



70068066 TDT 6395-10D

Factory inspection report according to
MID directive 2004/22/EC, Annex D
made by Electromagnetica SA,

Arnhem, 27 December 2010

Inspector Phoebe Wong
KEMA T&D Testing Services
Calibration & Metering

By order of Electromagnetica SA, Romania

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Summary

Overall conclusion

The overall conclusion of the inspection is indicated below:

- | | | | |
|----|---|--|-------------------------------------|
| 1. | No unsatisfactory finding(s) | Grant or continue certification. | <input checked="" type="checkbox"/> |
| 2. | Unsatisfactory finding(s)
(major (A) or/and minor (B)) | Manufacturer shall prove the
implementation of corrective action(s). | <input type="checkbox"/> |
| | | In case of a follow-up audit:
Within 1 week (category A) for major findings
and within 2 months (category B) for minor
findings. | |
| 3. | Critical unsatisfactory
finding(s) | Certification refused/suspended and
repeated factory inspection required after
the manufacturer has confirmed
implementation of corrective action(s). | <input type="checkbox"/> |

A list of findings is given on the next page.

Findings, including taken corrective action

Paragraph	Major (A) / Minor (B)	Inspector's points taken including corrective action from the manufacturer
2.1	Minor (B)	<p>The incoming inspector inspected the integrity of and marking on reels of SMD components. This is inconsistent with the inspection criteria (i.e. integrity body component and conformity mark on SMD component) as defined in Control Plan 31 for RS80941 C[X] [X] [X] [X].</p> <p>Evidence provided by Manufacturer: Control Plan PC-31 point 10.2-10.5 had been revised to ensure that the inspection methods of SMD components to be more consistent with the inspection criteria. New inspection methods had been implemented in incoming inspections. Control Plan PC-31 and records of FISA MAS SMD comp were reviewed and verified.</p> <p>This finding is closed.</p>
2.1	Minor (B)	<p>Results of incoming inspection were partly recorded such that two data points were recorded for a sample of 315 capacitors.</p> <p>Evidence provided by Manufacturer: The inspection records of incoming inspection of SMD components (capacitors) had been revised in Control Plan PC-31 point 10.6; FISA MAS- set borne .doc and Tabel masuratori anexa la Fisa masuratori Set borne .xls. The records of FISA MAS- set borne .doc and Tabel masuratori anexa la Fisa masuratori Set borne .xls were reviewed and verified.</p> <p>This finding is closed.</p>
2.1	Minor (B)	<p>There is no record of the inspection for integrated circuits at incoming inspection as required in Control Plan 31 for RS80941 C[X] [X] [X].</p> <p>Evidence provided by Manufacturer: The inspection method for integrated circuits had been defined in Control Plan PC-31 point 10.3. Control Plan PC-31 and FISA MAS C.I.doc were reviewed and verified.</p> <p>This finding is closed.</p>

2.2	Minor (B)	<p>There is no record for verification of certificate of conformance at incoming inspection including verification of the product, quantity of items covered, the specification to which the products conform, the production date and supplier authorization.</p>
<p>Evidence provided by Manufacturer: The method for verification of certificate of conformance at incoming inspection had been defined in Control Plan PC-31 point 10.2-10.6. FISA MAS- set borne .doc and Tabel masuratori anexa la Fisa masuratori Set borne .xls , FISA MAS C.I.doc , FISA MAS CABLAJE.doc”, “FISA MAS cutie.doc”, “FISA MAS NUMARATOR.doc”, “FISA MAS POLICARBONAT.doc”, “FISA MAS THT comp.doc” were reviewed and verified.</p>		
<p>This finding is closed.</p>		
<hr/>		
3.3	Minor (B)	<p>According to PL-105 Plantare Automata TIP S.M.T. A Componentelor TIP S.M.D. Edition 3, the solder paste used in printing machine should be stored below -5°C. However, the solder paste was stored in normal refrigerators that the temperature is +4°C. There is no temperature monitoring record for the condition for storage and before use.</p>
<p>Evidence provided by Manufacturer: The technical specification for the solder paste storage at 0-5°C in Procedure PL-105 “Plantare automata SMT a componentelor tip SMD” Chapter 6.5.2 point 4. Procedure PL-105 “Plantare automata SMT a componentelor tip SMD” were reviewed and verified.</p>		
<p>This finding is closed.</p>		
<hr/>		
3.3	Minor (B)	<p>During the factory audit, it is observed that the temperature reading for GTH1150 Digital Thermometer is inconsistent with the temperature reading on Digital Solomon soldering irons. The observed temperature difference was greater than 20 degree C.</p>
<p>Evidence provided by Manufacturer: The method of verification of temperature of soldering irons and the information regarding the working temperature to be used for each type of soldering process had been defined in Procedure PL-026 LIPIREA CU FLUDOR CU SAU FARA Pb FOLOSIND CIOCAN ELECTRIC DE LIPIT SAU STATII DE COSITORIT TERMOSTATATE . Procedure PL-026 imposes that each change on the soldering irons (including soldering pin) has to be followed by a new verification made by the Metrological Laboratory. “PL-026-R4-actualiz 3.DOC” were reviewed and verified.</p>		
<p>This finding is closed.</p>		

3.4	Minor (B)	There is no evidence to show that the thickness of solder paste on PCB is being monitored by visual inspector per PL-105 Plantare Automata TIP S.M.T. A Componentelor TIP S.M.D. Edition 3.
<p>Evidence provided by Manufacturer: PL-105 Plantare Automata TIP S.M.T. A Componentelor TIP S.M.D. Chapter 6.5.2 point 5 and the Working Technology Instruction ITL 328537-1 had been revised and now specified that “the acceptance criteria of the visual inspection consist in checking the uniformity and completeness of the deposited paste layer on pads. The records of first good part will be documented in FCC-PS 084 FISA CHESTIONAR DE CONTROL PENTRU PROCESUL SPECIAL.</p>		
<p>This finding is closed.</p>		
3.5	Minor (B)	Currently, the manufacturer monitored the rejected for purchased parts, from assembly line and total rejects. The trends of test results of other inspections (visual inspection, functional check, calibration, register checking and final verification of meters) are not monitored and reported to the production and management authorities.
<p>Evidence provided by Manufacturer: The trends of the test results and inspections in all meter production stages are collected and reviewed in weekly rejects data. videnta trend defecte pe faze tehnologice 2011.xls were reviewed and verified.</p>		
<p>This finding is closed.</p>		
4.3	Minor (B)	The inspection method and acceptance criteria for verification of mechanical register are not clearly defined in ITL-80941 Single Phase Electronic Watt-hour Meter RS80941CXXXX.
<p>Evidence provided by Manufacturer: working technology instruction had been revised to include the inspection method of the mechanical register. ITL 80 941_CXXXX_revb.doc were reviewed and verified.</p>		
<p>This finding is closed.</p>		

6.1	Minor (B)	The sensor used to sense the pulses from the calibrated source in calibration (initial adjustment) system is not verified on a periodic basis.
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Evidence provided by Manufacturer:

The annual maintenance program performed by our Maintenance Department. The scheduled technical inspection will be made at each 6 months and the list of operations to be performed was updated by introducing the overall accuracy check for the system by using 20 meters previously measured using the Final Verification System ZVE3-22 cl.0.05 Serial Number 65083-0.1.1 in the Metrological Laboratory.

This finding is closed.

9.1	Major (A)	There is no evidence that a declaration of conformity is drawn up for each instrument model (or batch or consignment) and shall be kept at the disposal of the national authorities for 10 years after the last instrument has been manufactured.
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Evidence provided by Manufacturer:

Electromagnetica updated versions of the procedures for documents and records control "PG-S-01 Controlul documentelor.doc" and "PG-S-02-Controlul inregistrarilor.doc", in which Electromagnetica has added specific chapters concerning the meters, certified according European Directive 2004/22/CE. For this type of products, all documentation of the Quality Management Integrated System will be kept at the disposal of the national authorities for 10 years after the last instrument has been manufactured. The documents covered by this chapter is also listed in the procedures chapter 6.10 and Annex 1 point 14 in PG-S-01, chapter 6.5 and Annex 1 point 32 in PG-S-02. "PG-S-01 Controlul documentelor.doc" and "PG-S-02-Controlul inregistrarilor.doc" were reviewed and verified.

This finding is closed.

9.2	Major (A)	<p>There is no evidence that the manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities:</p> <ul style="list-style-type: none">- the documentation concerning the quality system- any decisions and notifications of the notified body concerning any intended changes or modifications of the quality system- the decisions and reports of the periodic audits- the decisions and reports of any unexpected visit to the manufacturer <p>Evidence provided by Manufacturer: Electromagnetica updated versions of the procedures for documents and records control "PG-S-01 Controlul documentelor.doc" and "PG-S-02-Controlul inregistrarilor.doc", in which Electromagnetica has added specific chapters concerning the meters, certified according European Directive 2004/22/CE. For this type of products, all documentation of the Quality Management Integrated System will be kept at the disposal of the national authorities for 10 years after the last instrument has been manufactured. The documents covered by this chapter is also listed in the procedures chapter 6.10 and Annex1 point 14 in PG-S-01, chapter 6.5 and Annex 1 point 32 in PG-S-02. "PG-S-01 Controlul documentelor.doc" and "PG-S-02-Controlul inregistrarilor.doc" were reviewed and verified.</p> <p>This finding is closed.</p>
15.6	Major (A)	<p>There is no documented procedure ensuring that the Certification Body has accepted changes to the construction of certified products, before any implementation into a certified product.</p> <p>Evidence provided by Manufacturer: Procedure PL-053 MODALITATEA DE EFECTUARE A MODIFICĂRILOR ÎN DOCUMENTAȚIA CONSTRUCTIVĂ, TEHNOLOGICĂ, DE CONTROL, DE PREZENTARE, UTILIZARE ȘI SERVICE had been revised to show how the changes in the design, technological, control, presentation and service documentation are to be made, which now contains on chapter 6.6. The obligation of informing the notified body about the content of the Advice of changes together with the new product documentation. The Advice of changes will become active only after approved by the notified body.</p> <p>This finding is closed.</p>

16.1	Minor (B)	Appropriate environmental conditions were not specified for storage and testing in incoming store, incoming inspection area, calibration (initial adjustment of register), and finished goods store.
<p>Evidence provided by Manufacturer: Environment conditions required for components, parts, subassemblies and final products during storage, fabrication and delivery are defined in code PL-242 and Annexes 1-10, which contain details about environment conditions and monitoring for each working place. Code PL-242 and Annexes 1 -10 were reviewed and verified.</p>		
<p>This finding is closed.</p>		
<hr/>		
16..1	Minor (B)	There is no evidence that the production employees have received ESD training. During the factory, it was noted that some production operators/inspectors wore the ESD wrist strip on the top of their non-ESD gloves.
<p>Evidence provided by Manufacturer: A training documentation was elaborated and is attached in file "Instruire privind Descarcarea Electrostatica (ESD).pptx" and all personnel involved in the meter assembly area was trained on January 6, 2011.</p>		
<p>This finding is closed.</p>		
<hr/>		
16.1	Minor (B)	There is no ESD policy in energy meter production.
<p>Evidence provided by Manufacturer: The ESD policy and ESD training are documented in PL-243 CERINTE ESD. (DESCARCARE ELECTROSTATICA). A training documentation was elaborated and is attached in file "Instruire privind Descarcarea Electrostatica (ESD).pptx" and all personnel involved in the meter assembly area was trained on January 6, 2011. New ESD materials such as wrist strips and AR-CA: CheckE Calibrator for AR & E, Conductive overshoe ESD and ground connection had been purchased.</p>		
<p>Evidence provided by Electromagnetica SA on January 20, 2011: Electromagenticia have acquired the second wrist and footwear tester to be mounted on the second entry in the SMD assembly room. So we have now two such devices, one is the existent Kwikchek 23-5507 and the second is the new AR-8E device. One of these will be used for daily check of the personnel equipment in the SMD assembly line area. "AR-8.jpg", "AR-CAL.CHECK-E.jpg", "AR-8.pdf", "AR_Cal.Check.pdf", "AR-8 Certificate.pdf" and "AR-8E-Invoice.pdf" were reviewed and verified.</p>		
<p>This finding is closed.</p>		

16.1	Minor (B)	<p>There is no record of periodic monitoring/audit of ESD status in production area, for example, ESD mat, workstation, rack, chair and grounding.</p> <p>Evidence provided by Manufacturer: New ESD materials such as wrist strips and AR-CA: CheckE Calibrator for AR & E, Conductive overshoe ESD and ground connection had been purchased.</p> <p>Evidence provided by Electromagnetica SA on January 20, 2011: Electromagnetica have acquired the second wrist and footwear tester to be mounted on the second entry in the SMD assembly room. So we have now two such devices, one is the existent Kwikchek 23-5507 and the second is the new AR-8E device. One of these will be used for daily check of the personnel equipment in the SMD assembly line area. "AR-8.jpg", "AR-CAL.CHECK-E.jpg", "AR-8.pdf", "AR_Cal.Check.pdf", "AR-8 Certificate.pdf" and "AR-8E-Invoice.pdf" were reviewed and verified.</p> <p>This finding is closed.</p>
16.2	Major (A)	<p>Per PLL01 Verificare Controare Statice Monofazate Edition 1 , the final verification of meter should be performed on temperature and relative humidity is $23^{\circ}\text{C}\pm 2^{\circ}\text{C}$ and 40%-70% respectively. During the factory audit, the employees are performing final verification in relative humidity was around 30% that was inconsistent with SR EN 50470-3 standard and PLL01 Verificare Controare Statice Monofazate Edition 1.</p> <p>Evidence provided by Manufacturer: In order to comply with the humidity conditions when we will start again the production, we have already ordered 4 large capacity humidifiers of type PurLine Hydro 60 to be placed in the production area.</p> <p>Electromagnetica have received 4 pieces of large capacity humidifiers of type PurLine Hydro 60. After installing the first one in the final verification room, when set to 50% humidity, it takes around one hour to reach this value, after that it starts again very rarely (few hours) only for adjusting the humidity according to the preset value. We are working now to install the remaining 3 pieces. HYDRO60_1.jpg", "HYDRO60_2.jpg", "HYDRO60_EN.pdf", "Hydro60E_Invoice.pdf" were reviewed and verified.</p> <p>This finding is closed.</p>

Inspector's evaluation (informative)

The quality management system documentation of Electromagnetica S.A. such as quality policy, quality manual (MEM EM Manualul Sistemului Integrat de Management edition 10.2), quality management system procedures and manufacturing work instruction and related records were reviewed. The parts lists of Single Phase Static Meter for Active Energy (R80941 Cxxxx Nomenclator Contor Static Monofazat de Energie Electrica Activa Edition C), relevant process flow-chart, control plan, work instructions of Electronic single-phase two-wire energy meter Direct connected RS80941 Cxxxx were controlled by PG-S-01 Document Control Procedure (Controlul documentelor). The change control of part list is managed per PL-053 Modalitatea de efectuare a modificarilor in documetatia constructiva, tehnologica, de prezentare, utilizau si Service edition 3.1/10.08. All quality inspection and records are controlled and retained per PG-S-02 Control of Record (Controlul Inregistrarilor Edition 09.2. All required incoming inspection, in-process inspections and final testing were performed during the factory inspection and the detailed information of reviewed inspections were documented in Annex B.

External accredited laboratories calibrated the testing and monitoring equipment. The calibration records indicated that all calibration is traceable to an IAF accredited institute or equivalent. The calibration statuses for the following testing and monitoring equipment were reviewed: #0590454 Keithley 2002 Digital Multimeter (cal. due 06/10/2010) #445034 Caliper 6090 (cal. due 03/2011) #49362 01.01-849/2010 95 Cale Plan Paralele L=0.5mm...100mm (cal. due 25/06/2011); f.s18/4541 Pivan Temperature Control 574/A (cal. due 06/2011); Seial # 08/1997 GTH1150 Digital Thermometer (cal. due 31/01/2011); #884413 SL-30 Solomom (cal. due 01/2011); #507586 Model RM-10-01 Metronic Single Phase Energy Meter (cal. due 09/06/2011); #506340 Model RM-10-01 Metronic Single Phase Energy Meter (cal. due 14/04/2011); 10085316 RH/Temperature Monitor (cal. due 12/2011) The final verification bench for energy meters was calibrated once a year. Single-phase Energy Meter Calibration Equipment (serial # 65083-0.1.1 ZVE 3-22 cl. 0.05 (cal. due 21/07/2011) 0746 DKD-K-44 DJ-101 (serial no.: 04120210) was calibrated on the July 21, 2010 and #38605 SRS121.3 Stationary Reference Standard (cal. due 21/07/2011);

The internal audit, customer complaints and control of non-conforming products are performed per PG-S-03 Internal Audit (Audit Intern edition 10.2), PL-066 Control of Customer Complaint Controlul si Analiza Reclamatiiilor Clientilor Edition 2) and PG-S-04 Control of nonconforming products (Controlul Neconformitatilor Edition 2) respectively. The records of internal audit report, customer complaints, and weekly quality data reports were reviewed. The All findings identified during this factory inspection were documented in the findings section of this report. The manufacturers (Electromagnetica S.A.) are required to propose and resolve the identified findings within timeline.

1 Introduction

The inspection was carried out at the site listed below to verify if the quality of the production process is in accordance with Annex D of the MID directive 2004/22/EC.
Time in the factory was 12 hours.

Data related to the inspection:

Date of inspection : December 27, 2010

Applicant : Electromagnetica SA
Contact person : Mr. Ionel Fratila
Address : Calea Rahovei 266-268 Sector 5, 050912, Bucuresti
Country : Romania

Manufacturer : Electromagnetica SA
Address : Calea Rahovei 266-268 Sector 5, 050912, Bucuresti
Country : Romania

Record the names and position held of the main people involved in the inspection:

Name	Position
Traian Stancu	: Deputy General Director
Stefan Anton	Quality Director
Ionel Fratila	Head of Design Department
Liviu Caltea	Meter Designer
Silvia Munteanu	Quality Assurance Inspector
Lyana Marta	Engineering Department
Florin Iliescu	Head of moulding injection workshop
Valeriu Ciocaniu	Head of Production Assembly Department
Luminița Petre	Head of Sales Department
Dumitru Parpala	Head of Metrological Laboratory
Zefirina Bardac	Incoming Receiving Inspector
Mihaela Pascu	Head of Incoming Store
Rajen Saroj	Maintenance Department
Aurel Musat	Head of meter assembly workshop

The EC- type examination certificates applicable to this factory inspection:

Report No.	Type
700680066-TDT-6395-10	CSM-Cxxxx, Electromechanical Electronic single-phase two-wire class 1 or energy meter Direct connected class B

2 Goods Inwards Inspection

2.1	Are materials, components and sub-assemblies product verified by the manufacturer as complying with appropriate specification.	yes	no	NA
2.2	If the manufacturer relies on Certificates of Conformity, do they clearly identify the product, quantity of items covered, the specification to which the products conform, the production date and are they signed or stamped by a person authorised by the supplier?	yes	no	NA

3 Production Line Inspection and Routine Tests

3.1	Are the Quality Assurance and Assembly Personnel adequately briefed on their duties?	yes	no	NA
3.2	Do they have readily available up-to-date documents, assembly and test instructions, photographs, drawings or samples? Give details of all test and inspections performed by the manufacturer and enter in the table Test Data Sheet (annex B)	yes	no	NA
3.3	Is the temperature of solderings baths controlled and monitored.	yes	no	NA
3.4	Is there a documented procedure to ensure that all products will be tested or inspected according to the manufacturer's requirements?	yes	no	NA
3.5	Are trends of test results monitored and reported to the production and management authorities?	yes	no	NA
3.6	Are repaired and reworked products re-inspected in accordance with documented procedures?	yes	no	NA

4 Functional Check on Test and Measuring Equipment

4.1	Did the inspector witness the correct functioning of the equipment even if certified products were not in production?	yes	no	NA
4.2	Is a functional check conducted with intervals which will allow previous production to be retested if incorrect functioning is detected?	yes	no	NA
4.3	Is there a documented procedure for the functional checks?	yes	no	NA
4.4	Is there a documented procedure describing actions to be taken if a functional check is found to be unsatisfactory?	yes	no	NA

5 Production During Visit

- 5.1 Identify type number and any certification mark that appeared on products seen in production at the time of the visit. If no certified products were seen, indicate what kind of products were manufactured at the time of visit.
The manufacturing process should nevertheless be examined.

Electromagnetica CSM CFBEF 50Hz 230V 0.25-5 (60)A 1600 Imp/KWh with CE M10 0344 and 6395-10 Mark

6 Calibration of Test and Measuring Equipment

- | | | | | |
|-----|---|-----|----|----|
| 6.1 | Is test and measuring equipment calibrated? | yes | no | NA |
| 6.2 | Is the equipment provided with a label or similar method indicating the next "calibration due" date? | yes | no | NA |
| 6.3 | Do the calibration records indicate that calibration is traceable to an IAF accredited institute?
Provide details for 6.1 – 6.3 for at least one measuring equipment on the Inspector's Evaluation Sheet | yes | no | NA |

7 Handling and Storage

- | | | | | |
|-----|--|-----|----|----|
| 7.1 | Are the finished products stored and handled in such a way as to ensure that they will continue to comply with the applicable standards? | yes | no | NA |
|-----|--|-----|----|----|

8 Product Verification Tests (PVT)

8.1	Are required PVT conducted? Describe which tests are conducted and at what sampling rate on Test Data Sheet (Annex B). If conducted at a location other than the manufacturers premises, then specify on the Inspectors evaluation Sheet page where performed.	yes	no	NA
8.2	Is appropriate equipment required for conducting tests available?	yes	no	NA
8.3	Are the tests conducted in accordance with documented procedures? Specify on the Test Data Sheet (Annex B).	yes	no	NA
8.4	Is there a documented procedure describing actions to be taken if PVT are found to be unsatisfactory?	yes	no	NA

9 Records

9.1	A declaration of conformity is drawn up for each instrument model (or batch or consignment) and shall be kept at the disposal of the national authorities for 10 years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.	yes	no	NA
9.2	The manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities: <ul style="list-style-type: none"> - the documentation concerning the quality system - any decisions and notifications of the notified body concerning any intended changes or modifications of the quality system - the decisions and reports of the periodic audits - the decisions and reports of any unexpected visit to the manufacturer 	yes	no	NA
9.3	Are the records listed below maintained and satisfactory?	yes	no	NA
9.3.1	Incoming inspection records.	yes	no	NA
9.3.2	Test records of the routine tests.	yes	no	NA
9.3.3	Test records of product verification tests	yes	no	NA
9.3.4	Records of results of functioning checks of test and measuring equipment.	yes	no	NA
9.3.5	Records of calibration of test and measuring equipment. If records were countersigned, provide details below. If not, explain below why not.	yes	no	NA

10 Corrective Actions

- | | | | | |
|------|--|-----|----|----|
| 10.1 | If there were any unsatisfactory findings entered in the previous inspection report, have these been corrected?
Provide details regarding the corrective actions that have been taken . | yes | no | NA |
|------|--|-----|----|----|

11 Quality System

- | | | | | |
|------|--|-----|----|----|
| 11.1 | If the manufacturer has a Quality System certified or assessed by an accredited Body,
provide details of QMS standard, scope, name of certification body and certificate expiry date. | yes | no | NA |
|------|--|-----|----|----|

SR EN ISO 9001:2008; EN ISO 9001:2008 Certificate no:005

Certification Scope:

Products:

Design, development, manufacturing, marketing and service of telecommunication terminals and equipment, automotive subassemblies and relays, automation elements and equipment, power supply units, equipment intended for electric power distribution and measurement, metal structures and containers, injection moulds and plastic deformation tools.

Services:

Electric energy production and suppl; installation, commissioning, technical assistance and service for own products, design and execution of inside electrical installation for civil and industrial constructions, air and underground connections at 0,4 kV rated voltage; design and execution of air/underground power lines and transforming stations at rated voltages ranging from 0,4 to 20kV.

The Quality Management System of Electromagnetica S.A. is certified by Accredited Body for Management Systems (AEROQ). The certificate will be expired on May 30, 2013.

12 Audits of the Quality System

- | | | | | |
|------|---|-----|----|----|
| 12.1 | Does the manufacturer regularly check that all documented procedures as required by the Certification Body(ies) are followed? | yes | no | NA |
| 12.2 | Are records regarding results and actions taken available? | yes | no | NA |
| 12.3 | Is the personnel carrying out above required checks appropriately trained and independent of the process being audited? | yes | no | NA |

13 Non-Conforming Products

- | | | | | |
|------|---|-----|----|----|
| 13.1 | Are non-conforming products clearly identified and/or segregated to prevent unauthorised use? | yes | no | NA |
|------|---|-----|----|----|

- | | | | | |
|------|--|-----|---------------|---------------|
| 13.2 | Is there a documented procedure covering the way to handle non-conforming products?
If "no", then describe the process on the Inspector's Evaluation Sheet. | yes | no | NA |
| 13.3 | Is the procedure and the way in which it is applied satisfactory? | yes | no | NA |

14 Customer Complaint

- | | | | | |
|------|--|-----|---------------|---------------|
| 14.1 | Are records kept of customer complaints? | yes | no | NA |
| 14.2 | Are corrective actions regarding customer complaints recorded? | yes | no | NA |
| 14.3 | Does the manufacturer review customer complaints? | yes | no | NA |

15 Changes to Certified Products

- | | | | | |
|------|--|----------------|---------------|---------------|
| 15.1 | Is there a parts list or similar evidence available specifying the components /parts to be use during production/ assembly of certified products? | yes | no | NA |
| 15.2 | Is there evidence that this parts list is under the control of the Licence Holder? | yes | no | NA |
| 15.3 | Is there a documented procedure ensuring that no changes to the construction of certified products will be implemented without the permission of the Licence Holder? | yes | no | NA |
| 15.4 | If any change has been made to the certified product, has this change been made with the authorisation of the licence holder? | yes | no | NA |
| 15.5 | If any change has been made to the certified product, has the Notified Body been informed on this change? | yes | no | NA |
| 15.6 | If the Manufacturer is the Licence Holder:
Is there a documented procedure ensuring that the Certification Body has accepted changes to the construction of certified products, before any implementation into a certified product? | yes | no | NA |

16 Environmental Conditions

- | | | | | |
|------|--|-----|----|----|
| 16.1 | Is the policy with regards to ESD sufficient? | yes | no | NA |
| 16.2 | Is the climate on the final test location monitored and controlled?
Provide details on the Test Data Sheet (Annex B). | yes | no | NA |

17 Selection and Shipping of Sample(s)

Regarding samples requested by the Certification Body please refer to annex A and enter details as appropriate.

- 17.1 If you did not personally select the samples, explain why not and who did?

Factory inspector identified and selected samples for which detailed information was Documented in annex A title Identification of Selected Samples.

- | | | | | |
|------|--|-----|----|----|
| 17.2 | If the selected sample(s) do not bear the Certification Mark then provide the reason for selection in the table "Identification of selected samples" | yes | no | NA |
|------|--|-----|----|----|

Annex A. Identification of Selected Samples

Serial No.	Product/ type/ technical data	Production period	Remarks location	code
N/A	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	SMT assembly No Certification Mark	P
N/A	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	Reflow soldering No Certification Mark	P
N/A	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	Post-soldering Inspection. No Certification Mark	P
N/A	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	Post-soldering Inspection. No Certification Mark	P
00500058	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	PCB Assembly	P
00500058	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	Calibration Register	P
00500143	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	Functional Test	P
00500163	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	Functional Test	P
00500041-00500060	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	Verification of mechanical register	P
00500036	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	Metrological Final Control	P
00500041-00500060	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	Metrological Final Control	P
00500041-00500060	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	Packing	P
00500001-00500030	RS80941 C[X] [X] [X] [X] Single Phase Static Meter for Active Energy	December 27, 2010	Finished Goods Store	S

Code letters: **P** = Sample from Production or **S** = Stock; **F** = Forwarded by the Manufacturer; **A** = Shipped by the inspection Agency



Annex B. Test Data Sheet

paragraph	Tests	% Check	Factory limits	Failure indicated by	Remarks	Witnessed
2.1	Incoming Inspection – SMD components – Integrity body component (e.g. Rutronik resistor and capacitor)	AQL 10	Metoda”Zero acceptare”	Identify as nonconforming materials and follow reaction plan no. 004	Good Inward Instruction Inspection Measurement and Visual Inspection Data Sheet	Yes
2.1	Incoming Inspection – SMD components –Conformity Mark (e.g. Rutronik resistor and capacitor)	AQL 10	Metoda”Zero acceptare”	Identify as nonconforming materials and follow reaction plan no. 004	Good Inward Instruction Inspection Measurement and Visual Inspection Data Sheet	Yes
2.1 & 2.2	Incoming Inspection – SET BORNE INDIA terminal set RP445034	PDC, NC II, AQL 0.4//SCP CN II, AQL 0.4	Per Drawing and PDC, NC II, AQL 0.4//SCP CN II, AQL 0.4	Identify as nonconforming materials and follow reaction plan no. 004	Follow Instruction FCC-R-545	Yes
3	Post Plastic Injection	Once per shift	Without matte outer surface, without deformations, embossed marking	Identify as nonconforming products and follow reaction plan no. 001	Self-control Data Sheet and PL-003 Work Procedure	Yes
3	Post Plastic Injection	100%	Without matte outer surface, without deformations, embossed marking	Identify as nonconforming products and follow reaction plan no. 001	Self-control Data Sheet and PL-003 Work Procedure	Yes
3	Post Plastic Injection	5pcs per box	Conformity check piece	Identify as nonconforming products and follow reaction plan no. 001	Self-control Data Sheet and PL-003 Work Procedure	Yes



3	SMD Assembling – Ekip. Slim KIK	1 per 3200 piece	Per Working Parameters Fuji Line acc, PL105	Identify as nonconforming products and follow reaction plan no. 002	Drawing, Data Sheet Technology, Sample, Work Instruction PL-105 and FCC-PS-091	Yes
3	SMD Assembling- Visual	First piece per shift	Laying correctness and completeness	Identify as nonconforming products and follow reaction plan no. 002	Drawing, Data Sheet Technology, Sample, Work Instruction PL-105 and first good piece	Yes
3.6	Rework - Visual	100%	Laying correctness and completeness	Identify as nonconforming products and follow reaction plan no. 002	Drawing, Work Procedures 231	Yes
3	Manual Insertion	100%	Data sheet technology	Identify as nonconforming products and follow reaction plan no. 003	Self-control, Work Procedures PL155	Yes
3	THT Manual Insertion- Visual	100%	Drawing	Identify as nonconforming products and follow reaction plan no. 003	Self-control, Work Procedure PL155; FCC-PS-048	Yes
3	Cleaning PCB Assembly- Visual	100%	Data sheet technology	Identify as nonconforming products and follow reaction plan no. 003	Self-control, Work Procedure PL155	Yes
3	Test PCB - Visual and Test	100%	Test Instruction	Identify as nonconforming products and follow reaction plan no. 003	Self-control, Work Procedure PL155	Yes
3.6	Servicing PCB	100%	Test Instruction	Identify as nonconforming products and follow reaction plan no. 003	Self-control, Work Procedure PL155	Yes

3	Assembly	100%	Drawing	Identify as nonconforming products and follow reaction plan no. 003	Self-control, Work Procedure PL155	Yes
4.1	Calibration	100%	Per ITL Work Instruction 328535-1	Identify as nonconforming products and follow reaction plan no. 003	Calibration Bench RP99149C and Per ITL Work Instruction 328535-1	Yes
4.2	Servicing PCB- Visual	100%	Per ITL Work Instruction 328535-2	Identify as nonconforming products and follow reaction plan no. 003	Calibration Bench RP99149C and Per ITL Work Instruction 328535-2	Yes
4.1	Check Stepper Motor Counters	100%	Data Sheet Technology	Identify as nonconforming products and follow reaction plan no. 003	RS81054 Special Stand and PL155	Yes
3	Assembly - Visual	100%	Data Sheet Technology	Identify as nonconforming products and follow reaction plan no. 003	PL155 Work Procedure	Yes
3	Final Assembly - Visual	100%	Data Sheet Technology	Identify as nonconforming products and follow reaction plan no. 003	PL155 Work Procedure	Yes
4.1	Functional Test- Visual	100%	Correct functional at change voltage and verify tester with Dummy	Identify as nonconforming products and follow reaction plan no. 010	PL155 Work Procedure, RS 80890BV test stand and Following data-shift	Yes
8	Metrological Final Control - Visual	100%	drawing	Identify as nonconforming products and follow reaction plan no. 010	Drawing	Yes

8	Metrological Final Control – Conformal Marking According to C.S. 129/99 point 5.1	100%	Per Drawing and SF//C.S. 129/99	Identify as nonconforming products and follow reaction plan no. 010	According to C.S. 129/99 point 5.1	Yes
8	Metrological Final Control – Insulation Resistance cf. pct. 2.5.3.1	1%	SF//C.S. 129/99	Identify as nonconforming products and follow reaction plan no. 010	According to C.S. 129/99 point 2.5.3.1 and Register values of resistance insulation code PLL01-5	Yes
8	Metrological Final Control – Meter Operation cf. pct. 2.4.6	100%	SF//C.S. 129/99	Identify as nonconforming products and follow reaction plan no. 010	Work Laboratory Procedure 01-1	Yes
8	Metrological Final Control – No-load Operation cf. pct. 2.4.7	100%	SF//C.S. 129/99	Identify as nonconforming products and follow reaction plan no. 010	Work Laboratory Procedure 01-1	Yes
8	Metrological Final Control – Sensitivity cf. pct. 2.4.8	100%	SF//C.S. 129/99	Identify as nonconforming products and follow reaction plan no. 010	Work Laboratory Procedure 01-1	Yes
8	Metrological Final Control – Accuracy cf. pct. 2.4.2	100%	SF//C.S. 129/99	Identify as nonconforming products and follow reaction plan no. 010	Work Laboratory Procedure 01-1	Yes
8	Metrological Final Control – Register Test cf. pct. 2.4.10	100%	SF//C.S. 129/99	Identify as nonconforming products and follow reaction plan no. 010	Work Laboratory Procedure 01-1	Yes
3	Packing - Visual	100%	SF//C.S. 129/99	Identify as nonconforming products and follow reaction plan no. 003	SF//C.S. 129/99	Yes



8	Final Control – Checking Integrity of Seal and Individual Packing Correctly - Visual	2 per 54	SF//C.S. 129/'99	Identify as nonconforming products and follow reaction plan no. 010	SF//C.S. 129/'99	No, there is no customer order.
8	Final Control – Checking Declaration of Conformity	100%	SF//C.S. 129/'99	Identify as nonconforming products and follow reaction plan no. 010	SF//C.S. 129/'99	No, there is no customer order.
8	Final Control – Checking User Instruction	100%	SF//C.S. 129/'99	Identify as nonconforming products and follow reaction plan no. 010	SF//C.S. 129/'99	No, there is no customer order.
8	Final Control – Checking Sheet Packing	100%	SF//C.S. 129/'99	Identify as nonconforming products and follow reaction plan no. 010	SF//C.S. 129/'99	No, there is no customer order.
8	Final Control – Checking Correct Packing	100%	SF//C.S. 129/'99	Identify as nonconforming products and follow reaction plan no. 010	SF//C.S. 129/'99	No, there is no customer order.
17	Storage and Shipping	100%	SF//C.S. 129/'99 pct. 5.5	Declaration of Conformity	Correct condition by storage	No, there is no customer order.