



ziehm imaging

Supplier guidelines: Qualification and approval of new or changed supplier/raw material relationships



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1 Purpose

In order to ensure a uniform standard of the samples obtained from suppliers as well as their test reports, Ziehm Imaging GmbH defines in the following the procedure for the qualification and release of new or modified supplier/raw material relationships for electronic and mechanical materials. The proper sampling and series release of the products are a prerequisite for the series supply of the client by the supplier. Both the Supplier and the Customer are then free to conclude a separate supply contract for the relevant products. By signing, the supplier undertakes to comply with these guidelines. **This guideline is to be considered as an applicable document of the quality assurance agreement (QAA), provided that a QAA exists with the supplier.**

2 Terms and abbreviations

Abbreviation	Explanation
FAI	First article inspection
FAIR	First article inspection report
QAA	Quality Assurance Agreement

Term	Explanation
First article inspection report	The compilation of the results of initial sample tests by the supplier as well as the customer and their evaluation
Raw material	Parts, materials or preparations purchased from suppliers that are intended to be assembled or added to a semi-finished or finished Ziehm Imaging product

3 General principles

The following chapters provide general principles required to prepare the initial sample report, tailored to specific components.

3.1 Language

Ziehm Imaging and the Supplier shall communicate in German or English unless otherwise agreed. This document is published in German and English versions. In the event of any deviations, only the German version shall be binding.

3.2 Consultation obligation

The Supplier undertakes to consult with the Development and Purchasing Department of Ziehm Imaging GmbH in the event that an avoidable manufacturing problem occurs upon receipt of the specifications, drawings or other development documents.

Furthermore, the Supplier undertakes to consult with the Quality Assurance and Purchasing Department of Ziehm Imaging GmbH in the event that an avoidable manufacturing problem occurs during production of the sample and/or series parts, which affects the quality and/or condition of the material.

Furthermore, Ziehm Imaging GmbH undertakes to assist the Supplier in an advisory capacity in the event of any problems and/or questions concerning the production of samples. The consultation should preferably take place in written form.

3.3 Documents

All development documents provided by Ziehm Imaging GmbH and required for production, which are subject to the signature requirement by Ziehm Imaging GmbH, must be available as signed versions. Production without signed development documents is only permitted after consultation with Ziehm Imaging GmbH. Documents that which are subject to the signature requirement:

- Technical drawings of the material
- Vendor specifications
- Work instructions for suppliers

The Supplier undertakes to comply with the respective status of the customer's specifications when transmitting and storing data/information.

3.4 Sampling types

All the types of samples that are distinguished in the sampling process are listed below.

3.4.1 Initial sample

Initial samples are products or services that have been manufactured or provided by the Supplier for the first time in their entirety using standard operating equipment and under standard conditions (e.g. new parts). They are to be taken from a batch size representative of the series process.¹

3.4.2 Change samples

Change samples are samples that do not have to undergo a full initial sampling. Only the change related to the previous revision is considered since full initial sampling has already taken place for these products. It is assumed that the previously approved characteristics will continue to be met by the Supplier.

3.4.3 Repeat sample

Repeat samples are samples that are subjected to full sampling because their initial sampling took place several cycles ago.

¹ Ziehm Imaging GmbH specifies a standard order quantity of **3** samples.

3.5 Retention period

The FAIR must be retained, regardless of the submission level, must be retained in accordance with Annex 2 of the QAA. Unless otherwise agreed, the start date of the retention period of the FAIR (on the supplier side) shall be the date of the supplier's signature on the FAIR. If there is no QAA, a retention period of 15 years applies. The retention period shall continue to apply if the supply relationship between the Supplier and Ziehm Imaging GmbH ceases to exist.

3.6 Sending the initial sample report

The FAIR is to be sent by the Supplier in advance to FAI@Ziehm.com so that the report is available for Ziehm Imaging GmbH before the initial sample delivery is received. The subject of the email should contain at least the following information:

Ziehm Imaging material number / Supplier / Ziehm Imaging order number

Please note that the "Measurement report" appendix should still be sent as an Excel file attached to the email. All other documents attached to the report must be attached to the email as a signed PDF file; furthermore they should be merged into one overall file (PDF).

Additionally the completed and signed original FAIR should also be enclosed with the samples or the delivery papers of the sample delivery.

3.7 Labeling the initial samples

In order to ensure that the samples and the FAIR are correctly assigned to each other, the samples must be marked with consecutive numbers.

The assignment must be clearly identifiable in the test report. The type of labeling must be selected in such a way that it can be removed from the material again without leaving any residue. The labeling itself must not be applied to a surface-critical side of the material.

3.8 Labeling the packaging

The sample shipment and their delivery documents shall be properly packaged and clearly marked "Initial Sample".

3.9 Deliveries and services by third parties

In principle, the Supplier should manufacture the initial sample itself. If the Supplier procures supplies and/or services from third parties for the manufacture of the parts with the consent of Ziehm Imaging GmbH, or if the Supplier receives the parts from third parties with the consent of Ziehm Imaging GmbH, the Supplier must constantly check these supplies and/or services to ensure that they are free of defects. Furthermore, the Supplier must attach samples of the materials used by its sub-supplier to the FAIR, and mark it accordingly.

4 Trigger for sampling and submission levels

The trigger for sampling and the submission levels used with it are defined and explained below.

4.1 Trigger for sampling

Triggers that lead to (re)sampling are all changes to the production process and product that originate from the Supplier and/or Ziehm Imaging GmbH. They must be communicated before the start of production.

Unless otherwise agreed, triggers are in particular the following events:

- Introduction of new parts or new assemblies as raw materials in production
- Product changes (e.g. design, specifications, material changes) to existing and qualified raw materials
- Change of production process and production location
- Self notification of process changes from the supplier
- Change of the test procedures if Ziehm has made specifications for the test
- Failed series approvals

A change confirmation from the supplier can replace an initial sample inspection report (template level 1) in the following cases:

- Form / Fit / Function not affected or purely formal changes.
- All changed characteristics already verified by Ziehm

However, if the above changes result in a change to the known manufacturing process, an initial sample inspection is still required. In this case, the implementation of the change must be verified as an immediate measure at goods receipt. This is to be done via an immediate action with the content "Changes from ECR xxx implemented".

Ziehm Imaging GmbH reserves the right to deviate in individual cases not to have (new) sampling performed despite the existence of a trigger. In this case, the Customer shall inform the Supplier in due time.

4.2 Submission levels

The respective submission level for the product in question is determined by Ziehm Imaging GmbH and forwarded to the Supplier. The submission level specifies the type and scope of the initial sampling. Unless otherwise specified by Ziehm Imaging GmbH, the Supplier shall proceed according to **submission level 2**.

Level	Requirements
1	Only the cover sheet is submitted to Ziehm Imaging GmbH.
2	The cover sheet, sample and limited supporting data/documentation are submitted to Ziehm Imaging GmbH.
3	The cover sheet, sample and comprehensive supporting data/documentation are submitted to Ziehm Imaging GmbH.

Table 1: Submission levels

4.3 Electronic components

The following requirements apply to electronic components.

Criterion	Description	Submission level		
		1	2	3
Part submission confirmation	The cover sheet is to be completed by the Supplier.	V	V	V
Development, construction, modification documents	Indication of all documents used (specifications, circuit diagrams, etc.).	A	V	V
	Printed circuit boards excluded; drawings (teardrop drawing) according to Ziehm Imaging drawing.	A	V	V
	Separate documents approved by Ziehm Imaging GmbH concerning changes not integrated into the circuit diagram or other.	A	V	V
Proof of conformity	Type plate/label conforming to Ziehm Imaging specification, -drawing printed and attached; packaging specifications conforming to Ziehm Imaging specification	A	V	V
	For printed circuit boards only: preparation of a micrograph of the layer thicknesses, as well as indication of the measurement results.	n/a	n/a	*
	For materials that are programmed at the Supplier's only: indication of the software/firmware and version used.	A	X	V
	Comparison of the Supplier's and Ziehm Imaging's parts list	A	X	V
	Compliance with ESD protection	A	X	V
	UL-, RoHS- and REACH-conformity	A	V	V
Electronics test	Indication of all electronics tests performed at the Supplier's premises.	A	X	V
	Proof of the tests carried out (test report, acceptance report, etc.).	A	X	V
Qualitative and quantitative measurement results	Test report of all dimensional characteristics of Ziehm Imaging's drawing and accompanying specifications, qualitative test characteristics (e.g. gage accuracy, paint samples, surfaces, etc.) must be evaluated in a technically correct manner (no OK / NOK information).	A	X	V
Visual inspection	Visual inspection of solder joints, surfaces, components and, if applicable, the joining processes performed (e.g. crimping) by employees, in accordance with IPC-A-600/-610/-620/-630, SPEC_all_cables or other agreed leading documents.	A	V	V
	Manually visual inspection, mechanical visual inspection by AOI or other automatic testing equipment in accordance with IPC-A-600/-610/-620/-630 or other agreed leading documents.	A	V	V
Samples	Initial, modification and repeat samples manufactured under series conditions, with part identification, in series packaging according to previous specifications, must be submitted to Ziehm Imaging GmbH.	n/a	V	V
Operating equipment, test equipment	The operating resources used by the Supplier and relevant to production must be specified.	*	*	*
	The test equipment used by the Supplier and relevant to the test must be specified.	*	*	*
Process flows	Process flow diagram for the product or product family	*	*	*
	Product control plan	*	*	*
	Process FMEA	*	*	*

Table 2: Electronic components requirements table

V	Archived by the Supplier and submitted to Ziehm Imaging GmbH.
A	Archived by the Supplier and immediately available upon request by Ziehm Imaging GmbH.
X	Automatically requested by the Supplier for submission to Ziehm Imaging GmbH if a verification obligation arises due to the product change/introduction , otherwise archived by the Supplier.
*	Required by Ziehm Imaging GmbH on a case-by-case basis, otherwise not required.
n/a	Not applicable

4.4 Mechanical components

The following requirements apply to mechanical components.

Criterion	Description	Submission level		
		1	2	3
Part submission confirmation	The cover sheet must be completed by the Supplier	V	V	V
Development, construction, modification documents	Drawing (teardrop drawing) according to Ziehm Imaging's drawing	A	V	V
	Confirmation of the material according to Ziehm Imaging's drawing and specifications	A	V	V
	Surface finish according to Ziehm Imaging's drawing and specifications	A	X	V
Proof of conformity	Material data sheets (e.g. plastics, etc.)	*	*	*
	Type plate/label conforming to Ziehm Imaging specification, -drawing printed and attached; packaging specifications conforming to Ziehm Imaging specification	A	V	V
	RoHS- and REACH-conformity	A	X	V
Qualitative and quantitative measurement results	Test report of all dimensional characteristics of Ziehm Imaging's drawing and accompanying specifications, qualitative test characteristics (e.g. gage accuracy, paint samples, surfaces, etc.) must be evaluated in a technically correct manner (no OK / NOK information).	A	X	V
Visual inspection	Visual inspection of all surfaces according to Ziehm Imaging's drawing specifications.	A	V	V
Samples	Initial, modification and repeat samples manufactured under series conditions, with part identification, in series packaging according to previous specifications, must be submitted to Ziehm Imaging GmbH.	n/a	V	V
Operating equipment, test equipment	The operating resources used by the Supplier and relevant to production must be specified.	*	*	*
	The test equipment used by the Supplier and relevant to the test must be specified.	*	*	*
Process flows	Process flow diagram for the product or product family	*	*	*
	Product control plan	*	*	*
	Process FMEA	*	*	*

Table 3: Mechanical components requirements table

V	Archived by the Supplier and submitted to Ziehm Imaging GmbH.
A	Archived by the Supplier and immediately available upon request by Ziehm Imaging GmbH.
X	Automatically requested by the Supplier for submission to Ziehm Imaging GmbH if a verification obligation arises due to the product change/introduction , otherwise archived by the Supplier.
*	Required by Ziehm Imaging GmbH on a case-by-case basis, otherwise not required.
n/a	Not applicable

5 Client approval

After the samples and associated documentation have been submitted by the Supplier, Ziehm Imaging GmbH may carry out further tests at its own discretion, which can also be carried out on site at the Supplier's premises by arrangement in the case of **submission level 3** or as part of a production test run. One of the following decisions is made by Ziehm Imaging GmbH based on the FAIR and any tests performed by Ziehm Imaging GmbH.

5.1 Approved

Full approval of the supplier/raw material relationship means that the material provided by the Supplier as a sample meets all specifications and requirements. Furthermore, the order documentation is complete.

Ziehm Imaging GmbH records the technical approval on the FAIR and sends it to the Supplier.

5.2 Approved with conditions

Conditional approval allows the production material to be supplied for a **limited time** or **quantity** if the specifications have not been met by the Supplier or if there were inconsistent results in the FAIR (i.e. different supplier/client results). The samples are then conditionally accepted for further trouble-free or non-critical processing.

Ziehm Imaging GmbH records the technical approval on the FAIR and sends it to the Supplier.

Implementation of the measures at the Supplier's is ensured by Ziehm Imaging GmbH.

5.3 Rejected

The initial samples provided by the Supplier do **not** comply with the requirements or the specifications and therefore **cannot** be used as raw materials.

Ziehm Imaging GmbH records the rejection of the initial samples on the FAIR. The materials, the FAIR and a notice of defects are returned to the Supplier.

New samples must be taken in order to still be able to qualify the targeted supplier/raw material relationships. The new samples are then subjected to a full First article inspection (FAI) by the Supplier and customer again.

5.4 Revocation of approvals

An approval is unlimited in time until revoked. Ziehm Imaging GmbH reserves the right to revoke a granted approval if it is recognized that the standards defined in this document or related documents are violated in a way that affects the quality, reliability, processing or usability of the materials.

6 History

Version	Date	Author	Change description
1	see DMS	see DMS	Document was transferred to SAP ECTR DMS and is based on paper version A of AA7.4-07_A1. No changes in content
2	see DMS	see DMS	- Marking of samples has been simplified - Triggers for initial sampling have been updated

Replaced prior version Name	Version
n.a.	n.a.