IECEE OD-4001

Edition 1.~~3~~4 201~~3~~8-~~06xx~~06-05

IECEE
OPERATIONAL DOCUMENT

IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System)

Factory Surveillance Report

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CB-FSB	
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FOREWORD

Scope

To be determined

Document Owner

CFS

History of changes

Revision Date	Brief summary of changes
2018-01-29	Updates have been made to “general guidance” as well as subclauses 1.5 and 1.6.

Effective date	Next maintenance due date
2018-06-05	2021-06-05

Surveillance carried out by	
CB-FSB	
Reference number	

Introduction

The objective of the Factory Surveillance is:

- to evaluate the capability of a Factory to produce products within a consistent Manufacturing process.
- to verify that the Manufacturer's Quality Management Measures, Assembly line, Inspection and Testing Procedures, Facilities and Equipment etc. are set to comply with the applicable requirements.
- to cover any declared additional certification-related requirements of the National Certification Bodies.

The Factory Surveillance should be focused on the relevant Scope of Category(ies) and Standard(s) associated with the certified products concerned.

General guidance

Guidance on how to fill in the present form is given in the document OD-G-4001, Guidance for IECEE Factory Inspectors.

Surveillance carried out by	
CB-FSB	
Reference number	

Contents (to be updated when agreed)

Surveillance carried out by	
CB-FSB	
Reference number	

1 General information

1.1 Manufacturer's registered name and factory location	
Manufacturer's registered name	
Street address of the factory and number	
Postal code	
City	
County	
Country	
GPS-coordinates (optional)	

1.2 Manufacturer's representative name and contact data	
Manufacturer's representative name	
Position	
Telephone	
Fax	
Email	

1.3 Record below the names and position held of the main people involved in the Surveillance

☐ Same as mentioned under 1.2

If not the same as mentioned under 1.2, please give details below:

Manufacturer's representative name	
Position	
Telephone	
Fax	
Email	

1.4 Type of Surveillance

☐ Pre-certification ☐ Post-certification ☐ Surveillance

Surveillance carried out by	
CB-FSB	
Reference number	

1.5 Products covered by this surveillance			
Category	Product	PID Number	Vversion/issuing date
1.6			
Name of IECEE Factory Inspector		Date of surveillance (YYYY-MM-DD)	
~~IECEE FI Registration N°~~			

Surveillance carried out by	
CB-FSB	
Reference number	

2 Verification of purchased components and materials which have a safety implication on the certified product (Incoming Inspection)

2.1 Are materials, components and sub-assemblies verified by the manufacturer as complying with appropriate specification?	YES	N/A	NO
	☐	☐	☐

2.2 Does this verification also include the verification of any Certification Marks?	YES	N/A	NO
	☐	☐	☐

Description of procedure *(one or more boxes may be ticked)*
- ☐ Rely on suppliers' out-going inspection/ suppliers' quality plan
- ☐ Audit conducted at the suppliers' premises
- ☐ Supplier control based on manufacturers' check list
- ☐ Conduct own incoming inspection
- ☐ Identification check
  - ☐ Checked for correct type
  - ☐ Comparison to a reference
  - ☐ Rating
  - ☐ Certification mark
- ☐ Certificate of conformity
- ☐ Others *(please give details)*
- ☐ Details given on Inspector's Evaluation Informative page

Description of the procedure or ref. of documented procedure & revision or issue date:
- ☐ Details given on Inspector's Evaluation Informative page

2.3 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 properly issued?	YES	N/A	NO
	☐	☐	☐

2.4 Is there a procedure covering the way to handle non-conforming components and materials?	YES	N/A	NO
	☐	☐	☐

Description of the procedure or ref. of documented procedure & revision or issue date:
- ☐ Details given on Inspector's Evaluation Informative page

2.5 Are the procedure and the way in which it is applied satisfactory? (e.g.: components and materials clearly identified and/or segregated to prevent unauthorised use?)	YES	N/A	NO
	☐	☐	☐

	YES	N/A	NO
2.6 Are records of the incoming inspection maintained and satisfactory?	☐	☐	☐
2.7 Are records kept at least for the period between two Surveillance visits?	☐	☐	☐

3 Production Control, Inspection and Routine Tests

	YES	N/A	NO
3.1 Are the quality assurance and manufacturing personnel adequately briefed on their duties?	☐	☐	☐
3.2 Do they have readily available up-to-date documents, manufacturing and test instructions, photographs, drawings or samples on all those parts which have an impact on the safety of the finished products?	☐	☐	☐
3.3 Is there evidence that the production process ensures that the final product is identical to the reference version as described in clause 15.1?	☐	☐	☐
3.4 Is there a procedure to ensure that all products will be tested or inspected according to the manufacturer's requirements?	☐	☐	☐
Description of the procedure or ref. of documented procedure & revision or issue date: ☐ Details given on Inspector's Evaluation Informative page			
3.5 Is the production process controlled at appropriate stages?	☐	☐	☐
3.6 Are products inspected at appropriate stages of manufacture? (Production Line Inspection)	☐	☐	☐
Give details of all tests and inspections performed by the manufacturer and enter in the routine test table on the Test Data Sheet			
3.7 Do the Routine Tests entered on the Test Data Sheet sufficiently cover all routine test requirements?	☐	☐	☐

Surveillance carried out by	
CB-FSB	
Reference number	

	YES	N/A	NO
3.8 Is there a procedure covering the way to handle non-conforming products?	☐	☐	☐

Description of the procedure or ref. of documented procedure & revision or issue date:
☐ Details given on Inspector's Evaluation Informative page

Procedure of handling non-conforming products *(one or more boxes may be ticked)*
☐ Automated segregation process
☐ Manual segregation process
☐ Non-conforming products are destroyed
☐ Non-conforming products are repaired
☐ Others *(please give details)*
☐ Details given on Inspector's Evaluation Informative page

	YES	N/A	NO
3.9 Are the procedure and the way in which it is applied satisfactory? (e.g. non-conforming products clearly identified or segregated to prevent unauthorised use?)	☐	☐	☐

	YES	N/A	NO
3.10 Are repaired and reworked (corrected) items again subjected to appropriate tests/inspections in accordance with procedures?	☐	☐	☐

Description of the procedure or ref. of documented procedure & revision or issue date:
☐ Details given on Inspector's Evaluation Informative page

	YES	N/A	NO
3.11 Are test records of the routine tests maintained and satisfactory?	☐	☐	☐

	YES	N/A	NO
3.12 Are records kept at least for the period between two Surveillance visits?	☐	☐	☐

Surveillance carried out by	
CB-FSB	
Reference number	

4 Functional check on test and measuring equipment used for safety tests (Dummy Test)

	YES	N/A	NO
4.1 Is there a procedure describing how the functional checks shall be conducted?	☐	☐	☐
☐ Automated process ☐ Manual process			
Description of the procedure or ref. of documented procedure & revision or issue date: ☐ Details given on Inspector's Evaluation Informative page			
4.2 Is there evidence that the functional check of the equipment is conducted properly, even if certified products were not in production?	☐	☐	☐
4.3 Is a functional check conducted with intervals which will allow previous production to be retested if incorrect functioning is detected before it leaves the factory?	☐	☐	☐
4.4 Is the proper function of the test equipment verified with a simulated failure (dummy) or by other equivalent means?	☐	☐	☐
☐ Simulated failure (dummy) ☐ Test procedure according to the equipment manual ☐ Internal self-test; test program included in equipment certification ☐ Internal self-test; verified by the inspector			
4.5 Is there evidence that the simulated failure (dummy) (if used) represents the tripping limits?	☐	☐	☐
4.6 Is there a procedure requiring appropriate actions to be taken by the operator if a functional check is found to be unsatisfactory?	☐	☐	☐
Description of the procedure or ref. of documented procedure & revision or issue date: ☐ Details given on Inspector's Evaluation Informative page			
4.7 Is this procedure appropriate to ensure that improperly checked products are re-tested?	☐	☐	☐

Surveillance carried out by	
CB-FSB	
Reference number	

4.8 Are subsequent corrective actions taken recorded in all cases?	YES ☐	N/A ☐	NO ☐
4.9 Are the test records of results of functioning checks of test and measuring equipment maintained and satisfactory?	YES ☐	N/A ☐	NO ☐
4.10 Are records kept at least for the period between two Surveillance visits?	YES ☐	N/A ☐	NO ☐

5 Products seen in Production during the Visit

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 kinds of products were manufactured at the time of visit. The manufacturing process should nevertheless be examined.
At least one kind of product per product category and electrical insulation class shall be listed.

☐ No production
☐ Production seen

Complete Test Data Sheet for each kind of product per product category and electrical insulation class even if there is no production.
Record the products seen in Production during visit on the Inspector's Evaluation Informative page.

Surveillance carried out by	
CB-FSB	
Reference number	

6 Calibration of Safety Test and Measuring Equipment

6.1 Is test and measuring equipment used calibrated or verified?	YES	N/A	NO
	☐	☐	☐

(one or more boxes may be ticked)

☐ Verification done by the manufacturer by means of calibrated reference equipment

☐ Calibration done by:

- ☐ Laboratory accredited according to ISO/IEC 17025
- ☐ Test equipment manufacturer/supplier
- ☐ National metrology institute

☐ Other *(please give details)*

Provide details for at least one electrical measuring equipment:

Kind of equipment

Type reference

Calibration reference number

Date of last calibration

Calibration due date

6.2 Is the reference equipment (if used for verification) calibrated?	YES	N/A	NO
	☐	☐	☐

(one or more boxes may be ticked)

Calibration of reference equipment done by:

☐ Laboratory accredited according to ISO/IEC 17025

☐ Test equipment manufacturer/supplier

☐ National metrology institute

☐ Other *(please give details)*

6.3 Is the equipment provided with a label or similar indicating the next calibration/verification due date?	YES	N/A	NO
	☐	☐	☐

6.4 Do the calibration/verification records indicate that calibration is traceable to national/international standards of measurement?	YES	N/A	NO
	☐	☐	☐

6.5 Are the records for calibration/verification of test and measuring equipment maintained and satisfactory?	YES	N/A	NO
	☐	☐	☐

6.6 Are records kept at least for the period between two Surveillance visits?	YES	N/A	NO
	☐	☐	☐

Surveillance carried out by	
CB-FSB	
Reference number	

7 Handling and Storage

7.1 Are the components and materials to be used for production stored and handled in such a way as to ensure that they will continue to comply with the applicable standards?	YES ☐	N/A ☐	NO ☐
7.2 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 ☐	N/A ☐	NO ☐

8 (Reserved for future use)

9 Verification of Construction Identity against PID (Product Identification Document)

9.1 PID	YES	N/A	NO
Are all PIDs according to clause 1.5 available?	☐	☐	☐
9.2 Has it been verified that the components and materials from PID are used?	YES ☐	N/A ☐	NO ☐
List any component not listed on the PID on the Inspector's Evaluation Informative page. Unacceptable component changes shall be listed on the Non Conformity Sheet			
9.3 Has it been verified that the product is produced as described in the PID?	YES ☐	N/A ☐	NO ☐
List any constructional change/deviation from the PID, on the Inspector's Evaluation Informative page. Unacceptable constructional changes/deviations from the PID shall be listed on the Non Conformity Sheet			

Surveillance carried out by	
CB-FSB	
Reference number	

10 Follow up on corrective actions from previous surveillances

Are all corrective actions from previous surveillances completed and implemented?	YES	N/A	NO
	☐	☐	☐

11 Quality Management System

If the manufacturer has a QMS certified/registered or assessed by an accredited certification body, please provide details of QMS standard, scope, name of certification body/registrar and certificate expiry date, or provide copy of the certificate.

☐ QMS NOT certified
☐ QMS certified/registered by an accredited certification body/registrar
☐ QMS certified/registered by a non-accredited certification body/registrar
☐ Copy of the certificate (if any) provided as appendix to this report

Details of QMS standard:

Does the scope of the certification/registration cover the production of the certified product:
☐ Yes ☐ No

Name of certification body/registrar:
Certificate no.:
Certificate issued date:
Certificate expiry date:

12 (Reserved for future use)

13 (Reserved for future use)

Surveillance carried out by	
CB-FSB	
Reference number	

14 Customer complaints

The Manufacturer shall record any technical complaint regarding the certified product. *The questions in this section shall be answered even if no customer complaints have been received. In this case the questions should be applied to the process*			
14.1 Is there a procedure regarding how to handle customer complaints?	YES ☐	N/A ☐	NO ☐
14.2 Are the received complaints reviewed on a regular basis regarding whether they are related to single errors or system errors?	YES ☐	N/A ☐	NO ☐
☐ Actual case checked ☐ Procedure checked			
14.3 Are corrective actions and decisions regarding customer complaints recorded?	YES ☐	N/A ☐	NO ☐
☐ Actual case checked ☐ Procedure checked			
14.4 Is the originator of the complaint informed about the handling and the result of the complaint?	YES ☐	N/A ☐	NO ☐
☐ Actual case checked ☐ Procedure checked			
14.5 Are the records of customer complaints maintained and satisfactory?	YES ☐	N/A ☐	NO ☐
14.6 Are records kept at least for the period between two Surveillance visits?	YES ☐	N/A ☐	NO ☐

Surveillance carried out by	
CB-FSB	
Reference number	

15 Control of product changes

15.1 Is reference information about the manufactured product(s) available?	YES	N/A	NO
	☐	☐	☐

(one or more boxes may be ticked)
☐ Set of drawings
☐ Parts list
☐ Product description / Product Information Document (PID)
☐ Reference sample
☐ Photo-documentation
☐ Other specification *(please give details)*
☐ Details are given on Inspector's Evaluation Informative page

15.2 Is this reference under control of the:	YES	N/A	NO
	☐	☐	☐

☐ Certificate holder
☐ Manufacturer
☐ Others

15.3 Is there a procedure ensuring that no changes to the construction of certified products will be implemented prior to acceptance by the Certificate Holder? *(if any)*	YES	N/A	NO
	☐	☐	☐

Description of the procedure or ref. of documented procedure & revision or issue date:
☐ Details given on Inspector's Evaluation Informative page

15.4 If the manufacturer is also the Certificate Holder, is there a procedure ensuring that constructional changes of the certified product will be made only after approval by the Certification Body?	YES	N/A	NO
	☐	☐	☐

Description of the procedure or ref. of documented procedure & revision or issue date:
☐ Details given on Inspector's Evaluation Informative page

15.5 Does the manufacturer confirm that no changes or only authorized changes have been made to the concerned manufactured product since the last Surveillance?	YES	N/A	NO
	☐	☐	☐

☐ No changes
☐ Changes authorized by the certificate holder

Surveillance carried out by	
CB-FSB	
Reference number	

16 (Reserved for future use)

17 Inspector's evaluation

17.1	*List your findings on the Non Conformity Sheet by referencing the applicable clauses in this report (including comments, recommendations, etc.) and explain them to the manufacturer. If possible indicate also the corrective actions the manufacturer intends to take.*		
17.2	**Findings and recommendations to the responsible NCB**		
1	No unsatisfactory findings.	**No unsatisfactory findings.**	☐
		Product certification (if any) may continue.	
2	Minor unsatisfactory finding(s).	**Manufacturer's corrective action(s) shall be checked at the next visit.**	☐
		Product certification (if any) may continue.	
3	Major unsatisfactory finding(s). Safety not directly affected.	**Manufacturer shall confirm the corrective action(s).**	☐
		Product certification (if any) may continue after confirmation by the NCB. *(Special or early routine Surveillance recommended for checking corrective action(s)).*	
4	Critical unsatisfactory finding(s). **Safety directly affected.**	**Repeated factory Surveillance recommended after the manufacturer has confirmed implementation of the corrective action(s).** *(The corrective actions might include total re-evaluation of the product).*	☐
		Product certification (if any) likely to be suspended by the NCB.	
The Manufacturer has to inform the Issuing NCB.			☐
The result of this surveillance will be passed to the Issuing NCB.			☐

Surveillance carried out by	
CB-FSB	
Reference number	

17.3	Attachments added	YES ☐	NO ☐
	Attachments: *For page control, please write the reference number in the header of each attachment page.*		
	General pages	No. of pages:	
	Signature page		
	Copy of Quality Management Certificate		
	Non Conformity Sheet		
	Inspector's Evaluation Informative page		
	Test Data Sheet – Routine Tests (Annex 1)		
	Other		
	Additional requirements for :		
	Europe (Annex SR Europe)		
	ENEC (Annex SR ENEC)		
Total no. of pages of this report including all attachment pages:			

A copy of this report shall be provided to the undersigned contact person who should be aware of the contents and sign for its receipt.
☐ Printed copy provided
☐ Electronic copy provided

The responsibility for ensuring that a product is manufactured in accordance with the standard to which it was originally approved rests with the Manufacturer and the Certificate Holder (if any)

Surveillance carried out by	
CB-FSB	
Reference number	

Signature Page	
Surveillance duration (in hours):	
Date:	
Inspector's name (printed letters)	Contact person's name (printed letters)
Signature ☐ This report is an electronic report and is valid without signature	Signature ☐ This report is an electronic report and is valid without signature
☐ For signature, see attached separate page	

Surveillance carried out by	
CB-FSB	
Reference number	

Non Conformity Sheet

Non Conformity Sheet No /			
Finding:			
Surveillance report item:			Level (see 17.2):
The Manufacturer has to inform the CB-FSB about the root cause and proposed corrective actions within _____ weeks. from the issuing date of related FSR OD 4001			
Manufacturer's representative:			Inspector:
Root Cause Analysis:			
Corrective Action:			
Root Cause Analysis accepted	YES	NO	Inspector / Representative of FSB:
Corrective Action accepted	YES	NO	Inspector / Representative of FSB:
Date implemented:			Implementation verified on (date):
Implementation satisfactory	YES	NO	Inspector / Representative of FSB:
	☐	☐	

Surveillance carried out by	
CB-FSB	
Reference number	

Inspector's Evaluation Informative page

Informative (optional) *Use separate Supplementary Page for different Certification Bodies if necessary*

Annex 1 Test Data Sheet – Routine Tests

☐ No production	
☐ Production seen	Certification mark (if any):
Product Category (e.g. HOUS):	Kind of product (e.g. vacuum cleaner):
Type number:	Electrical Insulation Class:
Rated voltage:	

TESTS		% check	Test value applied	Time	Factory limits applied:	Failure indicated by	Remarks	W / R
a	Earth continuity		V A	s	Ohm (max.)			
b	Insulation resistance		V d.c.	s	MOhm (min.)			
c	Leakage current		V		mA (max.)			
Dielectric strength	Basic insulation		V	s	mA (max.)			
	Supplementary insulation		V	s	mA (max.)			
	Reinforced insulation		V	s	mA (max.)			
e	Load deviation							
f	Functional test							

e Indicate method used (hot/cold, at mains voltage, low voltage resistance check, etc.).
f Are all controls and components checked during the test ?

W = test Witnessed by the inspector
R = according to records

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