

# **Quality Assurance Agreement**

between

(hereinafter referred to as "contractor")

and

BigRep GmbH Gneisenaustr. 66 10961 Berlin Germany

(hereinafter referred to as "BigRep")

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## preamble

BigRep develops and distributes additive manufacturing machines (material extrusion process MEX) as well as plasticbased materials for use in the MEX process.

This Quality Assurance Agreement (QAA) represents the framework for technical and organisational conditions as well as processes which are applied by BigRep and the contractor and which are necessary to achieve the jointly aspired quality objective. It describes the minimum requirements for the management system of the contractual partners and regulates rights and obligations with regard to quality assurance for the products to be supplied.

In particular, the QAA defines the requirements to be applied for the release procedure of the products and the production processes.

The contractor shall create the technical and organisational prerequisites to manufacture and deliver products of impeccable quality.

#### scope and contracts ١.

This QAA applies to all product groups delivered by the contractor on the basis of orders received and accepted by the contractor from BigRep during the term of this agreement. It is an indispensable component of the procurement contracts listed below:

- frame contract for the products
- individual orders
- Supplier-Guideline of BigRep

# objective

This QAA is a contractual instrument with the help of which the contractor and BigRep agree on technical and organisational procedures with the aim of producing fault-free products and delivering them on time, in quantity and in the right assortment. Jointly defined measures for fault prevention and early fault detection help to keep the manufacturing costs of the product low. The QAA contains rules for immediate and corrective actions in the event of complaints and tasks to promote the performance of both contractual partners.

The QAA is an essential contractual document for a long-term oriented supply partnership for mutual benefit.

# III. management systems of the contracting parties

The contractor works according to the following certified management systems:

The contractor's management system includes tasks and actions to ensure that employees behave in an environmentally and safety-oriented manner in all operational processes and in their handling of the materials and technical resources used. Both contracting parties undertake to constantly develop and improve their management systems in accordance with the state of the art, compliance with the regulations of this QAA and all other common contractual documents.

# principle

BigRep will provide the contractor with all existing product requirements (e.g. drawing, functional description, special features) in an understandable and meaningful way. The contractor will check the above-mentioned product requirements in all openness with the departments concerned for technical and economic feasibility and, if necessary, submit proposals for changes at an early stage. This also applies to information resulting from his manufacturing expertise on requirements that may be missing or incorrectly defined by BigRep.

The contractor appoints a project manager, defines the project tasks with appropriate deadlines and informs BigRep regularly about the current status of work. In individual cases, separate working methods may be agreed.

The contracting parties shall disclose their respective contact persons.

The contractor must immediately notify BigRep of any deadline risks and delays.

BigRep shall immediately notify the contractor in writing of any changes to the product requirements. The contractor shall check whether these changes are technically possible and what effects they will have on the order.

# product development

If the contractor's order includes development tasks, the requirements shall be specified in writing by the contracting parties, e.g. in the form of a requirement specification. The contractor undertakes to carry out project management already in the planning phase of products, processes and other crossdepartmental tasks and to grant BigRep inspection upon request. In the course of the contract review, the contractor shall check all technical documents such as specifications, drawings, parts lists, CAD data for feasibility upon receipt; the contractor shall immediately notify BigRep of any defects and risks identified. In the development phase, the contractor shall apply appropriate preventive methods of quality planning such as feasibility studies, reliability studies, FMEA, etc.. Experiences (process flows, process data, capability studies, etc.) from similar projects are taken into account.

#### technical terms of delivery VI.

- BigRep provides the contractor with Technical Terms of Delivery (TLB) as part of the order placement, in particular for safety-relevant and technically demanding products. In addition to the drawing specifications, these product group-related TLBs contain at least information on the delivery condition, labelling and, if applicable, special requirements for selected features. For each order, the product safety regulations must also be observed; these are described in Annex 2.
- The contractor shall integrate these specifications into his (2)quality and inspection planning.

# VII. first sampling and delivery release

- The delivery date stated on the first sample order is binding. A delay in delivery endangers the start of series production.
- The contractor shall provide BigRep with the clearly marked first sample test report (FSTR) and all documents of proof belonging to the specified submission stage. The number of first samples must be agreed with BigRep.



- The FSTR shall not be used to present deviations which (3)inevitably lead to subsequent sampling. All necessary coordination, even in the exceptional case of the use of equipment not yet in series production, must be carried out before first sampling and must be taken into account in scheduling. If first samples with non-conformity results are sent without approved deviation permit (AWE), they are rejected without testing. The same procedure is applied in case of missing documents. A new first sampling with conformity results or AWE must be submitted immediately.
- If BigRep has specified conditions, the subsequent sampling shall be limited to the deviations concerned and missing documents, unless otherwise specified.
- The contractor and BigRep shall archive the sampling documents 10 years after the end of series production, unless BigRep specifies a different deadline.
- BigRep determines when repeated first sampling is required (see Section XIII).

# VIII. incoming inspections of BigRep and failure announcement

- (1) BigRep or its associated partners will check immediately upon receipt of the products whether they correspond to the ordered quantity and type, whether there are externally visible transport damages or externally visible defects. If the partners consider further tests by BigRep to be necessary at times, they will be coordinated in particular with regard to test technology and test procedures and integrated into the written test plan of BigRep.
- If BigRep discovers any damage or defect during the (2)aforementioned inspections, the contractor will be notified immediately. Damages or defects not discovered in the receiving inspection shall be notified to the contractor as soon as they are discovered in accordance with the conditions of a proper course of business.
- BigRep shall not be liable to the contractor for any tests (3) and notifications other than those mentioned above.

#### IX. identification and traceability

- The contractor shall maintain a indentification and tracking system for all production lots and material batches with which it is possible to identify the delivery batch of the subcontractor in the event of quality defects. This system must also be able to identify the process data and inspection results belonging to the contractor's production lot. The system shall enable the detection of other products in circulation with the same quality defects and the analysis of the cause of the defect.
- The contractor must be able to trace back without any doubt and determine when he delivered which products to
- BigRep must also maintain an identification and tracking system, with which it can assign doubtlessly defective products to the responsible contractor with indication of the delivery data.
- The contractor must label each delivery unit to BigRep at least as follows: Manufacturer, article description and number, production lot number and quantity. If available, the labelling regulations of the product-specific technical terms of delivery apply.
- Contractor and BigRep undertake to continuously develop their product labelling systems so that, in the event of a

complaint and possible recall, defective products can be quickly identified and clearly allocated to production batches and material batches.

### method for deviations identified before Χ. delivery

If, in exceptional cases, the contractor intends to deliver BigRep products with specification deviations, the contractor must ask for a written deviation permit from BigRep.

# XI. method for complaints from BigRep

- BigRep will notify the contractor of quality defects as soon as they have been determined in the ordinary course of business, stating the delivery unit concerned, in a letter of complaint (RS).
- BigRep describes in the RS the product defects and their frequency, if feasible at this time, defines necessary immediate measures including dates for the handling of the faulty delivery quantity as well as the date for the first feedback of the contractor.
- If the contractor needs defective products or for example pictures in order to respond to the complaint, these must be requested immediately and sent by BigRep in the fastest possible way.
- In the case of quality defects for which the contractor is responsible, the contractor shall in principle have the priority right to carry out appropriate immediate actions to remedy the defect.
- BigRep will carry out a sorting action and/or troubleshooting only in consultation with the contractor. This procedure is also permissible without a vote in the following special situations:
  - the contractor does not keep a reasonable coordination date fixed in this respect
  - BigRep had to carry out immediate actions as part of a customer complaint and only later identified the contractor as the cause. In this case, BigRep must provide the contractor with appropriate evidence (non-conformity parts, pictures) as soon as possible.
- The contractor shall prepare a complete 8D report within the deadlines specified in the RS. Any foreseeable failure to meet the deadline, e.g. to demonstrate the effectiveness of corrective actions taken to prevent future errors, must be reported to BigRep at an early stage.

### XII. product and process changes

- If BigRep or, if known, its customer plans to change the further processing process and/or the function of the purchased part and if it cannot estimate whether the part specification must be adapted as a result, it must notify the contractor of this in writing prior to the change. The contractor shall inform BigRep in writing within an agreed period of time whether a change in specification and, if applicable, in price is necessary.
- If the contractor plans to change the materials, vendor parts, manufacturing processes, production sites, process and test conditions etc. used by him in relation to the process conditions in accordance with the first sample approval, he shall notify BigRep thereof in writing.
- The written information on the aforementioned changes must be provided in a timely and complete manner so that



- BigRep/subcontractor can review the scope of the changes and object to them before the respective change is applied to the subject matter of the contract.
- (4) BigRep's silence with regard to a change notified by the contractor does not relieve the contractor of its sole responsibility for the characteristics and reliability of the parts to be supplied in accordance with the contractually agreed specification.
- (5) BigRep decides on a case-by-case basis whether and to what extent repeated first sampling is necessary in connection with a process change.

# XIII. criteria and scope of requalification tests

- (1) The contractor shall carry out at least one requalification test per year for each product group, beginning with the date of initial sample release, in order to prove a stable quality level.
- (2) The requalification test must include all material, dimensional and functional specifications specified by BigRep for the product.
- (3) The requalification test is carried out in accordance with the specifications for the initial sample test.
- (4) The test results shall be documented by the employee and transmitted to BigRep upon request.

# XIV. auditing of the contractor by BigRep

- (1) The contractor enables BigRep to convince itself of the effectiveness of its quality assurance measures on site after scheduling coordination.
- (2) Especially in the event of quality problems, BigRep supplier and product audits help to effectively secure the common goal: "Restoration of a quality-capable process".
- (3) For this purpose, the contractor shall grant BigRep access to all production facilities, testing facilities, warehouses and adjacent areas during normal operating and business hours as well as access to all quality-relevant documents, unless the confidentiality interests of the contractor or third parties demonstrably conflict with this. If necessary, audits shall be carried out jointly with the contractor at the subcontractor's premises.
- (4) Current internal audits and those of approved certification bodies are taken into account during the audit process.
- (5) The measures defined jointly as a result of the audit are to be consistently implemented by the responsible office of the contractual partners.
- (6) The costs of an audit shall be borne by each party itself.

# XV. supplier evaluation from the mutual point of view

- (1) The performance of BigRep depends to a large extent on the stable performance of the contractor. That is why BigRep continuously evaluates essential performance criteria such as delivery date, quantity reliability, product quality, flexibility and communication.
- (2) BigRep carries out a supplier evaluation at defined time intervals for essential measurable and, if necessary, 'soft' criteria such as communication and flexibility. The results are communicated to the contractor, evaluated with him and, if necessary, joint corrective and improvement measures are derived.
- (3) Unless otherwise agreed, the contractor shall be responsible for selecting subcontractors. The contractor is

responsible for ensuring that the subcontractors achieve and maintain or improve the quality standards required by BigRep. In addition, the contractor shall be responsible for all tasks connected with the subcontractor and the end product delivered.

# XVI. mutual information obligations

- (1) This paragraph concerns mutual information which is not already contained in other sections of this QAA.
- (2) BigRep shall inform the contractor in writing in particular in the following situations:
  - Modification of technical terms of delivery and introduction or modification of factory standards
- (3) The contractor shall inform BigRep in writing in particular in the following situations:
  - Proof of current management certificates
  - Modification of technical terms of delivery and factory standards, if applicable
  - foreseeable non-compliance with delivery criteria such as deadline, quantity and quality including intended special release
  - Product requirements or test procedures are incomplete, faulty or could be implemented more economically by the contractor if changed
- (4) The contractor's obligation to retain test records and acceptance test certificates shall be at least 10 years.
- (5) The Annex 1 'contact persons' belonging to this QAA regulates the responsibilities of both contractual partners for each QAA issue.

# XVII. confidentiality

- (1) Each partner shall use all documented information and knowledge received in connection with this agreement only for the purposes of this agreement and shall keep them secret from third parties with the same care as its own documented information and knowledge if the other partner designates them as confidential or has an obvious interest in keeping them secret.
  - This obligation shall commence upon receipt of the documented information or knowledge for the first time and shall end 36 months after the end of the agreement.
- (2) The above obligation of secrecy does not apply to information, discussion contents and facts that can be proven to be confidential:
  - were already publicly known at the time of notification to the receiving partner or subsequently become publicly known without violation of the present obligation, or
  - were already known to the receiving partner prior to disclosure by the other partner, or
  - are lawfully communicated to the receiving partner by third parties, or
  - have been developed by the receiving partner independently of the information provided by the other partner.

# XVIII. liability

Liability shall be determined in accordance with the agreements on which the delivery is based.



# XIX. applicable law

Legal relations in connection with this agreement shall be governed by German substantive law.

# XX. duration of the agreement

This agreement may be terminated by any partner at the end of any calendar month with three months' notice.

# XXI. other applicable standards and directives

The following essential external standards and guidelines in the respectively valid version are an integral part of this QAA contract:

- DIN EN ISO 9001 "Quality management systems -Requirements
- DIN EN 10204 "Metallic products Types of test certificates".

Both contracting parties must independently ensure that these rules and regulations are up to date.

# XXII. general

- Place of jurisdiction is Berlin, Germany. BigRep is also entitled to appeal to any other competent court.
- Both parties waive the right to conduct proceedings for the issue of documents (§ 592 et seq. ZPO) under the contract. The parties shall also waive the right to appeal to an arbitral tribunal and shall settle any dispute before the ordinary courts.
- Should one or more provisions of this contract and any (3) further agreements be or become invalid, this shall not affect the validity of the remaining provisions.
- The English version of this Agreement constitutes a mere convenience to the user. The German version alone is authoritative and shall take precedence over the English version in the event of contradictions or deviations. This shall apply mutatis mutandis to all other related documents such as other applicable documents.

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Signature

Quality Assurance Agreement

Signature

Place, Date



# Annex 1: contact persons

1.	contractor				BigRep			
subject	division	name	email address	division	name	email address		
modification of the QAA	-	-	-					
change management								
supplier evaluation								
change TLB or factory standards								
modification of process conditions in series production				-	-	-		
information on non- compliance with delivery criteria								
deviation permit								
management certificates								

BigRep GmbH



# Annex 2: Product Safety Regulations (PSV)

For a product with CE marking, technical documentation in accordance with EU directives must be kept available so that it can be presented to the authorities if necessary or in the event of product liability. With the acceptance of the order, the contractor undertakes to comply with the following provisions or claims, if applicable, in the current version at the time of placing on the market:

- Machinery Directive 2006/42/EC
- EMC Directive 2014/30/EU
- Low Voltage Directive 2014/35/EU
- other community legislation of the EU, where applicable, e.g.
  - General Product Safety Directive 2001/95/EC
  - WEEE electrical and electronic scrap 2012/19/EU
  - RoHS Directive 2011/65/EU
  - REACH Regulation 1907/2006
- Employer's liability insurance association regulations e.g. DGUV Regulation 3
- All harmonized European standards applicable to the ordered device, machine or plant, in particular e.g. EN 60204-1, EN 61010-1, EN ISO 12100, EN ISO 13849-1, EN ISO 13849-2, EN 62471, Type C standards, as well as relevant EMC standards.

For certain procurements, requirements of other countries or product-specific requirements may also apply, e.g. UL, CSA. The contractor also undertakes to observe standards and technical terms of delivery.

Deviations from harmonized European standards or German standards and technical specifications shall be justified in writing by the contractor. The achievement of the same level of safety by other means must be proven and documented by the contractor.

The contractor is obligated with regard to devices, machines or plants,

- to affix the CE marking and issue a declaration of conformity if EU directives are applied. If the manufacturer is based outside the EU, the declaration of conformity must be drawn up by his authorised representative based within the EU.
- to provide technical documentation in accordance with the Machinery Directive for an incomplete machine and to include assembly instructions and a declaration of incorporation
- $\qquad \hbox{to enclose operating instructions (BigRep \ provided) in German \ and \ English \ language}$
- a test report of the electrical tests carried out according to DIN VDE 0100-600

On request, the contractor shall be obliged to provide equipment, machines or plants,

to hand over the risk assessment for the activities falling within the contractor's area of responsibility, as well as to supply calculations, test results and measurement reports

These obligations are part of the QAA and/or the supplier frame contract. If they are not fulfilled, the order shall be deemed not to have been properly executed.

We reserve the right to claim damages from the contractor due to defects and the resulting defects.