery/storage	Completeness of delivery contents (operating and assembly instructions, mounting material)	Packing list, delivery contract for subject for approval, AA-0817 (Rev. 02/17), packaging/delivery	Visual inspection, data comparison with contract data, delivery data	10 % per delivery	X	

[8] Please add further lines if necessary.

[9] No as given in section 4 (please copy this page for further products).

[10] At least incoming goods (if relevant), manufacturing (please specify the production stage), final inspection, further stages such as warehousing, shipping etc.

[11] Refer to documents if applicable.

8.2 Control of type approved characteristics for the approved type (regarding CoP test critera)

Approval object: 1 [9]

Characteristic to be tested	Requirement[12]	Requirement of		Test method[12]	Test frequency/ Sample size[12]	Records	ok	nok
		EU, UNECE, StVZO	Type approval[13], Other					
Mounted components	VA-03 (CoP confirma-tion), Parts List No. 103/ Drawing No. xy/004	x	x	Parts list nominal-actual comparison	Every 6 months	CoP report, Parts List No. 103	X	
Emitted radiation	UNECE-R 10, Annex 7 and 8	x		According to Annex 7 and 8 by inspection laboratory	Every 36 months	Inspection report from inspection laboratory zy	X	
Radiated immunity and conducted pulses	UNECE-R 10, Annex 9 and 10	x		According to Annex 9 and 10 by inspection laboratory	Every 36 months	Inspection report from inspection laboratory zy	X	

Sections 8.2 and 8.3 only concern the direct inspection of features and properties described in the approval and possible CoP inspections possibly particularly specified in the underlying regulations. Inspections accompanying manufacturing, incoming goods monitoring etc. are not relevant in this case. If it's significant for the type approvals. Special customer requirements for testing may be listed.

[12] If applicable, please specify name and/or source in the document (e.g. procedure, test instruction).

[13] Type approval = Approval + information document + Test report of the designated technical service.

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
1	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 Usually agreed inspections are required for the approval relevant characteristics. This is applicable in particular in the case of external manufacturing (e.g. circuit board mounting). Valid inspection plan/valid test instruction should be documented.	Inspection agreed - Test instruction for incoming goods of 12 March 2017 Contract manager carries out a 100 % inspection and supplies a factory report If material certificates are missing – no approval for manufacturing, handling of components as with detected defects (quarantine store) ABC inspects geometric features according to sampling plan Inspection records are available	X	
2	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 Briefing of production staff preferably according to established instruction plans. Work instruction/ testing instructions should be documented as example (issue date, revision level). Advancement of personnel should be recognisable.	Means of production appropriate; staff briefing on induction plans, following induction phase, foreman decides on implementation; training Program for personal qualification is available. Working instructions (with testing plan) available at workstations Preventive maintenance of equipment according to planning (each area)	X	
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 • Retention periods in KBA document "Retention periods for approvals and relevant quality records". The given periods should be treated as a recommendation. • Archiving also includes data security • For retention periods also note respective regulatory acts (regulations/directives) • Suitability and condition of test equipment also includes calibration • AH must be able to justify why they believe this arrangement to be suitable (staff, equipment, test conditions)	Appropriate tests established for proof of characteristics relevant to the approval. Induction of test staff as in manufacturing; suitable test desks in manufacturing; separate test room with measuring devices, test equipment calibrated, traceable to the national standard. The testing software for use is not documented in AA-25. Allocation to the final test of the current version of the subject for permit approval is not provided (F2). QA holds inspection records; retention periods set appropriately, between 3 and 10 years Protocols on the INTRANET; protection OK		F2

No.	Requirements to the approval holder	Arrangements of the approval holder/ of the production plant	ok	nok
4	CoP arrangements to ensure production/product conformity - Procedures and responsibilities are defined - Place of CoP testing - Test frequency and sample size are adequately defined - Procedures and arrangements are effective - Availability of test records for reporting to the KBA is guaranteed • The responsibility is normally not limited to the contact person to the KBA. • Training by KBA is not required. • Responsible for the performance of tests should be as possible an independent division (Usually QM or QC) • The legal requirements to the type approval shall be considered • The scope of testing shall be appropriate to the product with its approval relevant characteristics (may be defined in the control plan) • Resources shall be available	Responsible is department Homologation; CoP test plan exists in checklist form (QMP No. VA-03 (Rev. 02/16) CoP every 36 month (external EMC-lab test); 1 piece each (AO), test result of 20 September 2017 was checked. Completed checklist on the INTRANET, constantly updated. These is always available for KBA.	X	
5	Analysis of test results - Responsibilities are assigned - Results within the accepted range - Trend analysis - Corrective actions if necessary Include quality check, which are relevant for the assurance of the conformity of products by serial production. Consideration also of delivered goods. Analysis is not mandatory.	Evaluation stating that limit values and tolerances are met (responsible: Mr. Schmidt) In case of non-conformities: quarantine; information of manager; send non-conformity report	X	
6	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 • Internal/external errors • It has to be checked also, which mechanisms are planned and if response times are realistic and acceptable • Beside removal action also preventive action shall be planned to avoid same or similar errors • Interface to recall action should be recognisable	QMP No. AA- 32 (Issue: 10 Jan.11) "Non-conformity processing" 8-D-Report as basis for internal and external non-conformity management Management of corrective action under the responsibility of QM; effectiveness evaluate according to defined deadlines	X	
7	Traceability of products - Marking in production (e.g. part, batch, time, VIN) - Clearly recognisable and attributable - Appropriate retention period guaranteed[14] It has to be checked, how far the marking is usable for the performance of recall action.	Allocation of serial numbers for individual parts to the entire device Production period and contract number recorded. Documents will be stored for 10 years at least. This system is suitable as a basic of the localisation of produced products if a recall is necessary.	X	

[14] According to the legal requirement, see also KBA recommendation "Retention periods for approvals and relevant quality records".

No.	Requirements to the approval holder	Arrangements of the approval holder/ of the production plant	ok	nok
8	Approval compliant marking of the approval objects - Complete in accordance with the type approval - Size, readability, durability Kind, volume and dimension of the marking according to the specification of standard	Labelling according to type approval; label is a part of bill of material. Legibility and durability are guaranteed.	X	

Checks should generally be carried out to ensure that
- The monitoring of approved characteristics is properly organised.
- Responsibilities are clearly defined.
- Managers are aware of their duties, competent and the necessary resources are available
- Chains of communication are in place and effective, so that, if necessary, production may be stopped immediately and corrections and corrective actions can be started
- The necessary analyses are made in order to avoid deviations from the approved characteristics.

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
1	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 • As external documents KBA-Information sheets also may be relevant • External documents must be owned by approval holder mandatory; a (based on request) information system may be sufficient • The rights and duties are shown within the information sheet for initial assessment, chapter 3	MAB is known and communicated; current internal documents managed on the INTRANET, invalid documents are no longer accessible, electronic change management installed. EU regulatory acts and UN regulations regularly tracked via Eurolex and www.unece.org, Information about the change of legal requirements be tracked in cooperation with the technical service, necessity of changes is evaluated.	X	
2	Extension of type approvals are applied at the KBA – Prior to design changes – In case of administrative changes[15] – Prior to other alterations regarding the application – In case of replacement of suppliers (only if specified by the type approval or legally required) In case of design changes it must be considered, that the relevance of change is evaluated. Changes of the type approvals are normally applied after a consultation with technical service.	QMP No. VA-08 (Rev. 02/13) "Change management"; changes treated as new development; QM and Homologation evaluate relevance of planned change with regard to type approval and apply for amendment of the type approval if necessary.	X	
3	Responsibilities for MS are defined – Importers and distributors are informed about their duties – Definition of risks – Obligations are known – Communication channels are defined If an approved object according to UN-Regulation No. 10 is used in vehicles of Regulation (EU) 167/2013 or (EU) 168/2013 then it must also fulfil the requirements of these directives.	The approval holder has informed his importers and distributors about their duties according to the Regulation (EU) verifiable. The risks were verified with the distributors and the procedure was fixed together. This information is fixed in working instruction No. AA 0815-158 and has to be announced to new distributors before contracting.	X	

[15] This is valid for the Whole Vehicle Type Approval and for nameplates.

No.	Requirements to the approval holder	Arrangements of the approval holder/ of the production plant	ok	nok
4	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 • According to the EG-FGV [EG-*Fahrzeug-genehmigungs-Verordnung*] Par. 7, it must be ensured that the KBA is informed immediately in case of a "significant risk to traffic safety, health or environment". • Inspection must also take place on how recalls on the part of suppliers will be allocated to the final products and how own customers will be informed. • How does the approval holder verify and implement information of dealer and importer? • How will be taken information of distributors and importer to an authority into the system of the approval holder? • Non-conforming stock must be identified. • How is the effectiveness/thoroughness of a recall guaranteed? • Are there potentially different kinds of recall?	Complaints, market information (e.g. from dealers) lead to 8-D report; company management evaluates necessity of recall; QMP No. VA-10 (Rev. 01/13) regulates recall procedure; KBA will be informed. Has dealer or the importer informed an authority the approval holder will contact this authority immediately. The approval holder takes over all duties of recall and the coordination of the recall. He detects all affected products in other countries.	X	
5	Immediate information to the KBA – Administrative changes[16] – Suspension/termination of a certification/ verification - In case of definitive cessation of production of approved products[17] - In case of safety or environmently relevant deficites (2001/95/EC art. 5 (3) and par. 6 (4) German Product Safety Law (ProdSG)) It is no longer necessary to inform the KBA in the case of a temporary discontinuation (longer than one year) (Except for type approvals according to the German Road traffic Law (StVZO), see footnote 17).	It is known that the KBA must be informed of these changes. Mr. Mustermann is responsible for this as Head of Homologation. Information on safety-related and environmental-related deficiencies included in QMP No. VA-10 (Rev. 01/13) Recalls The information according to Product Safety Law will be given to KBA according to the Codex of KBA.	X	
6	Instructions for fitting or operating, CoC documents, data confirmation according to the annex to StVZO, template 2d, vehicle registration certificate (part II), etc. - Possible requirements, notes concerning scope of usage etc. are included - They are clear and understandable - Adequately handled/safely stored CoC-printout on special paper (fake aggravating).	Operation instructions are component of parts list; changes handled according to QMP No. VA-08	X	
			Not applicable	

Checks should generally be carried out to ensure that
- The appropriate approval relevant and legal requirements and other requirements related to quality are applied reasonably. (The amount of documentation should reasonably reflect the size of the company.)
- Responsibilities are clearly defined.
- Managers are aware of their duties and sufficient resources are made available to them.

[16] 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.

[17] 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.

10 Measures for manufacturing in external production plants

☐ Not applicable

			ok	nok
1	A document on the establishment of manufacturer's capacity is available according 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 • It is to be checked at random, if the specifications of the approval holder are known by the manufacturer and if they are practicable for the concrete situation • Possible is the "Declaration on the establishment of manufacturer capacity for vehicles/vehicle components in cases of external manufacture" (MAB Form 6.1) or the "Contract on the establishment of manufacturer capacity for vehicles/vehicle components in cases of external manufacture" (MAB Form 6.2) • If a product audit is scheduled the performance and documentation have to be checked	Contract exists and is submitted to the KBA. (Contract for external manufacturing of 12 February 2012 – Company A manufactures at company B) According to sample contract (Form 6.2) Product audits will be planned and carried out yearly in the production plants.	X	
2	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) Normally an initial assessment on site by the approval holder is expected	The approval holder has released the production process before starting the first charge. The tests are agreed and the using test equipment according to control plan of production plant is fixed.	X	
3	The conformity inspections are performed at the maker on behalf of the approval holder[18] - 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 In case of spot checks, which are given to technical service for testing, the sampling of the spot checks has to be defined.	The AH plans the CoP testing, approval subject to agreement with production plant; Tests are determined; test equipment is suitable, serviced and calibrated. This will be checked by audits on site. Determination: test 2 of 100 (internal lab test); information in case of negative results; tests recorded in verified protocols.	X	
4	The approval holder has appropriate information at any time (in particular about 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	Evaluation of results in incoming goods inspection (IGI); availability of protocols; evaluation: compliance with tolerance levels Contact person for the production site is Mr. Müller, Head of QC	X	

[18] This can be skipped if CoP-tests are performed by the approval holder or on his behalf by a designated laboratory.

			ok	nok
5	Action, if test results are not submitted or if they are not suitable as evidence of conformity - Stop of distribution - Procedures for management of non-conformities (incl. root cause analysis) - Procedure for new release of production is defined	If test records are not available, no approval by IGI, delivery stoppage according to contract of 12 Feb. 2012; Possibility of recall is assured (QMV No. VA-10 (Rev. 01 13); product identification by using delivery date and serial number In case of unsuitable (wrong) tests or test result a root cause analysis will be done. Corrective and (if necessary) preventive actions will be fixed. After a new test the production will be released by the approval holder.	X	
6	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	Interface is established (see contract, Par. 1); All non-conformities will be communicated to the approval holder. Not-passed checks of conformity will be assessed together. Recognised risks in terms of market surveillance will be communicated to the approval holder immediately. All changes have to be released by the approval holder before delivery..	x	

11 Summary

Particularly in the case of inspections as part of certification and verification procedures, the performance of corrective actions shall be evaluated in the following inspection and documented in the associated Report on CoP. In the case of significant non-conformities, the KBA in Dresden must be informed as soon as possible.

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 chapter 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: 31 January 2018

F1: Test criteria in the test plan and drawing not identical (see Non-Conformity report No. 1)
F2: Final test inspection software cannot be allocated to the current amendment (see Non-conformity report No. 2)

12 Additional comments/list of enclosures/opportunity for improvement

Reference to possibly attached non-conformity reports is permitted.

Lead inspector/ Auditor

City A	20 October 2017	Nazar
Place	Date	Name/Signature

Check by the technical service (Veto)

City B	13 November 2017	Schulze
Place	Date	Name/Signature

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