|  |  |  |
| --- | --- | --- |
| etics_logo (3) | APPENDIX TOASSESSMENT REPORTPAAG xxxx YAR | OD ECS 075Appendix |
|  |
| Testing Laboratory:NameAddress |
|  |
| **Dates of assessment: yyyy-mm-dd** |
|  |
| The complete European Assessment Report consists of two parts:The ECS Assessment Report ref. PAAG XXXX YARThis Appendix to the Assessment Report |
|  |
| **OD ECS 075 Appendix– April 2019** |  | Page 1 of 22 |

# OBJECT AND FIELD OF ASSESSMENT

### Object

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Assessment covering | ECS Assessment | Joint Assessment | Accreditation Body | Scope of Accreditation |
| Initial Assessment | [ ]  | [ ]  |  |  |
| Extension of Scope | [ ]  | [ ]  |  |
| Re-Assessment  | [ ]  | [ ]  |  |
| Follow-up Assessment | [ ]  | [ ]  |  |
| Re-Location Assessment | [ ]  | [ ]  |  |

NOTE: In a Relocation Assessment Report, a statement “No Change” represents a declaration of the assessed CBTL that the information provided in the previous Assessment Report is still valid. Verification of this information during a Relocation Assessment may be only partial at the discretion of the Lead Assessor.

### Product Categories

### Product Categories covered by the re-assessment

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BATT | CABL | CAP | CONT | E3 | ELVH | EMC | HOUS | HSTS | INDA | INST | LITE |
| [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| MEAS | MED | MISC | OFF | POW | PROT | PV | SAFE | TOOL | TOYS | TRON |  |
| [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |

### Product Categories covered by the initial/scope extension assessment

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BATT | CABL | CAP | CONT | E3 | ELVH | EMC | HOUS | HSTS | INDA | INST | LITE |
| [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| MEAS | MED | MISC | OFF | POW | PROT | PV | SAFE | TOOL | TOYS | TRON |  |
| [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |

### Previous Assessment Report

|  |  |
| --- | --- |
| Previous Assessment Report Number |  |
| Previous Assessment Date |  |

### Certification Schemes

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  ENEC | [ ]  ENEC+ | [ ]  HAR | [ ]  CCA |

### Complete legal entity name and address of the Testing Laboratory

|  |  |  |
| --- | --- | --- |
| Type | Candidate | Accepted |
| TL | [ ]  | [ ]  |
| SPTL | [ ]  | [ ]  |

|  |  |
| --- | --- |
| Legal Entity Name |  |
| Address |  |
| Contact Person |  |
| Email |  |
| Tel |  |
| Mobile |  |
| Fax |  |
| Website |  |

### Members of the Assessment Team

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name | Organisation | Country |
| Lead Assessor |  |  |  |
| Assessor |  |  |  |

### Place and dates of Assessment

|  |  |
| --- | --- |
| Main location |  |
| If applicable, other location(s) |  |
| Date of Assessment for main location and any other locations |  |

### Assessment Base

ISO/IEC 17025

PD ECS 050 - Requirements for the recognition and assessment of participants in the European Certification Schemes

PD ECS 073 Assessment Report templates for the European Schemes

The above documents are to be based upon the latest published editions

# ORGANISATION

# Certification Body undertaking the responsibility for the Testing Laboratory

|  |  |
| --- | --- |
| Legal entity name |  |
| Address |  |
| NCB Representative present at assessment | [ ]  Yes [ ]  No |

|  |  |  |
| --- | --- | --- |
|  | Contact person located at the CB | CB Representative present at assessment (if different to contact person) |
| Name |  |  |
| Email |  |  |
| Tel |  |  |
| Fax |  |  |
|  |  |  |

# Main Laboratory undertaking the responsibility for the Specialized Testing Laboratory

|  |  |
| --- | --- |
| Legal entity name |  |
| Address |  |
| CB Representative present at assessment | [ ]  Yes [ ]  No |

# Brief history of the Testing Laboratory

|  |
| --- |
|  |

# Organisation of the Testing Laboratory

|  |
| --- |
|  |

# PERSONNEL STRUCTURE

# Employees

|  |  |
| --- | --- |
| Number of overall people employed by the Testing Laboratory |  |
| Number of people working in the overall product testing area |  |
| Number of people involved with the product testing activity within the scope of this assessment |  |

# Responsible Managers for Testing

| Name | Position (title) and field of expertise | Years of relevant experience | Experience checked & appropriate | To whom do they report? |
| --- | --- | --- | --- | --- |
| Yes | No |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |

# Principal staff involved in Testing

| Name | Position (title) and field of expertise | Years of relevant experience | Experience checked & appropriate | To whom do they report? |
| --- | --- | --- | --- | --- |
| Yes | No |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |

# Staff involved in the Quality Management System of the Testing Laboratory

| Name | Position (title) and field of expertise | Years of relevant experience | Experience checked & appropriate | To whom does the quality management system staff report? |
| --- | --- | --- | --- | --- |
| Yes | No |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |

# Assessment of staff competence

|  |
| --- |
|  |

# TESTING PREMISES

|  |  |
| --- | --- |
| Total premises area | m² |
| Total testing laboratory area | m² |
| Total testing area in the scope of recognition | m² |
| Total office area in the scope of recognition | m² |

# POWER SUPPLY SYSTEM

# Electrical Power Supply System for Testing

|  | **Yes** | **No** |
| --- | --- | --- |
| Is the electrical power distribution system appropriate for the scope of recognition according to ISO/IEC 17025: sub-clause 5.3? | [ ]  | [ ]  |

# Electrical Power Supply Stability

|  |
| --- |
| When not otherwise specified in the testing standard, laboratory power sources used for testing meet the following criteria at the point where testing is performed under both loaded and no-load conditions : |
| Voltage stability: +/- 3 percent maximumFor 60598 +/- 1 percent maximum | [ ]  |
| Frequency stability: +/- 2 percent maximum | [ ]  |
| Total harmonic distortion: maximum 5 percent | [ ]  |

|  | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- |
| Do the laboratory power supplies meet additional specific criteria required by the test standard? | [ ]  | [ ]  | [ ]  |
| IEC Standard Numbers/Titles and Clauses: |

# Electrical Power Supply Monitoring

|  | **Yes** | **No** |
| --- | --- | --- |
| The laboratory has an operating procedure to monitor, control and record characteristics of the laboratory power supplies used for testing to ensure continued conformance with the requirements of OD 5010. | [ ]  | [ ]  |
|  |

# Summary

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| Is the power distribution system appropriate in the scope of recognition? | [ ]  | [ ]  |
| Comments about the laboratory’s power distribution system and its capacity and stability for testing equipment within the scope of this assessment: |

# QUALITY MANAGEMENT SYSTEM

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **N/A** |
| Is the Testing Laboratory accredited by a reputable Accreditation Body? | [ ]  | [ ]  |  |
| Does the accreditation include the product categories covered by this assessment? | [ ]  | [ ]  | [ ]  |

|  |
| --- |
| Structure of the Quality System |
|  |
| Document control |
|  |
| Review of requests, tenders and contracts |
|  |
| Sub-contracting of tests |
|  |
| Purchasing services and supplies |
|  |
| Service to the client |
|  |
| Complaints |
|  |
| Control of non-conforming work |
|  |
| Corrective action |
|  |
| Preventive action |
|  |
| Control of records |
|  |
| Internal audits |
|  |
| Management reviews |
|  |
| ETICS Rules of Procedure and Guidance |
|  |
| ETICS Operational Documents |
|  |
| OSM Decisions |
|  |
| Use of appropriate IEC / EN standards |
|  |
| Current decisions |
|  |

# CRITICAL TECHNICAL PROCEDURES

|  |
| --- |
| Accommodation and environmental conditions |
|  |
| Test methods and method validation |
|  |
| Equipment |
|  |
| Measurement traceability |
|  |
| Sampling |
|  |
| Handling of test items |
|  |
| Assuring the quality of test results |
|  |
| Reporting the results |
|  |

# SUBCONTRACTED TESTING

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **N/A** |
| Does the laboratory subcontract testing? | [ ]  | [ ]  |  |
| Subcontract ProcedureFollowing tests are subcontracted:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| CAT | STANDARD | CLAUSE | TEST | SUBCONTRACTED ORGANIZATION |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

 |
| Is the subcontracting allowed by the CTL list? | [ ]  | [ ]  |  |
|  |
| Does the practice comply with OD-2012? | [ ]  | [ ]  | [ ]  |
|  |

# IMPORTANT EQUIPMENT BORROWED OR RENTED

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **N/A** |
| Does the laboratory borrow or rent testing equipment? | [ ]  | [ ]  |  |
|  |
| Please note if the borrowed/rented equipment are under the “R” or “S” on the CTL list of equipment |
|  |
| Does the practice comply with IECEE OD-2012? | [ ]  | [ ]  | [ ]  |
|  |

# TESTING IN MANUFACTURERS’ TESTING LABORATORIES / CUSTOMER TESTING FACILITIES

|  |  |  |
| --- | --- | --- |
| **Does the Testing Laboratory carry out testing upon the request of the CB?** | **Yes** | **No** |
| TMP/CTF Stage 1 | [ ]  | [ ]  |
|  |
| WMT/Stage 2 | [ ]  | [ ]  |
|  |
| SMT/CTF Stage 3 | [ ]  | [ ]  |
|  |

|  |  |  |
| --- | --- | --- |
| **Does the Testing Laboratory carry out assessment according to ISO/IEC 17025 upon the request of the CB?** | **Yes** | **No** |
| TMP/CTF Stage 1 | [ ]  | [ ]  |
| WMT/CTF Stage 2 | [ ]  | [ ]  |
| SMT/CTF Stage 3 | [ ]  | [ ]  |

# PROFICIENCY TESTING PROGRAMMES

|  |
| --- |
|  |

# TESTING WITNESSED DURING THE ASSESSMENT

| **Test according to standard** | **Clause/ Description** | **Person performing test** |
| --- | --- | --- |
| CATEGORY1 |
|  |  |  |
| evaluation |  | OK / FAIL |
|  |  |  |
| evaluation |  | OK / FAIL |
| CATEGORY |
|  |  |  |
| evaluation |  | OK / FAIL |
|  |  |  |
| evaluation |  | OK / FAIL |

# TEST REPORTS REVIEWED DURING THE ASSESSMENT

| ***Order Number*** | ***Product*** | ***Standards*** | ***Tested By*** | ***Reviewed By*** |
| --- | --- | --- | --- | --- |
| CATEGORY |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |
| CATEGORY |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |

# ADDITIONAL INFORMATION

See PAAG XXXX IAR

# NUMBER OF NON-CONFORMITY REPORTS ISSUED

See PAAG XXXX IAR

# RECOMMENDATIONS OF THE ASSESSMENT TEAM

This assessment has been a sampling exercise and thus every aspect of the Testing Laboratory’s activities has not been covered. It does not follow, therefore, that non-conformances do not exist in areas where none have been reported in this assessment report.

See PAAG XXXX IAR

# SIGNATURES OF THE ASSESSMENT TEAM

Date: YYYY-MM-DD

|  | Printed name | Signature |
| --- | --- | --- |
| Lead Assessor |  |  |
| Assessor |  |  |

# Acknowledgement by the assessed organization

[ ]  We acknowledge and agree with the content of the Assessment Report.

[ ]  We acknowledge the content of the Assessment Report and we disagree for the following reasons:

Date: YYYY-MM-DD

|  | Printed name | Signature |
| --- | --- | --- |
| Testing Laboratory Representative |  |  |
| NCB Representative |  |  |

# Annex 1A Standards of the current accepted scope selected for this Re-assessment

| Product Category | Standard | Number of Test Reports issued during the last three years | Assessment Team acceptance |
| --- | --- | --- | --- |
| Yes | No |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |

Note: For the organization’s full scope please see the ETICS Website

**Annex 1B Assessment Scope for Specialized Testing Laboratory**

|  |  |  |  |
| --- | --- | --- | --- |
| Name of the Test | Standard | Clause of the Standard | Assessment Team acceptance |
| Yes | No |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |

# Annex 2 Organisation chart

# Annex 3 Accreditation Certificate relevant to the TL for the European Certification Schemes

# Annex 4 Application of uncertainty of measurement concepts in the Testing Laboratory

|  |  |  |
| --- | --- | --- |
| **1. Laboratory procedure for application uncertainty of measurement** | **Yes** | **No** |
| Does the Body have a documented operating procedure on application of uncertainty of measurement? | [ ]  | [ ]  |
|  |

|  |  |  |
| --- | --- | --- |
| **2. Uncertainty of measurement references in the Laboratory** | **Yes** | **No** |
| Does the Body have access to the ISO/IEC Guide 98-3, Guide to Expression of Uncertainty in Measurement? | [ ]  | [ ]  |
| Does the Body have access to the IEC Guide 115, “Application of Uncertainty of Measurement to Conformity Assessment Activities in the Electrotechnical Sector”? | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **3. Competency of Laboratory staff in uncertainty of measurement concepts** | **Yes** | **No** |
| Does all the laboratory staff have knowledge of the basic concepts of uncertainty of measurement? | [ ]  | [ ]  |
| Can the Laboratory staff select instrumentation and make pass/fail decisions taking uncertainty of measurement into account? | [ ]  | [ ]  |
| Are selected laboratory staff sufficiently expert in uncertainty of measurement to calculate measurement uncertainties associated with test equipment and testing performed? | [ ]  | [ ]  |
| Names of persons:  |
| Were the training records of the selected laboratory staff checked? | [ ]  | [ ]  |
| Were examples of uncertainty of measurement calculations for actual tests performed in the laboratory by the select laboratory staff reviewed and found to be acceptable? | [ ]  | [ ]  |
|  |

|  |  |  |
| --- | --- | --- |
| **4. Laboratory compliance with the uncertainty of measurement requirements** | **Yes** | **No** |
| Does the Body comply with all the above Measurement Uncertainty Requirements? | [ ]  | [ ]  |

# Annex 5 “Independence and impartiality” including “Commercial consultancy”

**Already checked in previous Assessments**

|  |  |  |
| --- | --- | --- |
| **1. General Operating Procedure** | **Yes** | **No** |
| Does the Body have a documented procedure for independence and impartiality that as a minimum includes the following while carrying out conformity assessment activities:a) to be objective,b) to identify, avoid, mitigate and manage conflicts of interest, andc) to ensure independence, so as to increase the amount of trust, confidence and value that those activities have in the market place | [ ]  | [ ]  |
| Document title: |

|  |  |  |
| --- | --- | --- |
| **2. Reference Document** | **Yes** | **No** |
| Does the Body have access to ISO/IEC 17025:2005 and in particular Sub-clause 4.1.4 (including Note 2, 4.1.5 B) and 4.1.5 d)? | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **3. Knowledge, training and decision making** | **Yes** | **No** |
| Does the Body’s staff have knowledge of the basic concepts of independence and impartiality? | [ ]  | [ ]  |
| Were the training records of the Body’s staff checked? | [ ]  | [ ]  |
| Does the Body’s selected staff have sufficient knowledge in the principles of independence and impartiality to provide initial training and retraining to other staff? | [ ]  | [ ]  |
| Names of person(s): |
| Were examples of training programs of the Body’s staff reviewed and found to be sufficient? | [ ]  | [ ]  |
| Does the Body’s staff select and make pass/fail decisions taking the principles of independence and impartiality into account? | [ ]  | [ ]  |
| Are the Body’s decisions based on objective evidence of conformity (or nonconformity) obtained by the Body’s staff?  | [ ]  | [ ]  |
| Are the Body’s decisions influenced by other interests or parties? | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **4. Documentation and Implementation** | **Yes** | **No** |
| Does the Body have documented and implemented (on an on-going basis) sufficient procedures to ensure the independence and impartiality of all staff? | [ ]  | [ ]  |
| Does the Body have documented and implemented (on an on-going basis) sufficient procedures to ensure that the remuneration of staff is free from pressures and inducements and is not dependent on the number, outcome of the result of their activities?Note: It is recognized that the source of revenue of the Body is its customers paying for its services and that this is a potential threat to independence and impartiality. | [ ]  | [ ]  |
| Does the Body have documented sufficient procedures for the identification, review, resolution and prevention of conflict of interest (including “commercial consultancy”) where conflicts of interest are suspected or proven (including subcontracted personnel) and does the Body keep records of such reviews and decisions?  | [ ]  | [ ]  |

|  |  |  |  |
| --- | --- | --- | --- |
| **5. Marketing and advertising materials** | **Yes** | **No** | **N/A** |
| Do the Body’s marketing materials give the impression that “commercial consultancy” activities are offered? | [ ]  | [ ]  |  |
| Is the Body linked to an organization that provides “commercial” consultancy services? | [ ]  | [ ]  | [ ]  |
| Is there a documented policy/procedure to ensure that there is an effective separation between all conformity assessment activities and consultancy services? | [ ]  | [ ]  | [ ]  |
| Does the Body’s certification staff participate in “commercial consultancy”?  | [ ]  | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **6. Staff declarations** | **Yes** | **No** |
| Does the Body require all staff acting on its behalf to declare any potential conflict of interest? | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **7. Compliance** | **Yes** | **No** |
| Does the Body comply with all the above independence and impartiality principles on an ongoing basis?Note: If the answer is NO a Non-Conformity Report must be issued | [ ]  | [ ]  |

# Annex 6 Testing Laboratory Risk Management Review Capabilities

**Not Applicable**

|  |  |  |
| --- | --- | --- |
| **1.1 Laboratory procedure for Risk Management** | **Yes** | **No** |
| Does the CBTL have a documented operating procedure on application of risk management? | [ ]  | [ ]  |
| Document title: Document number: |
| **1.2 Risk Management References in the Laboratory** | **Yes** | **No** |
| Does the CBTL use the current methodology of IECEE Guide OD 2044? | [ ]  | [ ]  |
| Does the CBTL apply the relevant edition of ISO 14971 in requesting objective evidence for compliance with this standard? | [ ]  | [ ]  |
| **1.3 Competency of Laboratory Staff in Risk Management Concepts** | **Yes** | **No** |
| Were the training records, CVs and other risk management qualifications of the select laboratory staff checked? | [ ]  | [ ]  |
| Do the laboratory personnel involved in risk management evaluations have knowledge of the risk management requirements in ISO 14971? | [ ]  | [ ]  |
| **Principal Staff Involved In Risk Management Evaluation** |
| **Name** | **Position (Title) and Field of Expertise** | **Years of Relevant Experience** | **Experience Checked & Appropriate** | **To whom do they report?** |
| **Yes** | **No** |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |
|  |  |  | [ ]  | [ ]  |  |
| Can the Laboratory staff select appropriate risk management file information and make pass/fail decisions taking risk management concept into account? | [ ]  | [ ]  |
| Do the reviewed Test Reports show objective evidence of compliance demonstrated by comments and specific references to manufacturer’s Risk Management documents? | [ ]  | [ ]  |
| **1.4 Laboratory compliance with the Risk Management requirements** | **Yes** | **No** |
| Does the Body comply with all the above Risk Management Requirements? | [ ]  | [ ]  |