Guidelines for initial sample testing (ISIR) / serial product and process approval for externally procured components

Version 04

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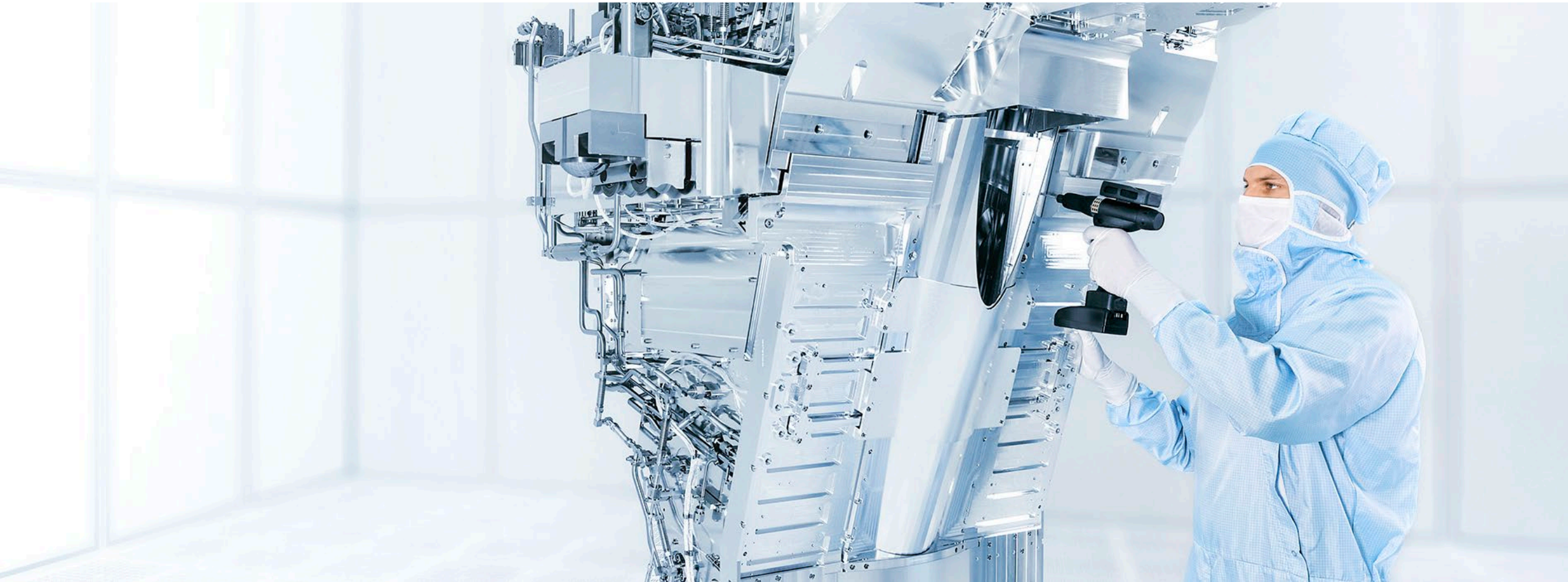
Carl Zeiss SMT Oberkochen

16. Juli 2024



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Aims of sampling

The sampling of purchased parts has the following overarching objective:

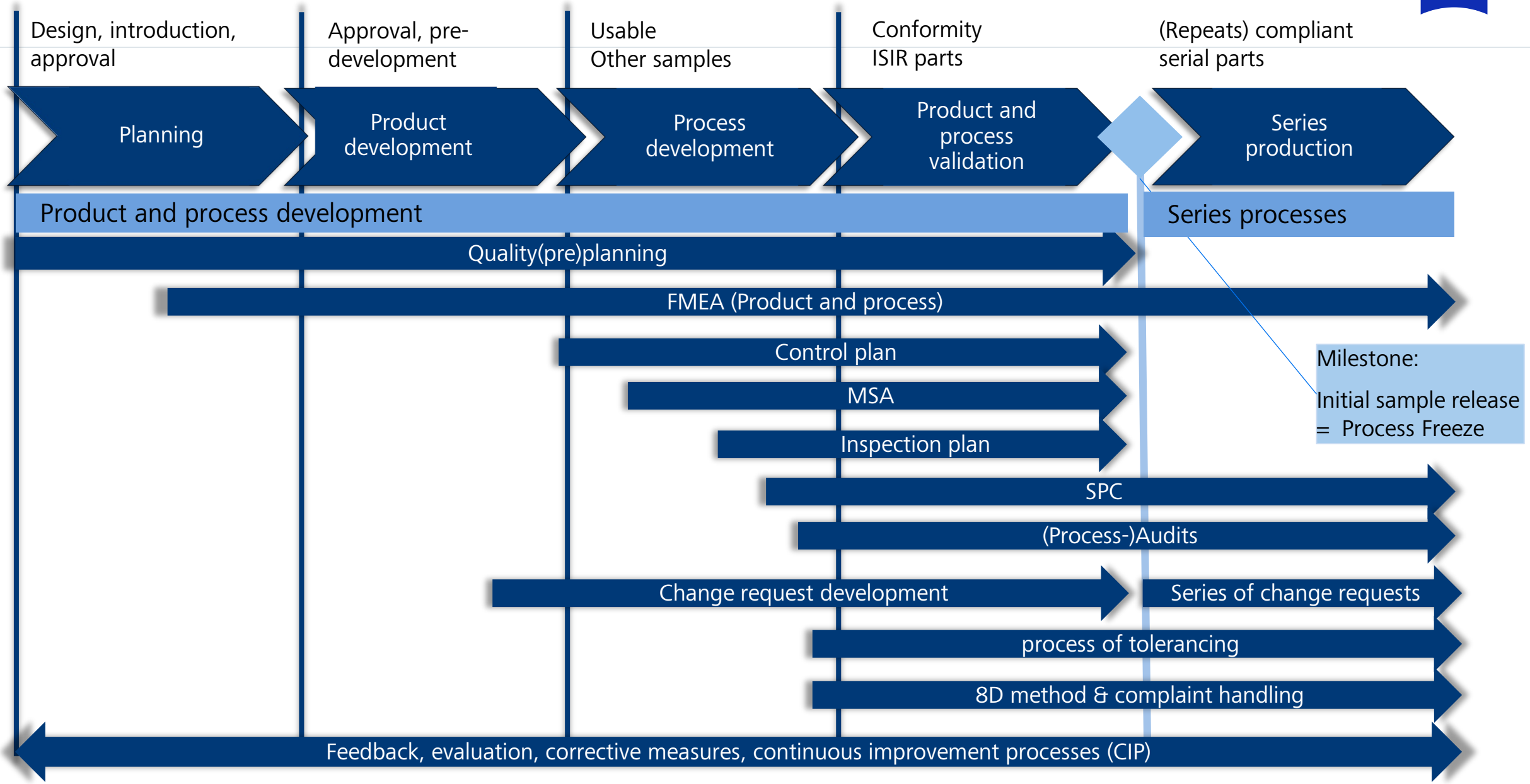
The sampling is used to ensure the maturity of products and to officially complete the quality advance planning and to verify the series production capability of products intended for customers.

This ensures that the components

- ✓ Repeated as specification-compliant products
- ✓ At the right time
- ✓ In the right quantity
- ✓ On the planned costs

in the manufacturing process.

Product creation process and quality advance planning



ISIR as completion of the development phase

The sampling is equivalent to **the completion of the development**:
- Component development (by supplier or customer) = **design freeze**
- Development of the manufacturing process = **process freeze**

Initial sample testing is **not a separate process**. Rather, it is the collection (and evaluation) of evidence at the end of the development process. The inspection does not only look at data on a single component, but also at the processes and methods that must be used in (process) development.

The included methods, the evidence of which is requested during sampling, should already **be integrated** into the **supplier's development processes** by default.

The implementation of the initial sample inspection shows that the supplier knows and understands **all of the customer's requirements** and can convert these into **compliant and reliable processes and products**.

Definitions / Explanations of terms

Initial samples are products which were manufactured under series production conditions using **"robust, frozen" processes** with serial tools, reliable and controlled. They fully comply with the underlying specifications, unless a deviation approval / special tolerancing authorized by the customer is available. The first parts produced are not automatically initial samples!

The **initial sample test report** and its appendices shall be **evidence of conformity** of the samples with regard to the underlying specifications and shall be true in all respects. The initial sample test report with all signed appendices must be sent as a PDF to Carl Zeiss SMT GmbH.

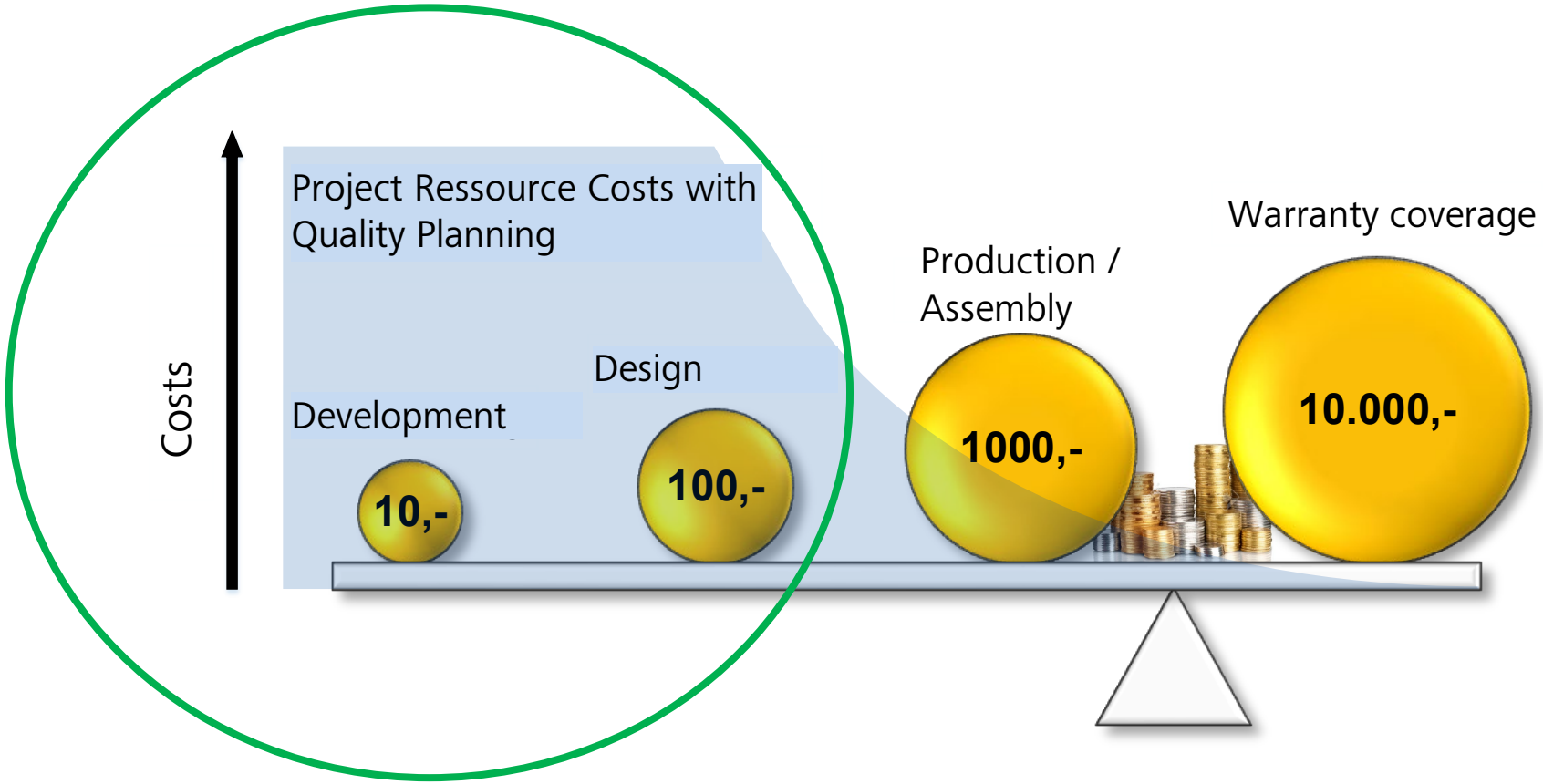
The scope of the initial sample inspection is defined by the customer and **depends on the presentation stage** of the initial sample inspection report, which in turn depends on **the classification** of the parts to be inspected. The scope of the content to be presented must be individually agreed with the supplier for each initial sample test report. Particular attention must be paid to the "special features".

Other samples (or components prior to ISIR) are samples from near-series processes which **do not yet fully correspond** to the series processes (e.g. preproduction series samples, design samples, development samples).

Cost leverage through quality advance planning

Plan (act) quality instead of correcting (reacting) errors

Quality advance planning (QAP) = quality management discipline geared to prevention



General requirements for initial sample testing

The template from ZEISS (including the corresponding attachments) must be used for **sampling approval**.

For elements #06 Production control plan, #07 Inspection plans, #08 Process/product FMEA and #11 Process audits, the corresponding **checklists** must be **truthfully filled** in by the supplier. Filling out the checklist does not release the supplier from the application and performance of the corresponding tasks/methods. As additional documents, your own verification documents must be added or made available for inspection.

If the other requested documents correspond to the content of the ZEISS ISIR templates, the supplier may also use **its own templates** after **consulting with ZEISS**.

If the capability of processes cannot be verified, a **100% inspection** of the characteristics must be performed (cf. #9 Repeatability / process capability)

The initial sample test report presented for approval may only contain **values that comply with the specification**. However, if there are any deviations, a **customer release** (special release) must be obtained in advance in order to be able to present the initial sample test report.

Documenting the initial sample test report requires **timely and careful coordination** between the supplier and the customer.

Components before ISIR / before series release

Since the purpose of the initial sample inspection or product and series release is to prove the **suitability for series production** of a purchased part, this release usually cannot take place with the first delivery. However, these parts are used to protect the series start-up phase when they are integrated into serial products that are delivered to our customers. These purchased parts **must comply with the specifications** in every detail.

The supplier must also provide SMT with information or documents on these purchased parts during the series startup phase. In particular, these are part-specific certificates which prove the **specification conformity** and ensure traceability for each purchased part in the pre-series.

Contents of the following elements are to be transmitted:

- #00 - Cover sheet (filled out and signed by supplier)
- #02 - Component/product drawings (including stamped drawing) *
- #03 - TA list and list of relevant specifications *
- #04 - Measurement report (including cleaning)
- #05 - Material conformity
- #15 - Serialization & traceability

* These two overviews are intended to document which specifications were used as the basis for the manufacture of the components

Components before ISIR / before series release

The **ISIR template** must be used to communicate with the suppliers and document the specifications. To do this, select the "Preproduction series" (or "Prototype") sample reason.

In addition to requesting the documents, an **acceptance call** can be conducted with the suppliers prior to delivery of the purchased parts, especially for complex modules and assemblies, together with a possible acceptance of the purchased parts on site by SMT employees. The acceptance call is a method to prevent risks.

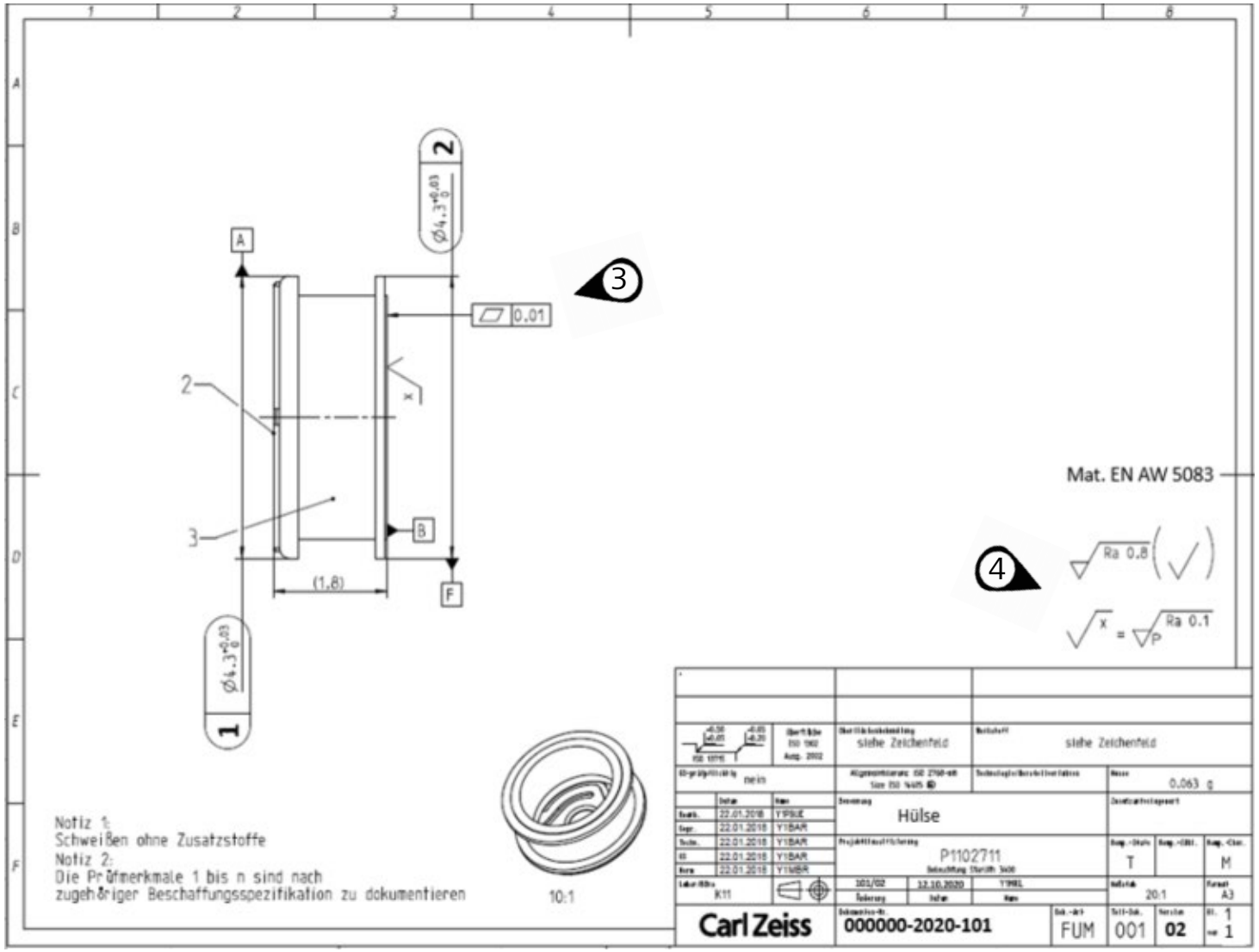
These pre-series components are purchased parts that **have not been manufactured completely** under standard conditions. Other samples must therefore not be used for initial sampling. The release of other samples **does not mean the release of the series** and does not justify a waiver of the initial sample procedure.

Example of a component

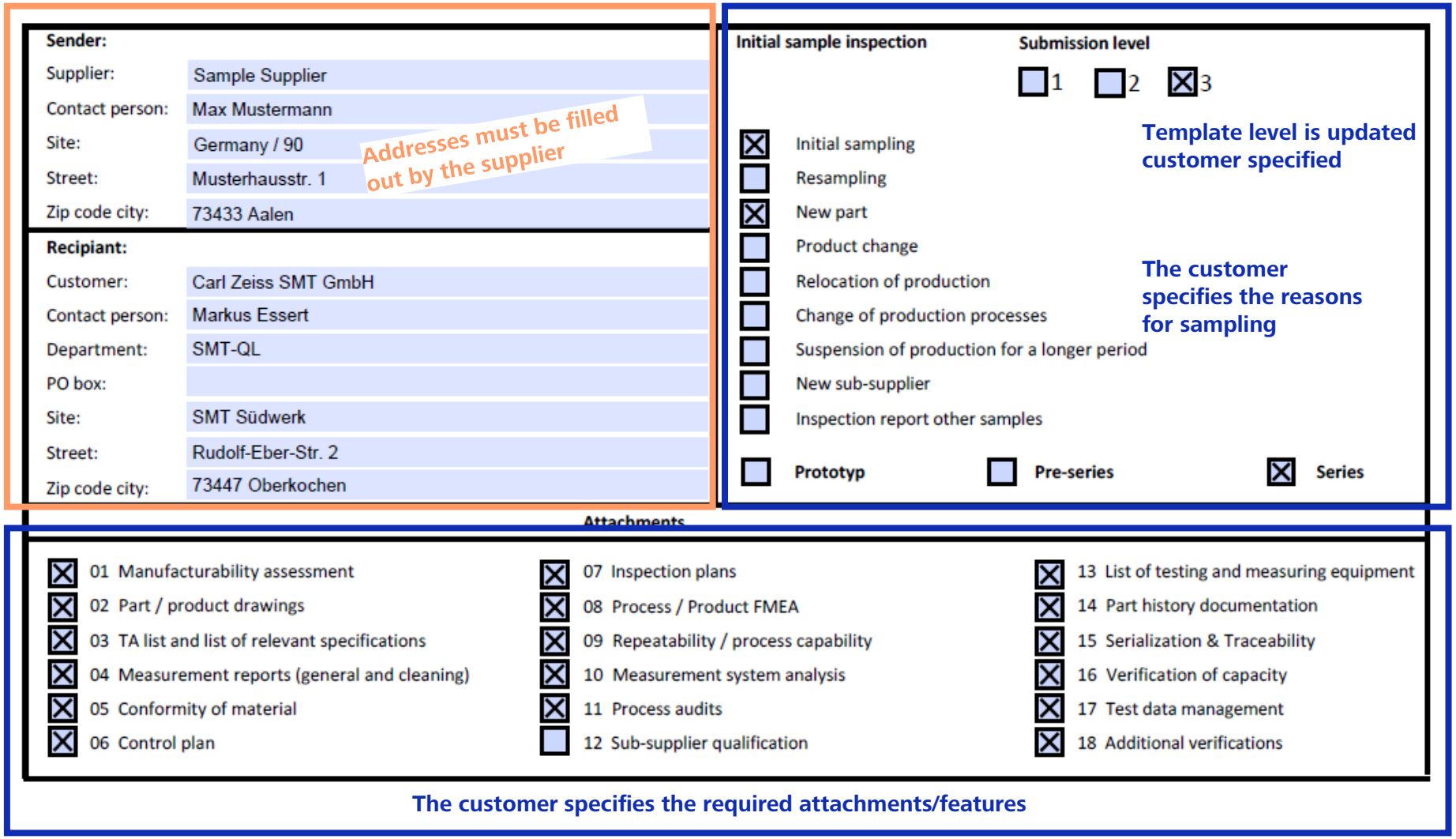
sleeve

Material no. 000000-2020-101

Manufactured by sample supplier



00a cover sheet (1)



Sender:

Supplier:	Sample Supplier
Contact person:	Max Mustermann
Site:	Germany / 90
Street:	Musterhausstr. 1
Zip code city:	73433 Aalen

Addresses must be filled out by the supplier

Recipiant:

Customer:	Carl Zeiss SMT GmbH
Contact person:	Markus Essert
Department:	SMT-QL
PO box:	
Site:	SMT Südwerk
Street:	Rudolf-Eber-Str. 2
Zip code city:	73447 Oberkochen

Initial sample inspection

Submission level

☐ 1 ☐ 2 ☒ 3

- ☒ Initial sampling
- ☐ Resampling
- ☒ New part
- ☐ Product change
- ☐ Relocation of production
- ☐ Change of production processes
- ☐ Suspension of production for a longer period
- ☐ New sub-supplier
- ☐ Inspection report other samples

Template level is updated customer specified

The customer specifies the reasons for sampling

☐ **Prototyp** ☐ **Pre-series** ☒ **Series**

Attachments

☒ 01 Manufacturability assessment	☒ 07 Inspection plans	☒ 13 List of testing and measuring equipment
☒ 02 Part / product drawings	☒ 08 Process / Product FMEA	☒ 14 Part history documentation
☒ 03 TA list and list of relevant specifications	☒ 09 Repeatability / process capability	☒ 15 Serialization & Traceability
☒ 04 Measurement reports (general and cleaning)	☒ 10 Measurement system analysis	☒ 16 Verification of capacity
☒ 05 Conformity of material	☒ 11 Process audits	☒ 17 Test data management
☒ 06 Control plan	☐ 12 Sub-supplier qualification	☒ 18 Additional verifications

The customer specifies the required attachments/features

! The cover sheet including the marked (required) elements serves as a specification for sampling the component

The following applies:

Fields with a blue frame must be completed by the customer

Fields with an orange frame must be completed by the supplier

00a cover sheet (2)

ID number, supplier:	ISIR_15_10_2021_2020-101_sample_supplier_V02	**ID number, customer:**	ISIR_15_10_2021_2020-101_sampe_supplier_V02
Test report number:	4711 0817	**Test report number:**	4711 0817
Material number:	404030-02	Material number:	000000-2020-101
Drawing number:	404030-02/01	Drawing number:	000000-2020-101/01
Version / date:	02/12.10.2022	Version / date:	02/12.10.2022
Change number:	40302134	Change number:	4512786
Part designation:	sleeve	Part designation:	sleeve
Order number / date:	19.10.2022		
Delivery number:	20201019 **Date:**	**Incoming goods no.:**	**Date:**
Batch:	5	Unloading place:	SLZ Carl Zeiss S
Part ID:	charge 2020404030-02	Order number / date:	19.10.2022

Component-related data of the supplier must be entered here

Panel-related data of the customer must be entered here

Delivery note information & initial sample information to be filled in by the supplier

Logistics information to be filled in by customer

Supplier confirmation:

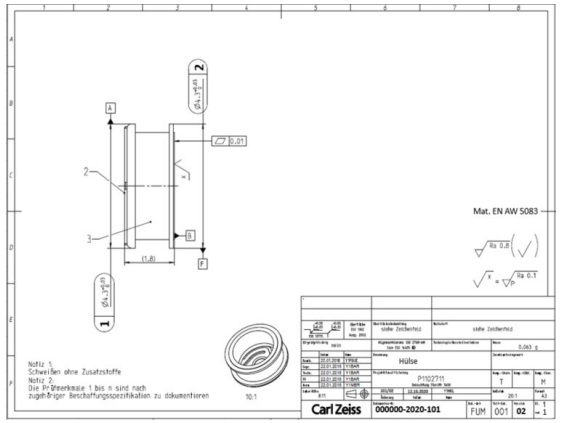
We herewith confirm that the initial samples presented have been manufactured and measured under series conditions with series equipment and have been released. The correctness of the determined actual values is hereby confirmed.

Name, company:	Max Mustermann	Remarks:	
Department:	Quality - initial sampling		
E-mail address:	max.mustermann@muster.de		
Date; signature:			

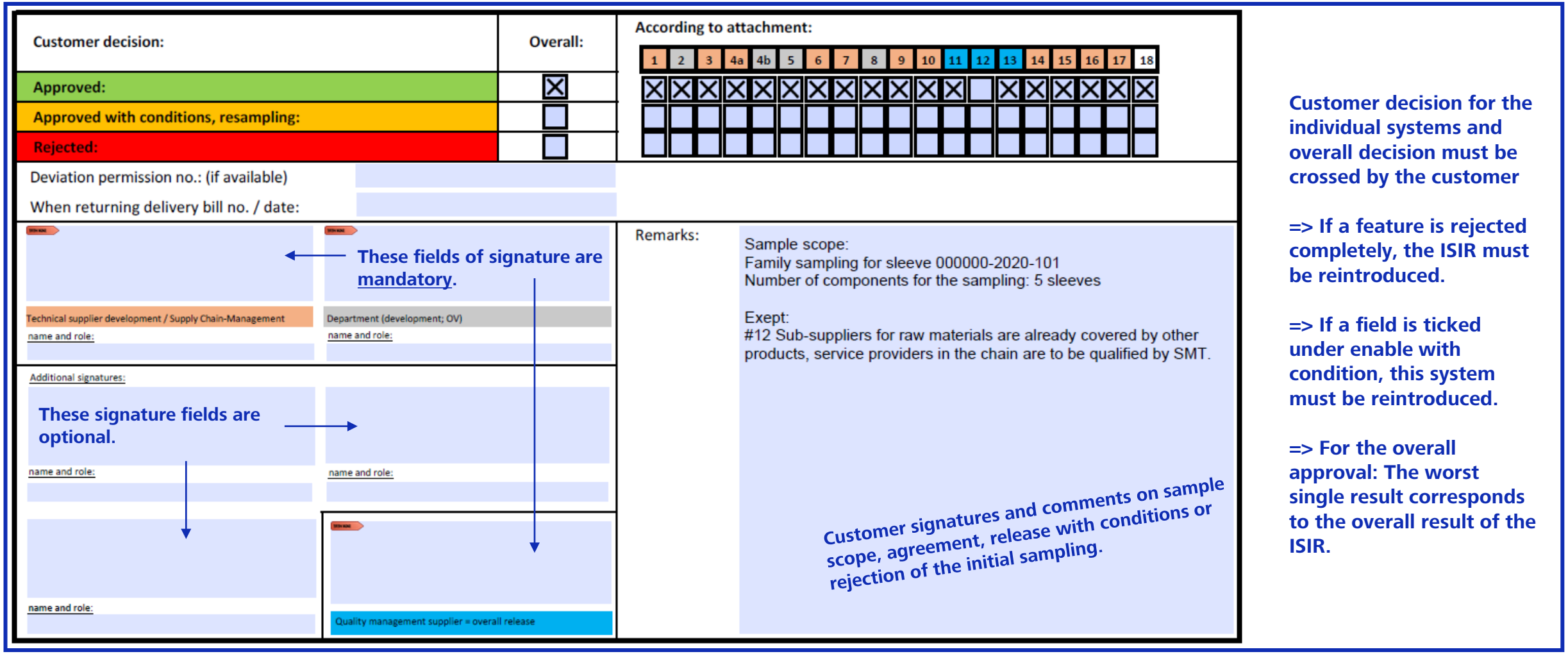
Manufacture of the components under series conditions is confirmed by signing the responsible person of the supplier, supplemented by remarks

ISIR systems are filled out as examples for training purposes

Example of a component: sleeve 000000-2020-101 V02 from sample supplier



00a cover sheet (3)



Customer decision for the individual systems and overall decision must be crossed by the customer

=> If a feature is rejected completely, the ISIR must be reintroduced.

=> If a field is ticked under enable with condition, this system must be reintroduced.

=> For the overall approval: The worst single result corresponds to the overall result of the ISIR.

00b cover sheet #2
Overview of systems

	Attachment:	Status, date:	Typ, scope and identification of the attachment:
☒	00 Cover sheet	15.10.2022	cover sheet, version 02
☒	01 Manufacturability assessment	08.12.2021	Manufacturability_2020_101_SMT_sample_supplier
☒	02 Part / product drawings	01.09.2022	test_drawing_2020-101_99
☒	03 TA list and list of relevant specifications	15.10.2022	pdf#03-no TA-list available
☒	04a Measurement report - general	01.10.2022	Accura_measurement_report_01
☒	04b Measurement report - cleaning	12.10.2022	release cleaning according to FU 10000711
☒	05 Conformity of material	01.05.2022	conformity_notifications SMT_2020-101
☒	06 Control plan	10.10.2022	ple_supplier_2020-101_V08
☒	07 Inspection plans	01.05.202	plan WEP_4711_V03
☒	08 Process / Product FMEA		FMEA_Hülse_SMT_V07
☒	09 Repeatability / process capability		evaluation_CPK_2020-101_SMT_V06
☒	10 Measurement system analysis	08.10.2022	MSA2_2020-101_V05
☒	11 Process audits	01.06.2022	pdf#11- no further attachments
☐	12 Sub-supplier qualification		n/a
☒	13 List of testing and measuring equipment	10.10.2022	pdf#13 - extract from text equipment monitoring
☒	14 Part history documentation	15.10.2022	pdf#14 - part history documentation
☒	15 Serialization & Traceability	20.04.2022	serialization_054
☒	16 Verification of capacity	12.06.2022	extract from mail_sales sample supplier to SMT
☒	17 Test data management	14.05.2022	pdf#17 text_data_management_326
☒	18 Additional verifications	21.05.2022	packaging data sheet SMT_V06

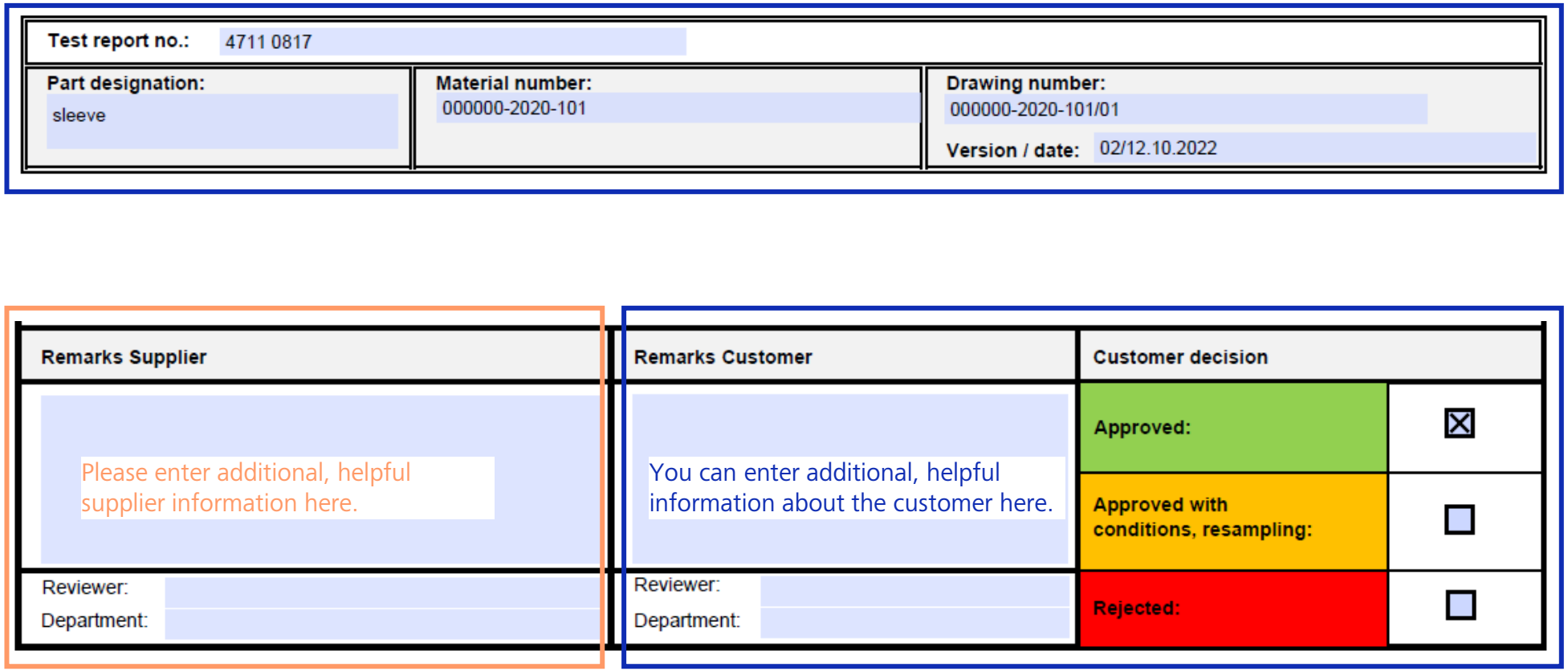
Attachments with detailed information must be filled out by the supplier, if attachments are available or required

- The system overview **helps** the supplier and the customer check if **all documents relevant** to the customer are available and attached.
- In addition, the installation is to be set up and designated for **subsequent traceability**.
- The selected attachments (crosses) are **automatically taken** over from the cover sheet.

!

Standard fields per ISIR element

The following default fields are available as corresponding headers and footers for each element



Test report no.: 4711 0817		
Part designation: sleeve	**Material number:** 000000-2020-101	**Drawing number:** 000000-2020-101/01 **Version / date:** 02/12.10.2022

Remarks Supplier	**Remarks Customer**	**Customer decision**	
Please enter additional, helpful supplier information here.	You can enter additional, helpful information about the customer here.	**Approved:**	☒
		Approved with conditions, resampling:	☐
Reviewer: Department:	Reviewer: Department:	**Rejected:**	☐

Header

Data is automatically transferred from the cover sheet

Footer

Supplier's signature and thus confirmation of the correctness of the information entered

Documentation of the decision and signature of the responsible department at the customer

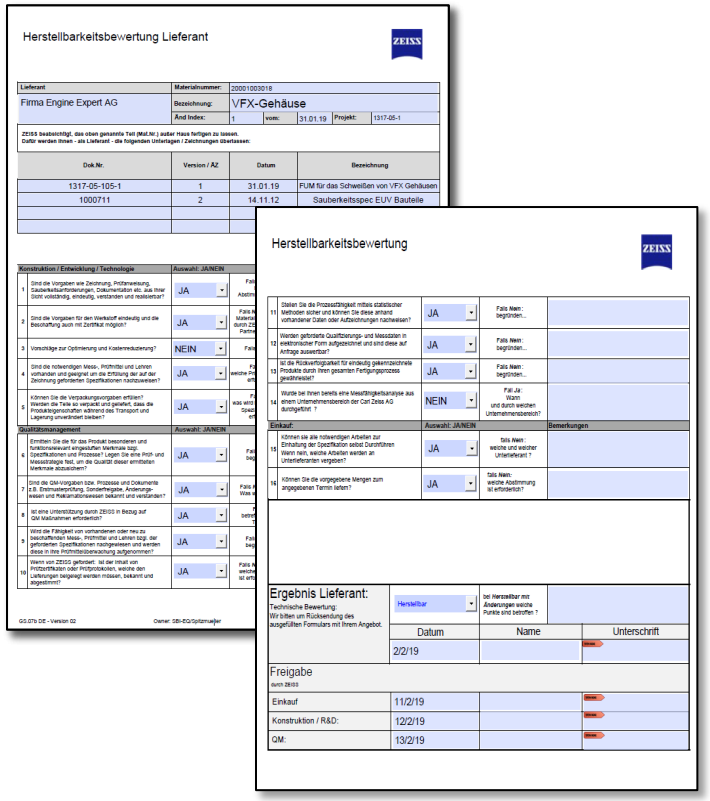
01 Manufacturability assessment

We hereby confirm that the sample scope presented was manufactured under controlled, series-production conditions. The quality and degree of maturity of the samples, including all manufacturing processes, fully comply with the specifications on which the cover sheet and the parts life cycle are based (see attachments 2 and 3) under series production conditions.

The manufacturability of the components under series conditions is additionally confirmed in the fully completed form GS.07b Manufacturability assessment (Zeiss template) and attached to this appendix.

Manufacturability assessment form (ZEISS standard):

Documents for suppliers | ZEISS



The Supplier confirms by signing that:

1) the producibility assessment form requested by ZEISS has been **completed** and **submitted**. The document is attached to the **report**.
2) the initial sample components were manufactured - **under series conditions** - and in compliance with the **relevant drawing version** (#02) and the **relevant specifications** (#03)

If the supplier can **manufacture the product subject to conditions**, this must be marked in the comments field and a TA list coordinated with the customer must be attached in appendix #03

02 Part / product drawings

We hereby confirm that the leading drawing/ 3D model corresponds to the current, approved status as stated in the cover sheet and in the part history documentation and is attached as an appendix to the sample presentation.

The agreed characteristics and criteria are marked in the drawing in such a way that a reference to the criteria and test results in the appendices of this document is possible at any time.

For assemblies and modules, the corresponding parts list shall be added as an appendix.

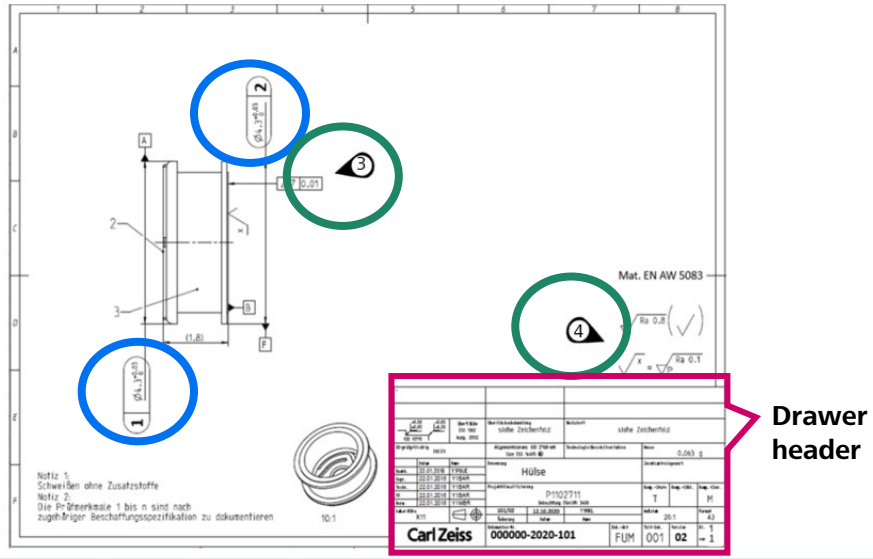
- In addition to the numbered balloon dimensions/characteristics of the customer (see #1 and #2 in the drawing), **additional (critical) features** agreed with the customer or dimensions required by the supplier to meet the specification should be stamped continuously by the supplier in the component/product drawing (see #3 and #4 in the drawing); no duplicate number sequences.
- The agreed characteristics and criteria are marked in the drawing in such a way that a **reference** to the criteria and test results in the appendices of this document is **possible at any time** (= stamped drawings available)

The drawing is the leading document.

The Supplier confirms by signing that:

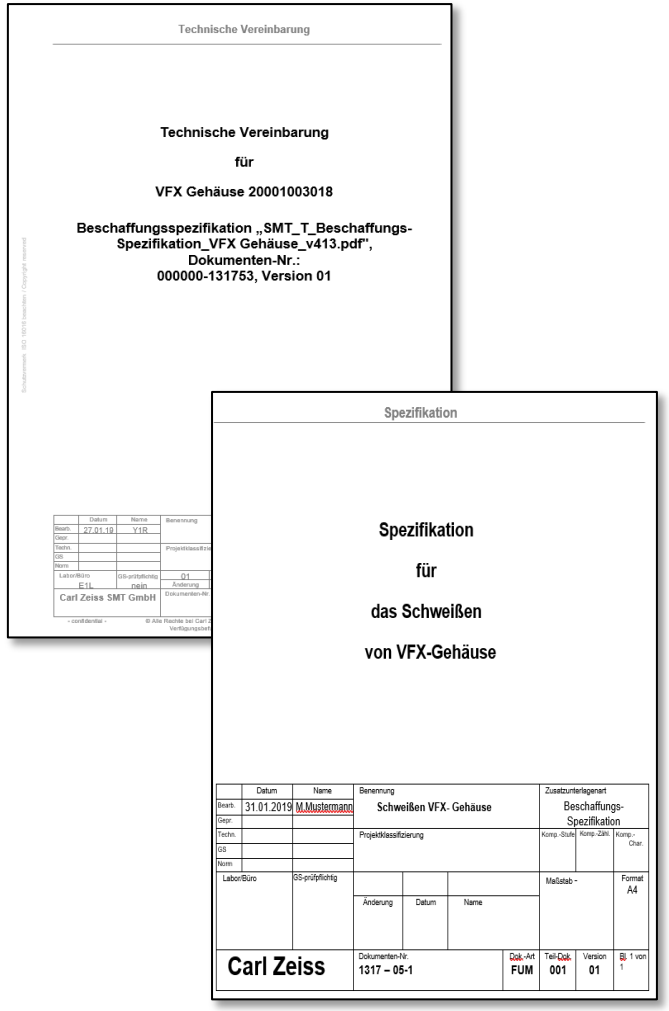
1) the valid drawing was understood by the supplier and the initial sample components were manufactured - under series conditions - and in compliance with **the relevant drawing version**.
2) the supplier has marked **the features** in the drawing and **stamped** them continuously. The stamped drawing must be attached to the report
- The drawing must be included as an attachment in the system overview

! For assemblies and modules, the **corresponding parts** list must also be **attached as an attachment**
- It must be possible to identify from which sub-assemblies the assembly/module was manufactured
- Which special specifications apply to the subassemblies



03 TA-list and list of relevant specifications

Pos.	Specification name:	Document number:	Version number:	Designation (+document no.) of the TA:	Remarks:
1	cleanliness_spec-not optics EUV	FU 1000711	02	TA 20201104 deviation	XPS sampling N
2	cleanliness_spec-not optics mec. additional	FU 1000962	01	./.	./.
3	material spec. for the cast- alu - alloy	FUM 2247-446/61	01	./.	./.



This is an **overview of the relevant specifications** (including version number) - valid for the initial sample components

! **All deviations agreed and accepted with ZEISS** must be documented in a TA list.
Subsidiary agreements in the form of e-mails or phone calls are not accepted and are not valid!

The TA list (if agreed) is **controlled in SAP** and thus has the status of a specification document (specification)

In the event of deviations in the specifications, the column "*Name (+Document No.) of the TA*" must be filled out with a reference to the TA agreed with the customer. Add a comment for the reason for the deviation in the Comments column.

04a Measurement report – general (1)

Ref. No.	TARGET – claim:	Measuring equipment:	Tolerance limits:		ACTUAL – values supplier:					Evaluation:		Remarks:	Reference specification:
			Min.- value / LSL	Max. value / USL	# 1	# 2	# 3	# 4	# 5	ok.	not ok.		
1	Diameter 4.3 + 0,03/-0	KMG 001/-12	4,3	4,33	4,318	4,3113	4,323	4,319	4,328	☒	☐	./.	drawing
2	Diameter 4.3 + 0,03/-0	KMG 001/-12	4,3	4,33	4,3288	4,3156	4,329	4,311	4,33	☒	☐	upper tolerance reached	drawing
3	Ra 0,8 due to material removal	surface	0,75	0,8	0,77	0,76	0,79	0,77	0,75	☒	☐	./.	drawing
										☐	☐		
										☐	☐		

Confirmation that initial sample components were manufactured in accordance with the specification

The measurement report is a result **report of the quantitative and qualitative characteristics** with reference to the respective specification or drawing stamped by the supplier (e.g. numbered sequential drawing characteristics, residual gas analysis (RGA)/electrical tests//pressure acceptance/leakage/ etc.)

! The table in the PDF serves as a template. If automatically generated measurement reports or measurement reports internal to the supplier are available, they must be attached! - In this case, the table does not have to be filled.

04a Measurement report – general (2)

Notes / specifications:

- The measuring equipment used must be **fully** documented
- For dimensions, the **nominal/nominal size**, the upper and lower tolerances must be specified for each measured value
- The **actual values** must be documented for each sample presented
- The assessment **OK/not OK** through the comparison of the actual values to the target requirements must be carried out by the supplier.
- Test method, documentation of evaluation settings as per CMM cookbook if possible, test equipment concept structure must be documented and **attached** (general tolerances are specified in the drawing header)

- The presented samples must be labeled in such a way that the measuring results can be **traced**. In the cover sheet or the Comments field, the **part ID** must be clearly assigned to the actual values in the measurement report

- The measurement report is a **completed/completed measurement plan** (see #07 - Measurement plans)
- Attention should be paid to the final measurement report, which serves as a "component acceptance"

04b Measurement report – cleaning
ZEISS technical specification

Cleanliness Specification	Version	Material group*	Cleaning location
FUM 1000021033	v1	stainless steel small parts	supplier
FU 1000711	v3	stainless steel small parts	cleaning service provider

* Material groups can be e.g.: Aluminium, Stainless steel, NIP, Black NIP, Copper, Cordierite, Ceramics / SiSiC, Elastomers, Synthetic material
The correct material group can be taken from the corresponding release document

The relevant release documents are to be attached as an appendix

All release documents per material group and cleaning location are to be delivered

Additional attachments can be included (e.g. photo documentation, etc.)

Responsibility

Technical responsibility / Qualification of the cleaning line Cleaning service provider:

- Carl ZEISS SMT

Understanding SMT:

This qualification does not relieve the corresponding suppliers of logistical responsibility (e.g. orders, timing, logistics, labeling, delivery location, etc.) for the components and the corresponding agreements.

The supplier must also be integrated into the **supplier management system** and process flow diagram of the responsible 1st/n tier.

- Depending on the **required cleanliness specifications**, the basic filling of the "master data" (which cleanliness specifications are available, where is cleaned, etc.) may differ
- As "minimum requirements" for attachments, **release document** for each cleanliness specification to be fulfilled. For pre-cleaning in accordance with FUM1000021033, for example, the manufacturers will be able to provide their own documents; if they have the ultra-fine cleaning in accordance with FU1000711 performed at a cleaning service provider, they must request the release document via the latter (e.g. the EMP certificate/certificate which we issue to the RDLs in the 5000s)
- Depending on the **criticality of the component** (or how the component performs in the pre-ISIR phase), we may require **additional cleanliness-relevant documentation/attachments**; these could be RGA reports, SCC(Surface cleanliness class) measurement reports, photo documentation, etc. This should be determined in conjunction with the supplier during the sampling coordination meeting.

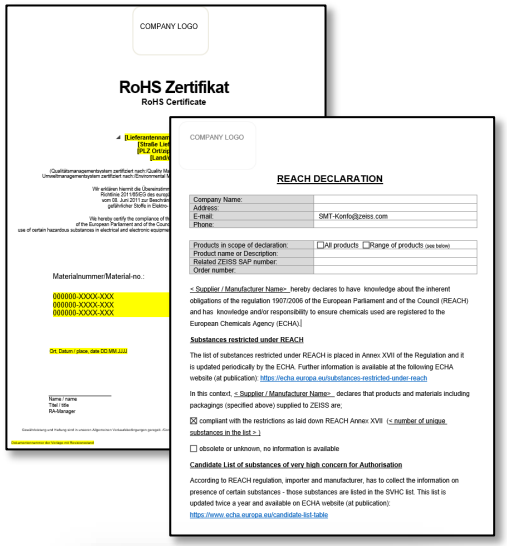
05 Conformity of material

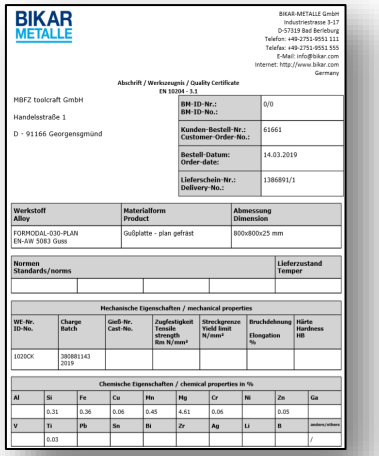
We hereby confirm that the materials of the samples presented comply with the guidelines and regulations in the currently valid versions. The documents marked below must be signed and attached to the sample.

☒ RoHS regulation in the version valid at the time of submission. See: Link to RoHS

☒ REACH regulation in the version valid at the time of submission. See: Link to REACH

☒ Required material test certificates/material data sheets of the materials used/process auxiliaries





The Supplier confirms by signing that:

1) The **legal requirements** are fulfilled (REACH & RoHS requirements with reference to the valid revision of the specification with revision status and date) and that the documents have been delivered to the corresponding departments.
2) The **material properties** are specification-compliant and are verified by **material-specific test results** with reference to the requirements in the specification (material test certificates/material data sheets). The test certificates are attached to the report

- Certificates must be included as an attachment in the system overview

06 Control plan

1.	We hereby confirm that the production control plan for the production of the scope of presentation is available and can be inspected. The following criteria are included in the production control plan:			
2.	The production control plan refers to ☐ Prototype ☐ Pre-series ☒ Series			
		Yes	No	Remarks:
3.	The production control plan includes or references a process flow diagram.	☒	☐	
4.	The production control plan contains all process steps including storage and transport starting from the receipt of purchased parts to delivery to the customer.	☒	☐	
5.	The production control plan contains the description of all work and test steps of the overall process.	☒	☐	

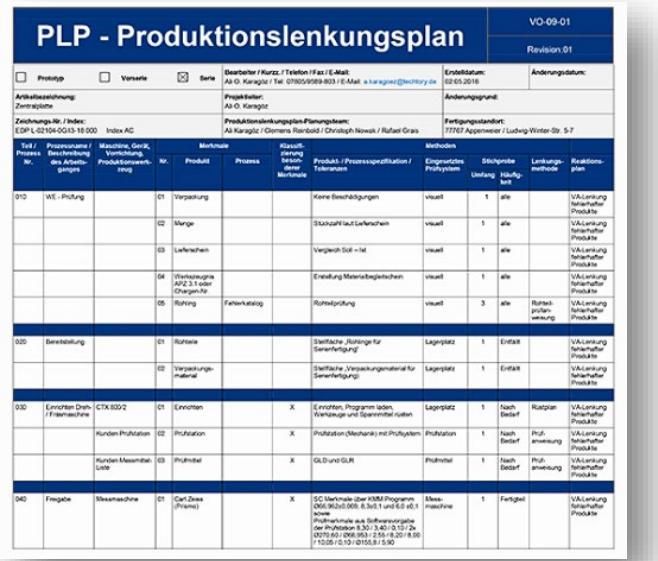
To be marked by the supplier, comments on document name/information to be filled in

- ☒ The production control plan is complete, up-to-date, and its content meets the requirements of the checklist presented above.
- ☐ The production control plan is additionally attached as a document to this appendix.
- ☐ The process flow diagram / process flow plan associated with the production control plan contains all process steps, is up-to-date and is attached as an appendix.
- ☒ The production control plan can be viewed on site at the supplier.

Checklist for checking all criteria in the control plan

Clear chronological display of all process steps of the product from receipt of goods to delivery to the customer:

- Display of **the special features**
- Specification of **work and test instructions** or reference thereto
- If "No" is selected, please enter **the reason** in the comment field

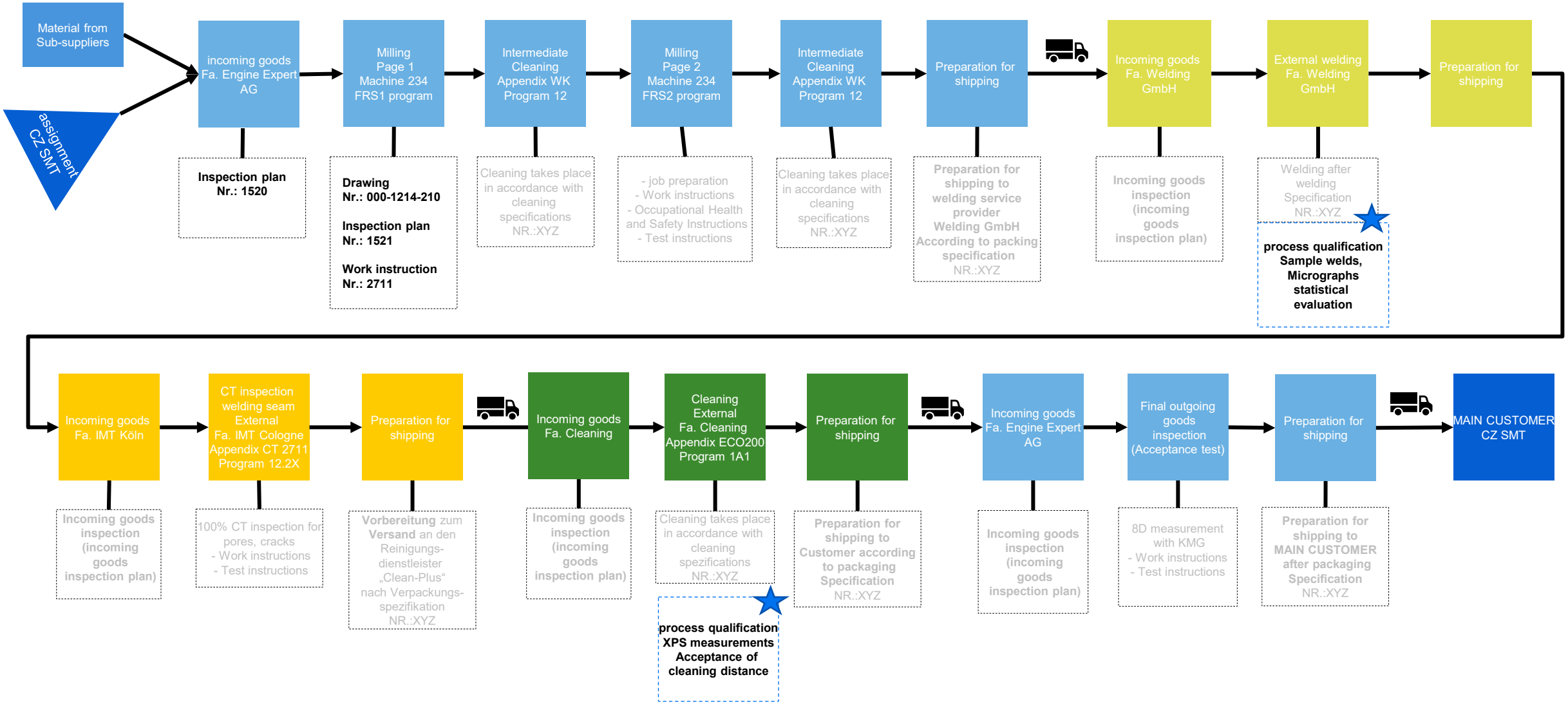

PLP - Produktionslenkungsplan

VO-09-01

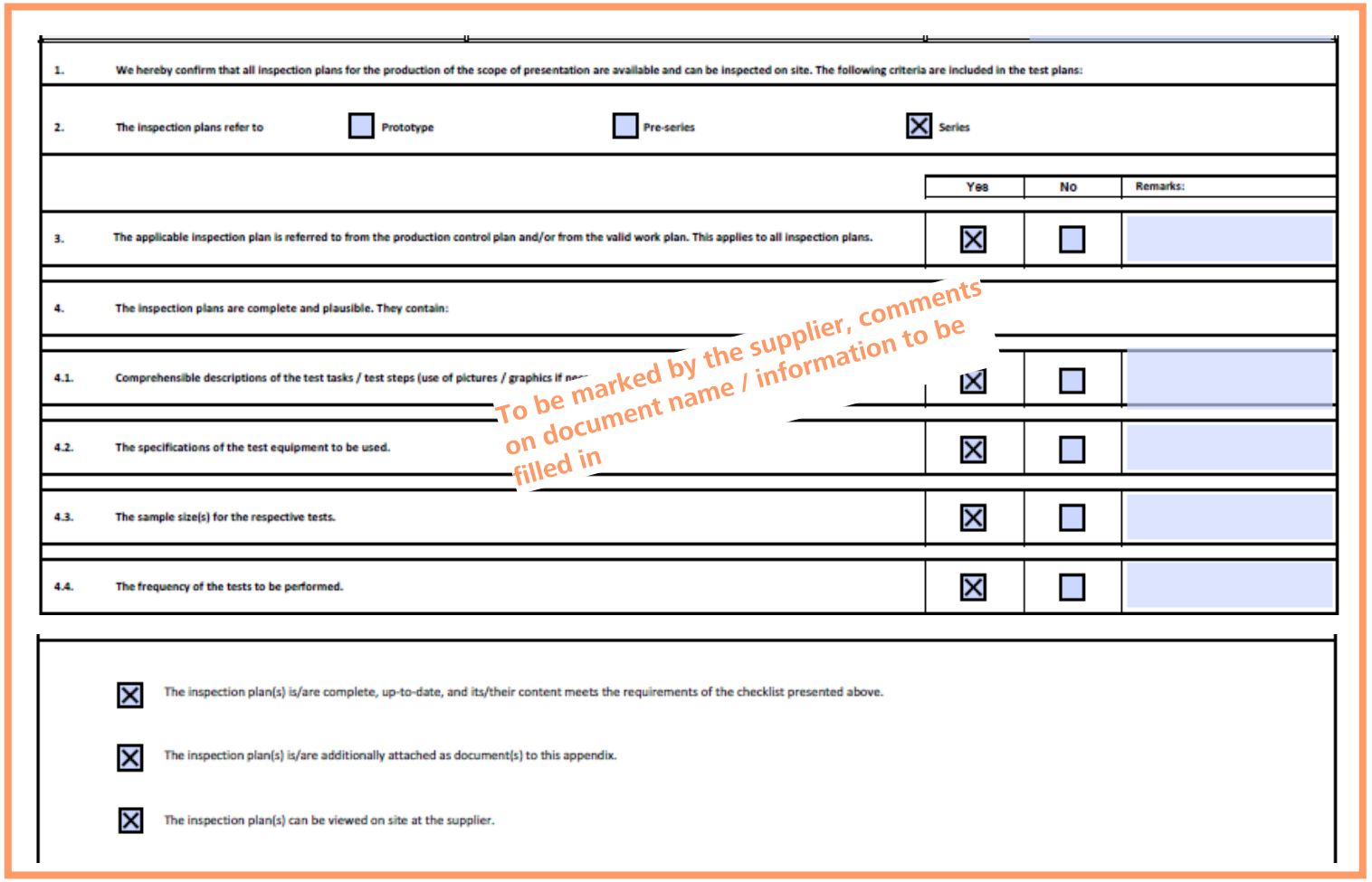
Revision:01

06 Control plan

Documented process sequence (example) - basis for documentation of the process freeze



07 Inspection plan



1.	We hereby confirm that all inspection plans for the production of the scope of presentation are available and can be inspected on site. The following criteria are included in the test plans:			
2.	The inspection plans refer to ☐ Prototype ☐ Pre-series ☒ Series			
		Yes	No	Remarks:
3.	The applicable inspection plan is referred to from the production control plan and/or from the valid work plan. This applies to all inspection plans.	☒	☐	
4.	The inspection plans are complete and plausible. They contain:			
4.1.	Comprehensible descriptions of the test tasks / test steps (use of pictures / graphics if ne	☒	☐	
4.2.	The specifications of the test equipment to be used.	☒	☐	
4.3.	The sample size(s) for the respective tests.	☒	☐	
4.4.	The frequency of the tests to be performed.	☒	☐	

To be marked by the supplier, comments on document name / information to be filled in

☒ The inspection plan(s) is/are complete, up-to-date, and its/their content meets the requirements of the checklist presented above.

☒ The inspection plan(s) is/are additionally attached as document(s) to this appendix.

☒ The inspection plan(s) can be viewed on site at the supplier.

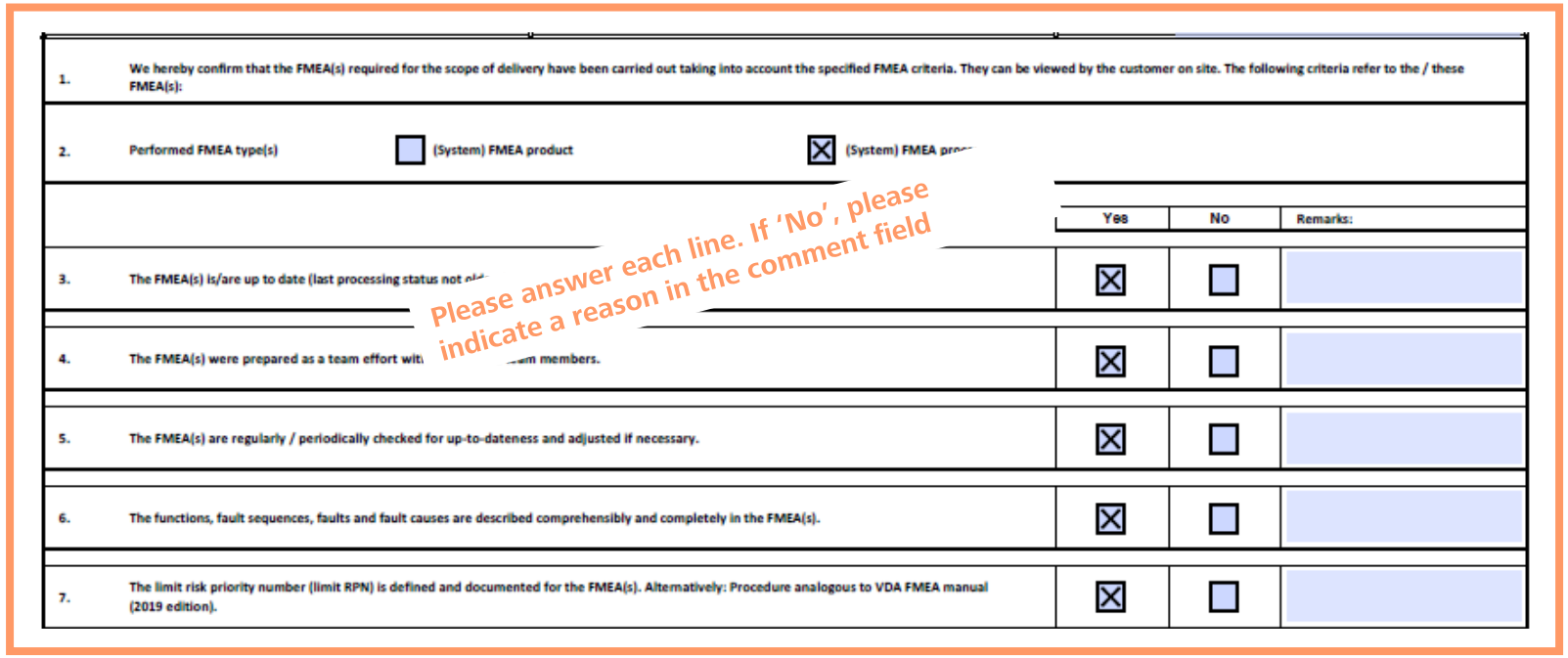
Checklist for checking all criteria in the measurement plan

Description of the tests to be performed::
- Nominal values (nominal values)
- Tolerances
- test frequency
- Test/measuring equipment to be used (test equipment number, if applicable)
- Classification: special features (SCs, CCs, SPC, A/B parts,...)
- Remarks / Notes
- If "No" is selected, please enter the reason in the comment field

Measurement plan for one work step

Description of the tests to be performed:
- Nominal values (nominal values)
- Tolerances
- test frequency
- Test/measuring equipment to be used (test equipment number, if applicable)
- Classification: special features (SCs, CCs, SPC, A/B parts,...)
- Remarks / Notes
- If "No" is selected, please enter the reason in the comment field

08 Process-/ Product FMEA



1.	We hereby confirm that the FMEA(s) required for the scope of delivery have been carried out taking into account the specified FMEA criteria. They can be viewed by the customer on site. The following criteria refer to the / these FMEA(s):			
2.	Performed FMEA type(s) ☐ (System) FMEA product ☒ (System) FMEA pro…			
		Yes	No	Remarks:
3.	The FMEA(s) is/are up to date (last processing status not ol…	☒	☐	
4.	The FMEA(s) were prepared as a team effort wit… …m members.	☒	☐	
5.	The FMEA(s) are regularly / periodically checked for up-to-dateness and adjusted if necessary.	☒	☐	
6.	The functions, fault sequences, faults and fault causes are described comprehensibly and completely in the FMEA(s).	☒	☐	
7.	The limit risk priority number (limit RPN) is defined and documented for the FMEA(s). Alternatively: Procedure analogous to VDA FMEA manual (2019 edition).	☒	☐	

Please answer each line. If 'No', please indicate a reason in the comment field

Checklist to check all specified FMEA criteria must be submitted

! FMEAs **may be viewed** on site!

FMEA components:

- **FMEA** in teamwork
- **Limit risk** defined
- Error map used defined and applied (meaning, detection, occurrence)
- **Measures** to reduce the limit RPZ have been defined
- Improvement measures have been implemented and effectiveness assessed
- No action open with exceeded limit RPZ and unapproved residual risk
- **Special features** have been defined
- **Process flow chart** (for P-FMEA) is available
- **Periodic review** cycle of FMEA has been defined (especially after complaints/tolerances)
- The FMEA is understandable and understandable (not meaningless terms, but clear descriptions
- If "No" is selected, please enter the reason in the comment field

09 Repeatability / process capability

Verification of capability for characteristics or features agreed with customers.

To the process capability study information in the table below, add the statistical evidence for each capability characteristic as a separate appendix.

Characteristic:	Nominal value:	Tolerance:	Sample size:	Test equipment used:	Procedures used:	Process capability:
Diameter	D=8mm	+/- 0,1mm	5 pieces x 25	caliper: InvNr.: 437438	DIN ISO 22514-2	Cpk=1,74
ablation measurement	0,2mm	+/- 0,2mm	20	digital micrometer	Minitab	Cpk=1,83

To be filled in by the supplier

Cp, Cpk, Ppk, Cmk - capability indices (e.g.: Cpk > 1.33, Cmk ≥1.67, Ppk ≥1.33) are specified and coordinated with customers.

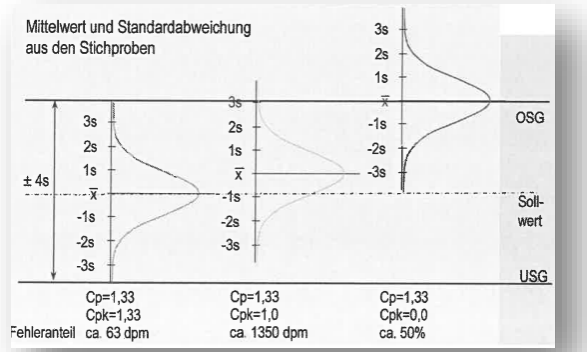
- Special features, capability characteristics are defined and coordinated with the customer
- **SPC characteristics** (SPC= Statistical process control) and coordinated with customer (if applicable)
- Random sample size, sample size defined and coordinated with customer
- Calculation method (software, tools: minitab, statistics software...) defined and coordinated with customer
- Test for **normal distribution** verified, otherwise adapted calculation
- Cp, Cpk, Pp, Ppk, Cm, Cmk capability indices (e.g.: Cpk > 1.33, Cmk ≥1.67, Ppk ≥1.33) and aligned with customer
- Measures for incapable processes defined (**100% inspection**)
- **Capability characteristics** defined in the production control plan (if necessary, in measurement plans)
- **Only capable test equipment** may be used for capability measurements of the characteristics (MSA/ Gage R&R...)

Verification to determine process, machine short-term capability, process qualification (Cpk, Cmk, Ppk).

Recommended values:
- Machine capability (short-term inspection) Cmk ≥1.67
- Process capability index Cpk ≥1.33
- Process performance index Ppk ≥1.33

Verification and target values can be determined individually - in consultation - and, if necessary, indirect verification is also possible. Process capability is statistically proven based on agreed product and process characteristics.

For processes that cannot be controlled under statistical process control, suitable proof must be provided that only products that meet the specifications are delivered (100% inspection).



10 Measurement system analysis

The measuring system analysis is used to check the suitability of test equipment or measuring equipment for a special measuring task.

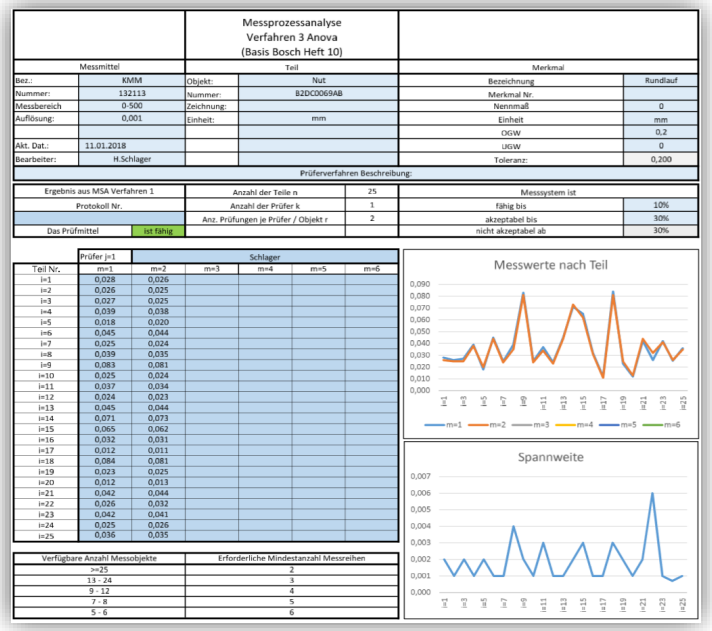
To the information on the measurement system analysis in the table below, the statistical evidence for each piece of test equipment that is/was used for a process capability analysis shall be added as separate attachments.

Characteristic:	Nominal value:	Tolerance:	Sample size:	Test equipment used:	Procedures used:	Process capability:
Diameter #5	D=8mm	+/- 0,1mm	3 measurement series	caliper Inv.Nr.:33567-3008	MSA-procedure 2 analog DC	Cgk=1,77
spring force	F=1N	+/- 0,2N	3 variants	spring scale Inv.Nr.:56874-2098	MSA-procedure 2 analog DC	Cgk=1,45

To be filled in by the supplier

The following are considered:

- Operator influence
- Repeatability
- Reproducibility
- Test equipment variability in the specified range
- No use of incapable test equipment (exception: use as test equipment to test non-customer-relevant requirements)
- Use of verified and validated statistics software (e.g. Minitab)
- Faults in the test process determined and taken into account
- Repetition of MSA is defined and described in the production control plan
- Specifications or reference to standards (Gage R&R, VDA Volume 5, ...)



Example: measurement process analysis procedure 3 Anova

11 Process audits (1)

Confirmation that all (critical) processes/process steps for the production of the components to be inspected have been audited internally:

1.	We hereby confirm that the underlying parts for all processes / process steps for manufacturing for the sampling scope have been audited internally.			
2.	Process audit results: ☐ Confirmations only ☒ Deviations			
	The following criteria were considered in the audits:	Yes	No	Remarks:
3.	Work plans complete and plausible	☒	☐	
4.	Individual test plans complete and plausible	☒	☐	
5.	Test equipment available and capable	☒	☐	
6.	Test equipment available and suitable	☐	☒	
7.	Production resources available & suitable	☒	☐	
8.	Machine(s) qualified and capable	☒	☐	
9.	Inspection and maintenance plans created	☒	☐	
10.	Workstations ergonomically suitable	☐	☒	in revision

Each line must be filled in. If "No", please enter the reason in the Comments field

To be filled in by the supplier

The **supplier must accept and approve its own component-related (critical) processes** in advance of the ISIR, evaluate and document them according to the **individual stages of product and process development**.

- The planning, development and introduction of **controlled and capable processes** is an essential part of the activity for launching **new or modified products**. The implementation of these activities is supported by documents and records. These include process FMEA, production control plan, work instructions, test plans, capability certificates, including the sub-suppliers in the audit planning.

- This is **often** linked to **internal process** releases, e.g. for the transfer of processes from Development to Operations.
  - Is this process described?
  - Is it used for components?
  - How is the supplier's quality department involved?

- In addition, SMT (customer) can check the supplier's approval process during an on-site meeting (e.g. supplier inspection, process audit) if necessary and prior notification is required.

11 Process-audits (2)

Overview of the audited processes / sub-processes:

	The following processes / sub-processes were audited:	no deviations or deviation closed	Deviation open	Remarks:
1	Goods receiving and goods receipt	☒	☐	
2	Picking of individual parts	☐	☒	set composition
3	Assembly of components at assembly station 2	☒	☐	reference assembly station
		☐	☐	
		☐	☐	
		☐	☐	

In the case of open deviations, please justification in the comments field

To be filled out and marked by the supplier

12 Sub-supplier qualification (1)

It is hereby confirmed that the scope of suppliers and sub-suppliers for the production of the samples has been monitored and qualified and that the underlying specifications have been met. The cover sheets with the issued sample releases of the suppliers and sub-suppliers are attached as Appendixes, where applicable. The scope of monitoring of supplier / sub-supplier performance in the supply chain for the manufacture of the samples presented is shown in the table below:

No.	Supplier name:	Tier-no:	Delivery performance:	audited hedging / verification measures at Tier 2 to Tier n:										
				Inspection plan for Incoming Inspection	CoC:	Quality Assurance Agreement (QAA)	FMEA:	Production control plan:	Supplier Audit:	Inspection plan for Outgoing Inspection:	Cpk:	Cgk:	ISIR / FAI - Status	Remarks:
1	parts supplier 1	2	steel ST 37	☒	☒	☐	☐	☐	☐	☐			F-R	released
2	parts supplier 2	2	guide rails	☒	☒	☒	☒	☒	☒	☒			F-R	
				☐	☐	☐	☐	☐	☐	☐			-	

To be filled out and marked by the supplier

Explanations:

Supplier name = name of the supplier, including site

Tier-n = (module) suppliers who deliver directly to ZEISS are referred to as tier 1. Suppliers generally work with other subcontractors. These are categorized as n-tier (2-tier, 3-tier, etc.) according to their position in the value chain.

GR = incoming goods inspection

CoC = Certificate of Conformity

WO inspection = outgoing goods inspection at sub-supplier

Cpk = Process capability value (Prozessfähigkeitswert)
Cgk = Measurement system capability value (Messystemfähigkeitswert)

ISIR-status:
F-R = Frei - Released
FA-RO = Frei mit Auflagen - Released with obligations
A-R = Abgelehnt - Rejected

13 List of testing and measuring equipment

The list of test equipment below contains all test equipment for producing the samples presented

Pos.	Inventory number:	Test equipment used:	Inspection equipment monitoring:	Calibration interval:	Next calibration:	Resolution:	Accuracy:	Capability [Cgk]:
1	43743847-628843	measuring stick	JA-YES	yearly	02.05.2022	0,01mm	0,1mm	Cgk=1,77
2	74327814-773473	measuring stick	JA-YES	yearly	08.04.2021	0,01mm	0,1mm	Cgk=1,60
3	773498294-378474	spring scale	JA-YES	6 months	10.12.2022	0,01N	0,1N	Cgk=1,45
			-					
			-					
			-					

To be filled in by the supplier

Explanations:

Inventory number = number to identify the test equipment

Test equipment monitoring YES / NO = Is the test equipment subject to test equipment monitoring? Or is it an inspection aid that is not used to check the conformity of specified properties?

Calibration interval = At what intervals (intervals) is the test equipment calibrated (e.g. annually..)?

Capability = What test equipment capability value does the test equipment have (from measurement system analysis)?

Notes:

- **Measuring machine identification and name** must **correspond to PLP** and test equipment capability certificate
- Expired test equipment is **not permitted**
- If the number of fields in the form is not sufficient, additional test equipment can be added as an attachment

The test equipment must be integrated into the supplier's test equipment monitoring (standard).

The test measuring equipment list is intended to show an **overview of the measuring and testing equipment** used (test equipment planning, PLP (#06), test plan (#07), measuring system analysis (10) for the production of the serial parts and ensuring the required specifications in the series process.

Test equipment monitoring contents:

- Identification of the test measuring equipment using the inventory number
- Defined calibration intervals
- Next calibration to be performed (error "Last calibration")
- Resolution of the measuring equipment
- Accuracy of the measuring equipment
- test equipment capability

14 Part history documentation

Pos.:	ISIR:	Other patterns:	Reason for the performance:	Referenced Specification:	Version:	Report no. Zeiss / Report no. supplier:	Report date:	Customer decision
1	☐	☒	Other samples (prototypes)	diverse after overview	--	ISIR_15_10_2019_2020-101	01/11/2019	F-R
2	☐	☒	Acceptance call	diverse after overview	--	acceptance-call_2020-101	01/07/2020	F-R
3	☒	☐	Initial sample inspection	according to EP overview	--	ISIR_12_08_2021_2020-101	16/08/2021	FA-RO
4	☒	☐	Resampling	FUM 2247-446/61	2	ISIR_08_06_2022_2020-101	13/06/2022	F-R
	☐	☐						-
	☐	☐						-

To be filled in by the supplier

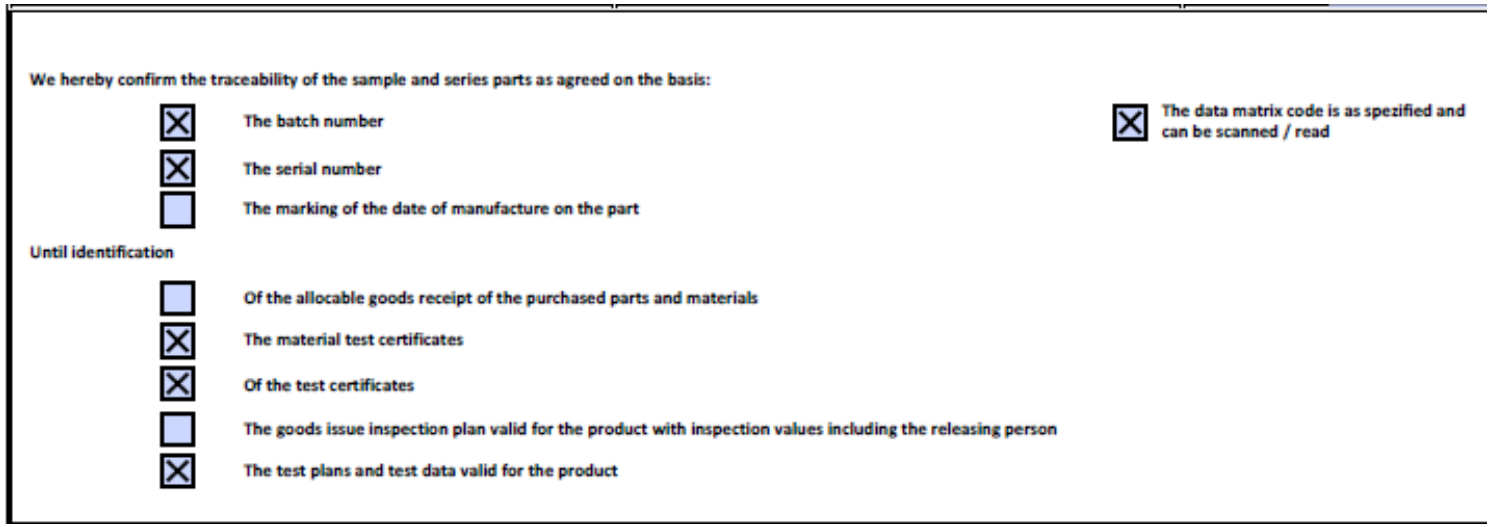
- Enables the traceability of (process/product) changes and **the sample history from the beginning** of the presentations
- From **dispatch** of the first sample components (other samples, initial samples) to resampling (after changes to the coordinated series process)
- Other samples are samples from near-series processes which do not yet fully correspond to the series processes, e.g. pre-series samples, other samples

Explanations

Type of sampling
ISIR = initial sample test report
Other samples = test report other samples (external like ISIR, but samples do not originate from series process)

Customer decision on the report
F-R = Frei - Released
FA-RO = Frei mit Auflagen - Released with obligations
A-R = Abgelehnt - Rejected

15 Serialization & Traceability



We hereby confirm the traceability of the sample and series parts as agreed on the basis:

- ☒ The batch number
- ☒ The serial number
- ☐ The marking of the date of manufacture on the part
- ☒ The data matrix code is as spezified and can be scanned / read

Until identification

- ☐ Of the allocable goods receipt of the purchased parts and materials
- ☒ The material test certificates
- ☒ Of the test certificates
- ☐ The goods issue inspection plan valid for the product with inspection values including the releasing person
- ☒ The test plans and test data valid for the product

To be filled in by the supplier

Check how traceability was agreed or how it is ensured at the supplier's site

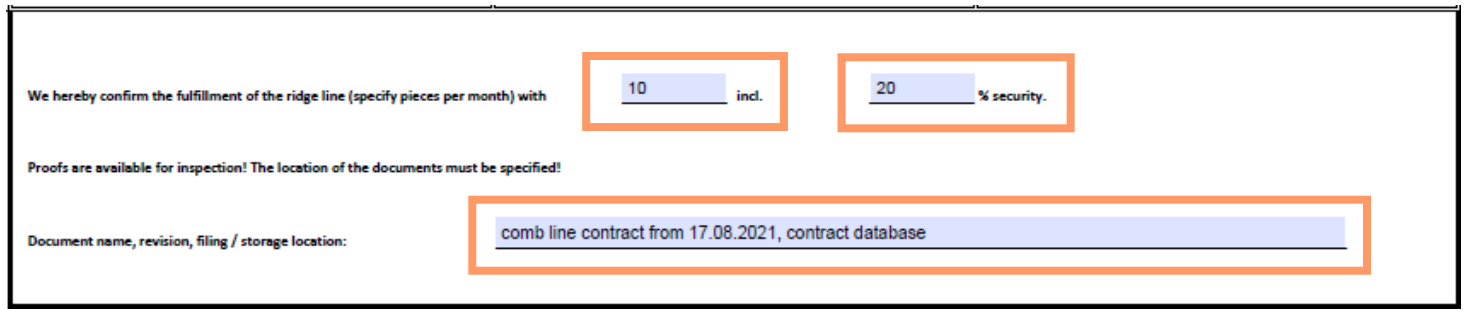
All serial parts must be labeled to ensure their **traceability.**

The IDs of the selected sample parts must be specified on the cover sheet (#00).

The displayed samples must be labeled so that the measuring results (#04) can be **assigned and traced**.

Proof that the Datamatrix code can be read out on the components and is compliant with the specifications.

16 Verification of capacity



To be filled in by the supplier, supported by corresponding attachments

Input of move rate in units per month

- The ISIR confirms the requested capacity (move rate) of the components, taking into account production under series conditions - including available reserves.
- **A plausible emergency plan** for the makeshift production of the parts under emergency conditions should be proven on site, for example. For this purpose, the document must be presented as a separate attachment or assessed by the customer in a process acceptance / process audit.
- Verification by the supplier of how the guaranteed capacity was calculated or evaluated internally (Are there bottle necks in the manufacturing process?, are important resources also used for other products?)

17 Test data management

We hereby confirm compliance with the valid specifications / guidelines for test data management according to the following documents

Document number	Version	Designation
1045000	01	procurement specification 1 for 2 POB 5xxx SiSiC Bauteile

The following system was used for data transmissi

☒ E-Mail	Aligned e-mail address:	Supplierdata@smt.zeiss.com
☐ DESC (Data Exchange SC)	Data / Documents via DESC:	
☐ Other		

The following data formats were transmitted to Carl Zeiss SMT:

- ☒ XML format
- ☐ JSON format

Calypso raw data includes FET format/ CHR format/ HDR format/ PDF

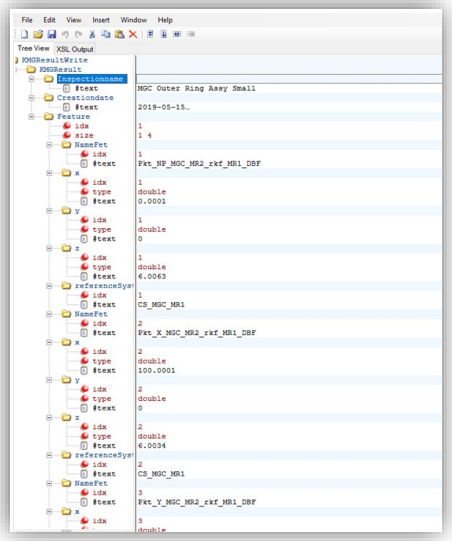
- ☐ FET format (Feature File/ Calculation basis / raw data - Calypso)
- ☐ CHR format (Measurement results according to test results of the test plan - Calypso)
- ☐ HDR format (Protocol header information- Calypso)
- ☐ PDF
- ☐ Binary Data e.g. iamges, PDF, Excel, other formats

The following criteria of the specification were met:

- ☐ The subject line of the e-mail corresponds to the naming convention in the specification (e-mail system)
- ☒ The file names of the attachments correspond to the naming convention of the specification (e-mail system)
- ☐ The data format complies with the specification in all respects (e-mail/DESC system)
- ☒ ASBuilt history was transmitted (DESC system)

! Inspection of #17 - inspection data management is **mandatory** for A and B parts. If no test data is required for the series, this must be noted in the comment field.

- In addition to the delivery of the components, the supplier's scope of delivery may also include **the transmission of (component) data.**
- Ensuring that data formats, content, delivery periods, data transmission interfaces, etc. are clarified and **transferred in series without being requested with or parallel to the components**.
- These may be measured values, parameters, analysis results, etc. that the customer requires for further processing



Example: data transfer excerpt

18 Additional verifications

The additional documentation required is specified by the customer

Description Subject and content of the additionally required proof (1)	Packaging and labeling Packaging data sheet	**Example for verification 1**
Description Subject and content of the additionally required proof (2)	Lens coating as a critical component of the value stream	**Example for verification 2**
Description Subject and content of the additionally required proof (3)	Development of the measuring system for the testing of the components is to be checked	**Example for verification 3**

We hereby confirm that the samples presented comply with the additional specifications defined above

This system is variable. If necessary, it can be adapted by the customer to the respective requirements of the part/module.

The template is freely definable for specific components for agreements which are not covered by elements #01 to #17.

Evidence may include:

- Proof of suitability of the load carrier and packaging
- Tool list
- Cleanliness concept
- ESD protection concept
- Factory and hall layout plans for production
- Qualification and competence of the employees
- Qualification of (critical) sub-processes or manufacturing processes
- Development of measuring equipment
- Etc.

Important links / Good to know

This download area contains all important documents. The following documents are available for both the Group and the business group:

Documents for suppliers | ZEISS

Lieferanten und Supply Chain | ZEISS SMT

Seeing beyond