QUALITY ASSURANCE AGREEMENT

BETWEEN: Kontron Austria Electronics GmbH, Wildbichlerstraße 2e, 6341 Ebbs/Österreich, hereinafter referred to as **KAE**

AND: CompanyName, Street, Postal Code City Country,
hereinafter referred to as the **Supplier**,

have reached the following agreement:

1 Introduction

1.1 KAE is a certified partner for innovative electronic development and production. It specialises in the areas of medical technology and medical equipment manufacturing, energy and the environment. KAE intends to purchase products and/or services from the supplier.

1.2 To ensure compliance with legal regulations and standards, as well as to satisfy the customer's requirements, the parties to this contract agree that – without affecting competitiveness – a high level of quality and reliability is needed for the technical products.

1.3 Quality management systems are to be laid down to achieve these goals and to make continual improvements.

1.4 All mentioned standards and directives always refer to the respective valid version.

2 Scope of contract / contract length

2.1 This quality assurance agreement, hereinafter referred to as **QAA**, applies to all commissions in connection to the orders, applicable specifications, standards, data sheets, drawings, delivery documents and certificates required to be produced.

2.2 The QAA comes into effect when signed by both parties and is concluded for an unlimited period of time.

2.3 Changes or additions must always be made in writing. If a new QAA is signed with a later release version, all previous editions lose their validity.

2.4 Notice must be given in writing and can be given by either party to the end of a calendar year with a notice period of three months.

3 Quality Management System (QMS)

3.1 The supplier observes a quality management system in line with the standards of EN ISO 9001 at the least. These, and any other additional certifications, are to be evidenced to KAE using the corresponding certificates. In case the supplier is not certified, the supplier will allow KAE to conduct quality audits in order to verify and proof the respective applied quality management system

3.2 In the manufacture and delivery of the products the standards of ISO 9001 and, for medical technical devices, ISO 13485 are to be met by the supplier, this is independent of the certification actually held by the supplier.

3.3 The supplier undertakes to immediately inform KAE in writing of any changes or revocation to certificates held; the amended certificates must also be provided. In the event of revocation of the ISO 9001 certification KAE is entitled to immediately terminate the contract without the need to observe a notice period.

3.4 The supplier is obliged to observe every relevant industry standard and norm (UL, CSA, IEC as examples) for all delivered products. Where applicable the supplier is also obliged to follow the EU directives 2011/65/EU (RoHS directive) and 2012/19/EU (WEEE directive) in their current version.

3.5 The supplier is obliged to use a reporting system which will inform KAE about all safety and quality-relevant events that make a delivery stop or product recall necessary. The supplier also undertakes to inform KAE immediately (within 24 hours) of any notification of a recall by the competent supervisory authorities. KAE may require the supplier to disclose all documents in connection with such an event and that are needed to evaluate, determine the root cause and to establish the corrective actions needed to minimise the risks for KAE.

3.6 The supplier will ensure that its suppliers have a comparable QMS which ensures the fault-free nature of the parts it purchases and/or externally processed parts. KAE may require the supplier to provide documentary evidence that the supplier has verified the effectiveness of such QMSs in its subcontractors and suppliers.

3.7 Each party will inform the other in writing of the quality management representative who is to carry out and coordinate the quality relevant points of this agreement and has to take or generate QM relevant decisions. A change of this QM representative is to be notified immediately in writing.

The QM representatives of the parties are:

	KAE	**CompanyName**
Name	Patrick Feller	
Dept.	Head of Quality Management	
Tel.	+43 (0)5373/43143-690	
E-Mail	patrick.feller@kontron.at	

4 Quality assurance (testing, marking, record keeping, transport)

4.1 The supplier must immediately check if a specification delivered by KAE is obviously incorrect, unclear, incomplete or clearly different from the guidelines. If the supplier feels that this is the case, it will immediately notify KAE in writing.

4.2 The supplier will keep records over the implementation of quality assurance measures, in particular of the measurement and test results. These will be kept along with any product samples in a clear and orderly manner.

4.3 In line with the requirements of ISO 13485 regarding the manufacture of medical technical products, the supplier agrees to keep any relevant test and quality reports for a period of at least 15 years and to make them available to KAE on request. The destruction of such documents at the end of the archive period requires the written agreement of KAE.

4.4 At KAE's request the supplier will include the appropriate test logs with each product delivery. If KAE does not request these logs, this does not relieve the supplier of the requirement to archive such reports.

4.5 Documents and records concerning the manufacture of products for KAE, even by sub-contractors, must be able to be produced consistently and fully in paper form or as a file on demand.

4.6 In general, the supplier's product quality will be ensured on the one hand by high process reliability and stability and the documented process capability and on the other hand by regular testing during the manufacture.

4.7 On request by KAE, every product is to be given a unique identification (bar code) with serial number management. This requirement will be defined by KAE in consultation with the supplier.

4.8 Fundamentally the supplier will maintain a batch related traceability system. In addition, KAE may require a serial number based system where needed and in particular for critical components.

4.9 If the supplier delivers products which are sensitive to electrostatic discharge (ESD), then the supplier must have an active ESD program. In particular an ESD processing and packing process where the packaging of such goods is to be such that it meets the requirements to protect against ESD. This applies to PCBs, electronic elements with exposed connections or components and to other equipment needing ESD protection. The supplier is obliged to keep records of completed tests and training.

4.10 The handling and transport of the goods in all phases of the process is to be undertaken with the necessary care and where needed on account of sensitivity, with the use of appropriate aids.

4.11 Regardless of the ESD measures needed, the supplier will generally use packaging to prevent contamination, corrosion or damage to the goods during transport or handling.

5 Audits

5.1 KAE is entitled to carry out system, product or process audits on the goods to be delivered, the associated documents, processes, records, tools and machines. This will be done following notice to the supplier and may be carried out by KAE itself, or by a third-party who is bound to secrecy. KAE, or the third party, having given reasonable notice may have access at any time to the production and storage rooms relating to this agreement. The supplier has to ensure that KAE have similar rights of access to its own suppliers. In addition, KAE has the right to carry out any quality audits which are to be conducted at the supplier; this includes those carried out jointly with the authorities or an end-customer's representative.

5.2 KAE will inform the supplier of the results of any audits that are carried out. If corrective measures are found to be necessary during an audit, the supplier is required to create an action plan within 30 calendar days, to implement this plan on time and to ensure KAE is properly informed of the plan and its results.

6 Supplier evaluation

6.1 A supplier evaluation is carried out regularly and is based on various criteria like, for example, delivery reliability, quality, complaint processing time, value for money and soft facts. The results are passed to the evaluated supplier at least yearly, at shorter intervals where needed, using an evaluation form.

6.2 Depending on the level allocated, the supplier may produce a statement or an action plan to take improvement measures if needed and to keep KAE informed properly about such measures.

7 Product changes, notification of changes

7.1 Product change suggestions from the supplier must be notified to KAE in writing and approved by KAE prior to any delivery. These include those in terms of the materials and processes which affect the shape, suitability, function, operational reliability, reliability, maintenance, performance, functional interchangeability, compliance with legal requirements, safety requirements, options or ability of spare parts to be swapped.

7.2 These also particularly include, but are not limited to, changes to the sources of materials or components, changes in the production process, the testing process and the manufacturing location, the change in the layout of the production facilities or replacement of equipment and every similar change that is planned by a subcontractor.

7.3 Products affected by changes may not be delivered to KAE, without the prior agreement in writing from KAE about the adoption of the amendment.

7.4 The change notification must include as a minimum:

- The article number of the affected components;
- The timing of the implementation of the change (first delivery date to KAE);
- The production or serial number from when the change is introduced;
- The reason for the change;
- Special features of the change and the data material that show the operational safety and reliability of the product are not affected by the change.

7.5 The change must not be implemented without the written agreement from KAE by the supplier; this consent shall, however, not be withheld without good reason.

7.6 KAE is entitled to demand samples from the supplier to carry out its own evaluations or arrange for such evaluations by third parties (e.g. testing laboratories, end-customers).

8 Returns / defective products

8.1 The supplier is required to repair, replace or offer a price reduction as KAE specifies and agrees to within 25 (twenty-five) days of notification of such defects in the case of faulty or defective products. Any other requirements on the supplier's part resulting from this QAA remain unaffected.

8.2 Where KAE requires it and in conjunction with this defect or failure report, the supplier must produce and pass to KAE an 8D report with detailed root cause analysis, suitable corrective measures and final effectiveness report. In such cases the defect is only considered solved on receipt of the 8D report by KAE.

8.3 The supplier must also upgrade returned goods to the latest version from any change processes if this is technically possible. If returned goods are no longer usable in the series due to the long processing times (an old version and cannot be upgraded), then the supplier is to cover the costs of the replacement of the product.

9 Guarantee and warranty

9.1 The supplier provides KAE with a guarantee that he is empowered and authorised to conclude this QAA and the meet all of the commitments made in this QAA.

9.2 The supplier guarantees KAE that the products fully meet the specifications.

9.3 The supplier also provides KAE that the products:

- Are complete, in good condition, new and free from defects of any kind, especially in the design, production or material;
- Correspond and comply with all applicable standards, laws and regulations.

10 Final provisions, other matters

10.1 The responsibility of the supply for the defect-free state of the supplied products is not limited by this QAA.

10.2 The contracting parties agree that the options provided for in this QAA may be added to or adapted if needed. The contracting parties undertake to work together amicably in this regard and to take all reasonable and practical efforts to take these needs into account.

10.3 Each contracting party is responsible for their own costs relating to the preparation, conclusion and implementation of this QAA, including any consulting fees.

10.4 If any provision contained in this QAA is in part or whole void, invalid or unenforceable in any respect, the validity and enforceability of the rest of the QAA shall not be affected by it. The invalid, ineffective or unenforceable provision is, to the extent permitted by law, to be replaced with a valid and enforceable provision that closest matches the economic purpose and object of the invalid, ineffective or unenforceable provision.

10.5 This QAA replaces all previous oral and written agreements regarding the obligations specified in this QAA between the two contracting parties, as long as there is nothing to the contrary expressly agreed within this QAA.

10.6 This QAA is provided in duplicate, each contracting party will receive a copy.

11 Additional agreements

The following additional agreements or changes to the points contained in this QAA were made:

N/A

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Signed on behalf of:
Kontron Austria Electronics GmbH
Wildbichler Straße 2e
6341 Ebbs /Austria

Authorized signature	
Name (in capitals)	
Position in company	
Date	

Signed on behalf of:
CompanyName
Street
Postal Code City / Country

	Authorized signature
	Name (in capitals)
	Position in company
	Date