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SUPPLIER QUALITY ASSURANCE GUIDELINES



EDITION	REDACTION NAME - FUNCTION	VERIFICATION AND APPROVAL	
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		SUPPLIER QUALITY ASSURANCE GUIDELINES	DATE: 15/01/2020

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1. INTRODUCTION

C-MAC Electromag BVBA requires a consistently high quality of delivered materials as these determine to a high extent the quality level of our finished products. As quality is a particularly important competitive factor towards Customer Satisfaction, continuous improvement is necessary and we expect from our Suppliers to operate an effective quality system.

1.1. Purpose

This document describes the Supplier Quality Assurance Guidelines (SQAG) to be followed by the C-MAC Suppliers in order to guarantee a faultless delivery in accordance with the terms of the contract.

These guidelines are intended to provide a clear basis for handling quality questions with our Suppliers and to help improve the level of quality to our customer's requirements. These guidelines highlight C-MAC's basic requirements for Suppliers and also refer to international standards and methods, which are necessary to achieve common objectives. Customer requirements may exceed C-MAC's basic requirements and have to be followed as part of our customer satisfaction policy.

Collaboration and mutual partnership with our Suppliers is part of C-MAC's strategy. It is our aim to involve Suppliers more at the development stage and to replace the testing of goods received by quality agreements.

It is essential that Suppliers apply the philosophy of "Zero-defect quality" and therefore have a clear strategy to achieve this goal. C-MAC expects a commitment from the Supplier to implement appropriate systems and controls to ensure the 100% on-time delivery of conforming defect free products.

1.2. Applicable area

These SQA guidelines shall apply to the Supplier (including participating Related Companies) providing Products (= any product to be manufactured, sold, delivered and/or provided) having an effect on the quality of the finished products of C-MAC Electromag BVBA (including participating Related Companies).

Supplier and participating Related Companies hereinafter referred to as "Supplier".

C-MAC Electromag BVBA (including participating Related Companies) hereinafter referred to as "C-MAC".

The Supplier shall ensure that the SQA guidelines are applied along the Suppliers supply chain (sub-suppliers) including C-MAC directed suppliers (directed buy).

1.3. Validity

As of the effective date this document embodies all terms and conditions between the Supplier and C-MAC with respect to the subject matter hereof and supersedes and cancels all previous agreements and understandings. There are no verbal statements which have not been embodied herein.

These SQA guidelines can be downloaded on the C-MAC website and become valid if there is no objection in writing within a 3-month period from the date it has been published.

2. DEFINITIONS

Product	Raw material, component, sub-assembly used for the manufacturing of a finished product and having an influence on its quality. Any product to be manufactured, sold, delivered and/or provided to C-MAC.
FIFO	First In - First Out

3. REFERENCES

3.1 C-MAC documents

F02-01	General Information Questionnaire
KF1119	Premium Freight document
CA1011	Code of conduct Suppliers

3.2 Standards

ISO9001	Quality Management System Requirements
IATF16949	Automotive Quality Management System Standard
ISO13483	Medical Quality Management System Standard
AS9100	QMS – Requirements for Aviation, Space and Defence Organizations
ISO14001	Environmental Management Systems
IPC-A-600	Acceptability of Printed Boards
AIAG	Automotive Industry Action Group Standards and Rules
VDA	German Association of the automotive Industry Standard and Rules
VDA Volume 2	Production process and product approval
VDA Volume 5	Capability of Measurement Processes; Capability of Measuring Systems
VDA Volume 6.3	Quality Management in the Automotive Industry – Process audit Part 3

3.3 National legislation

2000/53/EC	EU Directive on End of Life Vehicles (ELV)
2011/65/EU	EU Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
2015/863/EU	RoHS 3 Amendment Directive (EU) 2015/863: Amendment to EU RoHS 2 Directive adding four specific phthalate substances that will become restricted above a specific threshold July 22, 2019
1907/2006/EC	EU Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
2001/95/EC	EU Directive on general product safety
2017/822/EU	EU Regulation concerning minerals originating from conflict affected and high-risk areas

4. GENERIC REQUIREMENTS

Applicable to all C-MAC's Suppliers independent for what applications the materials will be used.

4.1 Statutory and Regulatory requirements

ISO 9001 clause 8.2.2

The Supplier shall conform to all applicable statutory, regulatory and safety requirements in the country of receipt, the country of shipment and the country of destination for all contracted products, processes or services, if not otherwise mutually agreed between C-MAC and the Supplier. Some legal requirements to be fulfilled are mentioned in paragraph 3.3 under national legislation.

The Supplier delivering materials used for automotive applications shall fulfil the requirements for the recycling and disposal of the supplied products (IMDS and ELV).

4.2 General System Requirements

In order to ensure the quality of the delivered materials, C-MAC expects the Suppliers to have a sufficient number of skilled personnel, adequate technical equipment and an effective organization for the prevention and recognition of defects, in conjunction with a Continuous Improvement Process.

4.2.1 Quality Management System requirements

Each Supplier should have at least one of the following quality management system certifications.

Industrial – ISO9001:

Suppliers delivering materials for industrial applications shall have at least an ISO 9001 Quality Management System.

Automotive - IATF16949:

Existing Suppliers delivering materials used for automotive applications shall have at least an ISO 9001 Quality System, with the goal of achieving an IATF 16949 certification.

New potential Suppliers delivering materials used for automotive applications must be IATF 16949 certified. The C-MAC QA Manager can admit a possible deviation.

Aviation, Space and Defence – AS9100:

Existing Suppliers delivering materials used for aviation, space and defence applications shall have at least an ISO 9001 Quality Management System, with the goal of achieving an AS9100 certification. New potential Suppliers delivering materials used for aviation, space and defence applications must be AS9100 certified. The C-MAC QA Manager can admit a possible deviation.

Medical – ISO13485:

Existing Suppliers delivering materials used for medical applications shall have at least an ISO 9001 Quality Management System, with the goal of achieving an ISO13485 certification. New potential Suppliers delivering materials used for medical applications must be ISO13485 certified. The C-MAC QA Manager can admit a possible deviation.

4.2.2 Environmental Management System requirements

The Supplier shall implement environmental systems in their facilities, which are compliant to ISO14001. Suppliers who are not certified must have a working plan to become compliant to ISO14001 available for review. The C-MAC QA Manager can admit a possible deviation.

4.2.3 Communication and updates regarding applicable Supplier certificates

Certified Suppliers must provide their initial and renewal certifications for all production locations defined with C-MAC within 10 days of receiving the certificates from their registrar. The Supplier shall immediately advise C-MAC in writing as to possible changes regarding its certification, particularly in case of expiry, cancellation or suspension.

The following E-mail address shall be used: Supplier-management@cmac.com

4.2.4 Audits

C-MAC Audits

ISO 9001 clause 8.4.2

The Supplier's Quality System can be evaluated by audits according C-MAC's internal procedure. The audits are based on the ISO 9001, IATF 16949, ISO13485 or AS9100 requirements.

The VDA6.3 manual for process audits is mostly used for the assessment of Suppliers.

The goal of these process audits is to check the conformity of the process with the requirements and specifications. The evaluation must consider what the resulting risks would be if the findings indicate that non-compliant products can be expected.

C-MAC customers who are certified according AS9100 can also audit Suppliers delivering materials used in avionic applications.

The C-MAC QA Manager decides whether an audit will take place on site. In principle this will be a process audit and takes place after a positive material qualification.

Suppliers that have been audited receive a quality status (approved Supplier or not) and are requested to put possible corrective actions in place arising from the audit findings.

C-MAC representatives are allowed by the Supplier to verify compliance with the agreed corrective actions.

Supplier Audits

ISO 9001 clause 9.2

The Supplier shall carry out internal planned audits for all the products delivered to C-MAC and all the processes linked with their development and production within a time period of 3 year to review effectiveness and efficiencies of applied methods, controls and processes.

Upon request of C-MAC the Supplier shall provide all audit results including documentation and updated action plans.

4.2.5 Feasibility study

ISO 9001 clause 8.2.3

With its quotation the Supplier shall submit a feasibility study, where the Supplier shall analyse its ability to meet all specified requirements for the offered contract product. The analysis shall be in regards to the project plan (timing), quantities, quality targets and technical, safety, environmental, statutory and regulatory requirements.

The analysis shall also consider potential risks, risk mitigation measures and lessons learned from previous (similar) projects/products.

Please note: The analysis of legal requirements is not limited to pre-defined C-MAC specifications. Each Supplier is responsible on its own to identify, analyse and comply with all necessary legal requirements (in process validation and series production).

4.2.6 Identification and traceability

ISO 9001 clause 8.5.2

The Supplier shall have an identification and traceability system, which considers its internal risk evaluation and ensures that the supplied products can be traced back to the manufacturing date, shift, equipment, tool number and the respective inspection/conformity results.

The Supplier shall ensure that in the event of a defect being discovered all other products which could be defective can be identified and blocked until subsequent measures have been agreed between the Supplier and C-MAC. These requirements must be cascaded down to the complete supply chain.

The Supplier shall clearly indicate his Lot Number and / or Date Code. Each packaging unit shall have a unique traceability code.

The Supplier has to deliver in respecting the FIFO-system.

4.3 Deliveries

4.3.1 Certificate of Conformity (CoC)

Where required as agreed between C-MAC and the Supplier, each delivery will be accompanied by a CoC. The Certificate of Conformity must contain the actual results confirming compliance with all identified requirements. The Supplier shall have a system capable of retrieving and submitting the requested Certificate of Conformity within 24 hours after C-MAC's request.

4.3.2 Incoming inspection of materials

Incoming goods inspection is restricted to a visual inspection of the transport packaging for external signs of damage, e.g. transport damage, a quantity check and an identity check based on the comparison of the delivery papers with the order documents. Insofar, the SUPPLIER waives its objection of belated notice of defects.

C-MAC is not obliged to undertake any further checks. Non-conformities of supplied Products may also be determined and found during processing (assembly) or Product field behaviour and can be claimed by C-MAC to the Supplier. In principle C-MAC uses a zero-defect acceptance level; a complete lot can be rejected in case of any defect detected during incoming inspection or in a later stage in the production or in the field.

4.3.3 Non-conforming products

ISO 9001 clause 8.7

The Products need to be free of any design, material or processing defects and must comply with the specifications and properties contractually agreed. In the event of a defective delivery, the Supplier will be informed without delay by means of a complaint or reject report. The complaint report will mention the dates by when a report is expected. In urgent circumstances these delays can be shortened by C-MAC.

The Supplier shall present interim reports on time on request. C-MAC has to be informed in writing in advance of any possible delays. Defective deliveries will influence the vendor rating quote of the Supplier.

The Supplier is asked to reply to every complaint within 10 working days using an 8D-format analysis report – see Appendix 2:

- 24 hours: Quick response - containment actions defined
- 48 hours: Containment actions fully implemented (D3 completed and sent to C-MAC)
- 10 working days: Root cause analysis done for occurrence and non-detection, permanent corrective actions defined and implemented (D4&5 sent to C-MAC)
- 20 working days: effectiveness of permanent corrective actions checked and recurrence prevented (D6&7 sent to C-MAC)

No Trouble Found (NTF) may trigger a review with C-MAC to conduct further analysis and/or tests and to apply additional measures.

C-MAC retains ownership rights of all products returned for analysis. If destructive testing is required to determine root causes, C-MAC shall be notified prior to testing by the Supplier. The destruction of any products returned for analysis without permission of C-MAC is not allowed. Products associated with a complaint, wherein responsibility of failure is indeterminate or under dispute, shall be returned to C-MAC for retention unless otherwise agreed.

Costs incurred in respect to defective Products deliveries will be charged to the Supplier.

If the defect is detected in C-MAC's incoming inspection or production, the delivered Products will be returned to the Supplier for credit at the original price and/or replacement. In the case of a replacement the Supplier will take the necessary actions to prevent a possible production stop at C-MAC. All costs following a possible production stop will be charged to the Supplier.

If the defect is detected on finished products, either in C-MAC or in the field, during the warranty period, all costs incurred will be charged to the Supplier.

Cost recovery will be communicated, if applicable with each claim through a cost breakdown. The cost recovery process will include but is not limited to contaminated stock at C-MAC plant, products in transit, assembly line downtime due to delivery or quality related issues, warranty returns, costs required to analyse and rectify the effects of a quality, warranty or delivery issue which result in a concern. Inspection costs, analysis costs, rectification costs, transit costs and costs to manage the implementation of a non-reversible corrective action may also be included. Level of cost recovery against concerns will be a significant factor in C-MAC sourcing decisions.

4.4 Deviations

ISO 9001 clause 8.7

The C-MAC QA department must be notified immediately if the Supplier is faced with major problems. Delivery of materials deviating from the technical requirements is only permitted with the written agreement of the C-MAC QA Manager.

For all changes mentioned below (PCN or PTN), the Supplier shall inform C-MAC before carrying out all changes in products and processes, both before and after SOP (Start of Production). The PCN or PTN shall be sent to the following e-mail address: Supplier-management@cmac.com. The Supplier can be charged for all requalification costs of the product.

4.5.1 Product/Process Change notification - PCN

The Supplier must provide information on any modifications to the material once qualified by C-MAC. This applies to:

- Any change to the raw materials (new manufacturer, recycled material etc.)
- The introduction of new production or processing methods
- Extensive tool modifications and / or repairs
- A change in the location of production (transfer)
- A change in the design
- The introduction of new, changed measurement and testing equipment, including testing software

These modifications must be notified at least 9 months in advance to C-MAC in writing. C-MAC will decide whether samples are to be provided including an up-to-date specification or data sheet and an Initial Sample Test Report.

4.5.2 Part Termination notification - PTN

In case of supplied customized products a lifetime supply (series and aftermarket requirements) must be ensured by the Supplier according the contractual agreements.

In case of unavoidable discontinuation of standard products, the Supplier shall send a PTN to C-MAC in writing minimum 24 months prior to such planned discontinuation.

All affected part numbers of C-MAC shall be identified with the PTN. The Supplier shall specify alternative products/solutions for replacement and determine necessary storage, handling and preservation methods in case the PTN leads to a last time buy by C-MAC.

4.6 Counterfeit parts

The Supplier need to prevent the use of counterfeit parts, prevention processes should consider:

- Application of a parts obsolescence monitoring program
- Requirements for assuring traceability of parts and components to their original or authorized manufacturers
- Verification and test methodologies to detect counterfeit parts
- Quarantine and reporting of suspect or detected counterfeit parts

4.7 Product Warranty

Products supplied to C-MAC must be covered by a warranty period as required by C-MAC's customers. The standard is a period of 36 months after receipt of the goods or it may be longer if required by C-MAC's customers.

4.8 Supplier monitoring – Vendor Rating

ISO 9001 clause 8.4.2

The Supplier's delivery performance is evaluated on a periodical basis. The evaluation criteria include order confirmation, on-time delivery, quality performance and certification status.

The Supplier shall define an improvement plan if the vendor rating is below target.

4.9 C-MAC requirements

C-MAC requirements are written in these Supplier Quality Assurance guidelines (CK0001), the code of conduct for Suppliers (CA1011), material specifications and control specifications. By accepting an order the Supplier, accepts the C-MAC requirements as mentioned in the latest edition of the C-MAC Supplier Quality Assurance guidelines (CK0001) and the C-MAC Code of Conduct for Suppliers (CA1011).

The Products ordered, shall be delivered according to the latest edition of the Material and Control Specification as mentioned on the Purchase Order.

A general information questionnaire (F02-01) shall be completed whenever changes occur or for each new Supplier to C-MAC.

The e-mail address Supplier-management@cmac.com shall be used for the following:

- Communication and updates regarding applicable supplier certificates
- Request of C-MAC requirements (CK0001 and CA1011)
- Request of material and control specifications
- Submission of all change notifications (PCN or PTN)
- Notification of premium freight incidents (KF1119)
- Submission of Initial sample test report (ISTR)
- Submission of the general information questionnaire (F02-01)

The following documents can be downloaded from the C-MAC Website www.cmac.com

- CK0001: Supplier quality assurance guidelines
- CA1011: Code of conduct for suppliers
- KF1119: Premium freight incidents
- F02-01: General information questionnaire

5. ADDITIONAL REQUIREMENTS

These requirements are only applicable to C-MAC's Suppliers delivering materials used for automotive and/or for aviation, space and defence applications.

In order to ensure the quality of the delivered materials, C-MAC expects from these Suppliers:

- To check the completeness of the necessary documents
- To obtain the necessary information on the processing of the materials to be delivered
- To use Design and Process FMEA's
- To use Process Control Plans
- To use Production Plans
- To use SPC on critical parameters
- To perform MSA
- To report premium freight incidents
- To submit an initial sample test report
- To prepare contingency plans and test them for effectiveness

5.1 FMEA

IATF16949 clause 8.3.5.1-8.3.5.2

The Supplier shall carry out preventive risk analysis (FMEA) for all products delivered to C-MAC and the processes linked with these and update the FMEA whenever deviations of product and/or process quality occur. Points evaluated as critical must be improved in the short-term by means of suitable actions to enable specifications, properties and product safety as well as capable manufacturing to be guaranteed. To implement the actions, deadlines and responsible persons have to be named and proved if required.

5.2 Control plan

IATF16949 clause 8.5.1.1

Within the control plan the results of the FMEA experience with similar processes and products as well as the utilization of methods of improvement have to be considered. Based on the control plan, the Supplier assures compliance with all the routine tests, taking the agreed measurement and inspection equipment as well as the sampling scheme into consideration.

5.3 MSA

IATF16949 clause 7.1.5.1.1

Before the delivery of serial production products, the Supplier shall evaluate the capability of the test equipment utilized. A gage R&R study (Repeatability & Reproducibility) shall be performed.

The rules as defined in Automotive Industry Action Group (AIAG) MSA manual or as documented in VDA Volume 5 MSA manual should be applied.

5.4 Premium Freight incidents

IATF16949 clause 8.4.2.4

The Supplier shall complete the document KF1119 whenever a premium freight incident occurs and send it to C-MAC. The use of this document is mentioned on every purchase order and should be requested to C-MAC using the following e-mail address: Supplier-management@cmac.com or can also be downloaded from the C-MAC website.

5.5 Initial Sample Evaluation – Initial Sample Test Report (ISTR)

IATF16949 clause 8.3.4.4

For product release, the Supplier is obliged to submit initial samples to C-MAC before the start of serial production; these samples must comply with all the specifications and properties specified in the contract.

Unless agreed otherwise, this proof must be brought on at least 5 parts. This allows any deviations to be corrected in good time, thereby preventing systematic errors in the serial production.

An initial sample evaluation has to take place for all new material used for automotive/medical/avionics applications and to all critical and/or non-standard materials.

It does not take place in case of standard electronic components (capacitors, resistors, diodes, transistors).

In the case an Initial Sample Test Report is required; the content will be agreed between the Supplier and the responsible C-MAC Quality Engineer. For materials used in applications for German automotive customers the ISTR form KF0599 must be used – see Appendix 1 (PPF requirements as referenced in the VDA Volume 2 manual).

In the initial sample report the capability for special characteristics must be proven. Target is a Pp/pk of 2 and Cp/pk of 1,67.

5.6 Contingency plans

IATF16949 clause 6.1.2.3

The Supplier is required to prepare contingency plans containing at a minimum the elements based on the IATF 16949 requirements including potential cyber-attack on IT systems to reasonably protect C-MAC's supply of contract products in the event of an emergency.

The plans shall include a risk evaluation, potential impact to C-MAC and a notification process to C-MAC. The plans shall be periodically (at least annually) reviewed and tested for effectiveness.

Upon request of C-MAC the Supplier shall provide the contingency plans and the evidence that the plans have been reviewed and tested for effectiveness.

6. APPENDIXES

Appendix 1 – Cover Page ISTR

Appendix 2 – 8D Problem solving technique

7. REVISION HISTORY

ED	DATE	DESCRIPTION MODIFICATIONS
00	24-03-93	First edition.
01	23-02-01	Complete revision.
02	04-11-02	Up-dated with ISO/TS 16949:2002 requirements.
03	12-12-03	5.8 adapted.
04	15-07-04	5.5 adapted.
05	28-04-08	Zero defect quality – ISO/TS and ISO14001 requirements updated.
06	01-04-14	5.4.3 and 5.6.3 adapted
07	21-08-17	5.4.4 added Acceptability of printed boards
08	22-02-19	5.3 and 5.8 modified, 5.6.4 added Premium Freight incidents, 5.9 added Counterfeit parts
09	15-01-20	Complete revision: Front page, logo and lay-out changed; Reference to standards (IATF16949/ISO9001/AS9100) added, Content added: 1.3 Validity 4.2.2 Environmental Management System requirements 4.2.3 Communication and updates regarding applicable Supplier certificates 4.2.4 Supplier audits 4.2.5 Feasibility study 4.2.6 Identification and traceability 4.3.3 Non-conforming products 4.5.2 Part termination notification 4.9 C-MAC requirements 5.1 FMEA 5.2 Control plan 5.3 MSA 5.6 Contingency plans

APPENDIX 1



Sender

Recipient

C-MAC ELECTROMAG BVBA
 Industriepark Klein Frankrijk
 Industriëlestraat 4
 B-9600 RONSE
 BELGIUM

Production Process and Product Release

Document with Long Term Archiving

Submission Level: _____

Samples

- New Part
- Product Change (Specification Change)
- Production Relocation
- Change of Production Processes
- Suspended for longer than 12 months
- Tool Change / Correction
- Change of purchased parts
- Change of supplier
- Other

Resampling

Samples

Report other samples

Equipment / Inspection		
<input type="checkbox"/> 01 Dimensional Inspection	<input type="checkbox"/> 09 EMC - Test - Prüfung	<input type="checkbox"/> 17 Test equipment list
<input type="checkbox"/> 02 Functional Test	<input type="checkbox"/> 10 Reliability Tests	<input type="checkbox"/> 18 Measurement system Analysis
<input type="checkbox"/> 03 Material Test	<input type="checkbox"/> 11 Design-FMEA	<input type="checkbox"/> 19 EU-Material Safety Datasheet
<input type="checkbox"/> 04 Haptic Test	<input type="checkbox"/> 12 Construction Release	<input type="checkbox"/> 20 Material Datasheet/IMDS
<input type="checkbox"/> 05 Acoustic Test	<input type="checkbox"/> 13 Process-FMEA	<input type="checkbox"/> 21 Transport / Packaging
<input type="checkbox"/> 06 Odor Test	<input type="checkbox"/> 14 Process Flow Chart	<input type="checkbox"/> 22 Certificate
<input type="checkbox"/> 07 Appearance Examination	<input type="checkbox"/> 15 Production Control Plan	<input type="checkbox"/> 23 Process Acceptance
<input type="checkbox"/> 08 Surface Test	<input type="checkbox"/> 16 Process Capability	<input type="checkbox"/> 24 Others
Supplier/Production site:		Customer: C-Mac Electromag BVBA
ID / DUNS-Code:		ID:
Report-Nr.	Index:	Report-Nr.
Description:		Description:
Partnumber:		Partnumber:
Drawing Number:		Drawing number:
Status/Date:		Status / Date:
Change Index:		Change Index:
Delivery-Nr./date:		Incoming Goods-Nr./datum:
Amount:		Order-Nr./-datum:
Batch Number:		Unloading station:
Sample Weight:		
Confirmation Supplier		
The supplier confirms that the sampling has been carried out in accordance with VDA Volume 2, Chapter 4		
<input type="checkbox"/> The IMDS Record is created under IMDS ID number: _____		
Name:		Remarks:
Department: Product Engineering		
Telephone:		
Fax:		
E-mail:		
Date / Signature		
Customer Decision		According to appendix
	Total	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24
Released	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Released with conditions, resampling required	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Rejected, resampling required	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Deviation Approval Number:	Valid Till:	Number of Pieces:
When returning: delivery note / date		Deadline for Re-sampling:
Name:		Remarks:
Department:		
Telephone:		
Fax:		
E-Mail:		
Date / Signature		

APPENDIX 2 – 8D Problem Solving Technique

- D1 – Form the Team** This is the first step of the 8D process and the first part of the 8D report. This step defines the composition of the 8D team. The team should be cross-functional and should include the process owner, a member from QA, and others who will be involved in the containment, analysis, correction and prevention of the problem. The names of the members as well as their positions in the company organization must be enumerated in this part of the report.
- D2 – Describe the Problem** This step involves a detailed assessment of the problem highlighted by the customer. Under this step, the 8D report provides background information and a clear picture of the problem being highlighted by the customer. It should include the following details: a) the identity of the customer; b) a description of the customer application; c) device information (device, package, lot #, date code, etc.); d) when the problem was encountered; e) where the problem was encountered; f) a specific description of the failure mode; and g) failure rate.
- D3 – Contain the Problem** This discipline explains the extent of the problem and bounds it. Based on initial problem investigation, all lots that are potentially affected by the same problem must be identified and their locations pinpointed. If possible, specific lot numbers and/or date codes of potentially affected lots shall be enumerated in this portion of the report. Lots that are still in the factory must be put on hold until their reliability has been properly assessed. They must only be released if the lots are either proven to be clean or the failures may be effectively screened. If the problem has an extremely high reliability risk and the application of the product is critical (e.g., failure of the product is life-threatening), lots already in the field may need to be recalled. However, recall must only be done under extreme cases wherein the impact of reliability risk is greater than the impact of recall.
- D4 – Identify the Root Cause** This step consists of performing the failure analysis and investigation needed to determine the root cause of the problem. The corresponding portion in the 8D report documents the details of the root cause analysis conducted. A detailed description of the actual failure mechanism must be given, to show that the failure has been fully understood. The root cause is then presented, showing how it triggered the failure mechanism identified. All events emanating from the root cause and leading to the failure mechanism must be included in the explanation. As much evidence as possible must be provided to show that the root cause is the real culprit behind the problem. The root cause must also be correctively actionable. Techniques such as 5 WHY and Ishikawa should be used to identify the root cause
- D5 – Formulate and Verify the Corrective Actions** This next discipline identifies all possible corrective actions to address the root cause of the problem. The owners of the corrective actions and the target dates of completion shall be enumerated in this section of the report. It is also suggested that the rationale behind each corrective action be explained in relation to the root cause. Sometimes, identification of the best corrective action(s) for the root cause requires preliminary evaluations and studies before they can be implemented. This is referred to as 'verification of the corrective actions.' This must be done especially in cases wherein the affected volume is very large, since an incorrect solution deployed over a large inventory will result in wastage of crucial time and money.

- D6 – Correct the Problem and Confirm the Effects** The sixth discipline of the 8D process involves the actual implementation of the identified corrective actions, details of which must be documented in the corresponding portion of the 8D report. The dates of completion and owners of the corrective actions must be shown in this section. Data showing that the corrective actions are effective in preventing the root cause of the problem must be presented. Any deficiency in the effectiveness of the corrective actions must be addressed by improvements in or additions of corrective actions.
- D7 – Prevent the Problem** This next discipline should not be confused with 'correcting' the problem. Prevention of the problem entails the identification of devices or packages that are similarly vulnerable to the same problem highlighted by the customer, even if not affected under the current situation. Actions necessary to prevent these from being affected by a similar problem in the future are called preventive actions. All preventive actions must be enumerated, along with their owners and target dates of completion. An important aspect of this discipline is the standardization and deployment of corrective actions or process improvements to all products that may possibly be subjected to the same issue.
- D8 – Congratulate the Team** The last step of the 8D process and the last portion of the 8D report consists of an acknowledgement from management of the good work done by 8D team. Approvals for the 8D report are also shown in this last discipline.