



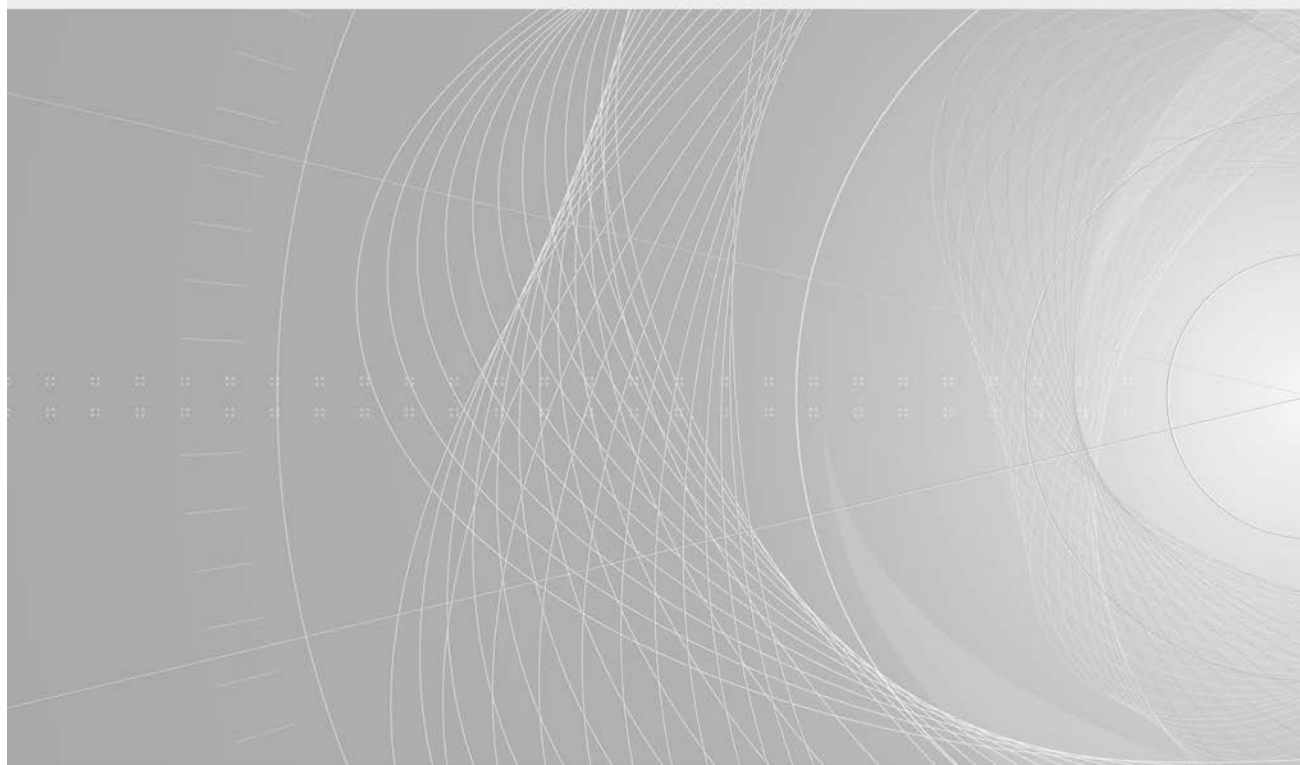
IECEE OD-4001

Edition 1.4 2018-06-05

IECEE OPERATIONAL DOCUMENT

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

Factory Surveillance Report





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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



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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.

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Contents (to be updated when agreed)

Item	Title	Covered / Included
1	General information	<input type="checkbox"/>
2	Verification of purchased components and materials	<input type="checkbox"/>
3	Production control, inspection and routine tests	<input type="checkbox"/>
4	Functional check on test and measuring equipment	<input type="checkbox"/>
5	Products seen in production during visit	<input type="checkbox"/>
6	Calibration of safety test- and measuring equipment	<input type="checkbox"/>
7	Handling and storage	<input type="checkbox"/>
8	Reserved for future use	
9	Product Identification Document verification	<input type="checkbox"/>
10	Corrective actions	<input type="checkbox"/>
11	Quality Management System	<input type="checkbox"/>
12	Reserved for future use	
13	Reserved for future use	
14	Customer complaints	<input type="checkbox"/>
15	Control of product changes	<input type="checkbox"/>
16	Reserved for future use	
17	Inspector's evaluation	<input type="checkbox"/>



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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	
<input type="checkbox"/> 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	
<input type="checkbox"/> Pre-certification <input type="checkbox"/> Post-certification <input type="checkbox"/> Surveillance	



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1.5 Products covered by this surveillance			
Category	Product	PID Number	Version/issuing date
1.6			
Name of IECEE Factory Inspector		Date of surveillance (YYYY-MM-DD)	



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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
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Does this verification also include the verification of any Certification Marks?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Description of procedure (<i>one or more boxes may be ticked</i>)			
<input type="checkbox"/> Rely on suppliers' out-going inspection/ suppliers' quality plan <input type="checkbox"/> Audit conducted at the suppliers' premises <input type="checkbox"/> Supplier control based on manufacturers' check list <input type="checkbox"/> Conduct own incoming inspection <input type="checkbox"/> Identification check <ul style="list-style-type: none"> <input type="checkbox"/> Checked for correct type <input type="checkbox"/> Comparison to a reference <input type="checkbox"/> Rating <input type="checkbox"/> Certification mark <input type="checkbox"/> Certificate of conformity <input type="checkbox"/> Others (<i>please give details</i>) <input type="checkbox"/> Details given on <u>Inspector's Evaluation Informative page</u>			
Description of the procedure or ref. of documented procedure & revision or issue date:			
<input type="checkbox"/> Details given on <u>Inspector's Evaluation Informative page</u>			
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
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4 Is there a procedure covering the way to handle non-conforming components and materials?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Description of the procedure or ref. of documented procedure & revision or issue date:			
<input type="checkbox"/> Details given on <u>Inspector's Evaluation Informative page</u>			
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
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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2.6 Are records of the incoming inspection maintained and satisfactory?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.7 Are records kept at least for the period between two Surveillance visits?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3 Production Control, Inspection and Routine Tests

3.1 Are the quality assurance and manufacturing personnel adequately briefed on their duties?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.4 Is there a procedure to ensure that all products will be tested or inspected according to the manufacturer's requirements?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Description of the procedure or ref. of documented procedure & revision or issue date: <input type="checkbox"/> Details given on <u>Inspector's Evaluation Informative page</u>			
3.5 Is the production process controlled at appropriate stages?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.6 Are products inspected at appropriate stages of manufacture? (Production Line Inspection)	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Give details of all tests and inspections performed by the manufacturer and enter in the <u>routine test table</u> on the Test Data Sheet</i>			
3.7 Do the Routine Tests entered on the Test Data Sheet sufficiently cover all routine test requirements?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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3.8 Is there a procedure covering the way to handle non-conforming products?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Description of the procedure or ref. of documented procedure & revision or issue date: <input type="checkbox"/> Details given on <u>Inspector's Evaluation Informative page</u>			
Procedure of handling non-conforming products (<i>one or more boxes may be ticked</i>) <input type="checkbox"/> Automated segregation process <input type="checkbox"/> Manual segregation process <input type="checkbox"/> Non-conforming products are destroyed <input type="checkbox"/> Non-conforming products are repaired <input type="checkbox"/> Others (<i>please give details</i>) <input type="checkbox"/> Details given on <u>Inspector's Evaluation Informative page</u>			
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
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.10 Are repaired and reworked (corrected) items <u>again</u> subjected to appropriate tests/inspections in accordance with procedures?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Description of the procedure or ref. of documented procedure & revision or issue date: <input type="checkbox"/> Details given on <u>Inspector's Evaluation Informative page</u>			
3.11 Are test records of the routine tests maintained and satisfactory?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.12 Are records kept at least for the period between two Surveillance visits?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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

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



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

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.



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6 Calibration of Safety Test and Measuring Equipment

6.1 Is test and measuring equipment used calibrated or verified?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>(one or more boxes may be ticked)</i>			
<input type="checkbox"/> Verification done by the manufacturer by means of calibrated reference equipment <input type="checkbox"/> Calibration done by: <ul style="list-style-type: none"> <input type="checkbox"/> Laboratory accredited according to ISO/IEC 17025 <input type="checkbox"/> Test equipment manufacturer/supplier <input type="checkbox"/> National metrology institute <input type="checkbox"/> Other <i>(please give details)</i>			
<i>Provide details for at least one electrical measuring equipment:</i> 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
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>(one or more boxes may be ticked)</i>			
Calibration of reference equipment done by: <ul style="list-style-type: none"> <input type="checkbox"/> Laboratory accredited according to ISO/IEC 17025 <input type="checkbox"/> Test equipment manufacturer/supplier <input type="checkbox"/> National metrology institute <input type="checkbox"/> Other <i>(please give details)</i> 			
6.3 Is the equipment provided with a label or similar indicating the next calibration/verification due date?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.4 Do the calibration/verification records indicate that calibration is traceable to national/international standards of measurement?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.5 Are the records for calibration/verification of test and measuring equipment maintained and satisfactory?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.6 Are records kept at least for the period between two Surveillance visits?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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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
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.2 Has it been verified that the components and materials from PID are used?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>List any component not listed on the PID on the <u>Inspector's Evaluation Informative page</u>. Unacceptable component changes shall be listed on the <u>Non Conformity Sheet</u></i>			
9.3 Has it been verified that the product is produced as described in the PID?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>List any constructional change/deviation from the PID, on the <u>Inspector's Evaluation Informative page</u>. Unacceptable constructional changes/deviations from the PID shall be listed on the <u>Non Conformity Sheet</u></i>			



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10 Follow up on corrective actions from previous surveillances

Are all corrective actions from previous surveillances completed and implemented?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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)



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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 <input type="checkbox"/>	N/A <input type="checkbox"/>	NO <input type="checkbox"/>
14.2 Are the received complaints reviewed on a regular basis regarding whether they are related to single errors or system errors?	YES <input type="checkbox"/>	N/A <input type="checkbox"/>	NO <input type="checkbox"/>
<input type="checkbox"/> Actual case checked <input type="checkbox"/> Procedure checked			
14.3 Are corrective actions and decisions regarding customer complaints recorded?	YES <input type="checkbox"/>	N/A <input type="checkbox"/>	NO <input type="checkbox"/>
<input type="checkbox"/> Actual case checked <input type="checkbox"/> Procedure checked			
14.4 Is the originator of the complaint informed about the handling and the result of the complaint?	YES <input type="checkbox"/>	N/A <input type="checkbox"/>	NO <input type="checkbox"/>
<input type="checkbox"/> Actual case checked <input type="checkbox"/> Procedure checked			
14.5 Are the records of customer complaints maintained and satisfactory?	YES <input type="checkbox"/>	N/A <input type="checkbox"/>	NO <input type="checkbox"/>
14.6 Are records kept at least for the period between two Surveillance visits?	YES <input type="checkbox"/>	N/A <input type="checkbox"/>	NO <input type="checkbox"/>



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15 Control of product changes

15.1 Is reference information about the manufactured product(s) available?	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>(one or more boxes may be ticked)</i>			
<input type="checkbox"/> Set of drawings <input type="checkbox"/> Parts list <input type="checkbox"/> Product description / Product Information Document (PID) <input type="checkbox"/> Reference sample <input type="checkbox"/> Photo-documentation <input type="checkbox"/> Other specification <i>(please give details)</i> <input type="checkbox"/> Details are given on <u>Inspector's Evaluation Informative page</u>			
15.2 Is this reference under control of the:	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Certificate holder <input type="checkbox"/> Manufacturer <input type="checkbox"/> 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? <i>(if any)</i>	YES	N/A	NO
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Description of the procedure or ref. of documented procedure & revision or issue date: <input type="checkbox"/> Details given on <u>Inspector's Evaluation Informative page</u>			
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
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Description of the procedure or ref. of documented procedure & revision or issue date: <input type="checkbox"/> Details given on <u>Inspector's Evaluation Informative page</u>			
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
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> No changes <input type="checkbox"/> Changes authorized by the certificate holder			

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16 (Reserved for future use)

17 Inspector's evaluation

17.1	<i>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.</i>		
17.2	Findings and recommendations to the responsible NCB		
1	No unsatisfactory findings.	No unsatisfactory findings.	<input type="checkbox"/>
		Product certification (if any) may continue.	
2	Minor unsatisfactory finding(s).	Manufacturer's corrective action(s) shall be checked at the next visit.	<input type="checkbox"/>
		Product certification (if any) may continue.	
3	Major unsatisfactory finding(s). Safety not directly affected.	Manufacturer shall confirm the corrective action(s).	<input type="checkbox"/>
		Product certification (if any) may continue after confirmation by the NCB. <i>(Special or early routine Surveillance recommended for checking corrective action(s)).</i>	
4	Critical unsatisfactory finding(s). Safety directly affected.	Repeated factory Surveillance recommended after the manufacturer has confirmed implementation of the corrective action(s). <i>(The corrective actions might include total re-evaluation of the product).</i>	<input type="checkbox"/>
		Product certification (if any) likely to be suspended by the NCB.	
The Manufacturer has to inform the Issuing NCB.			<input type="checkbox"/>
The result of this surveillance will be passed to the Issuing NCB.			<input type="checkbox"/>



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17.3	Attachments added	YES	NO
		<input type="checkbox"/>	<input type="checkbox"/>
Attachments: <i>For page control, please write the reference number in the header of each attachment page.</i>			
	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:			
<i>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.</i> <input type="checkbox"/> Printed copy provided <input type="checkbox"/> 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)			



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Signature Page	
Surveillance duration (in hours):	
Date:	
Inspector's name (printed letters)	Contact person's name (printed letters)
Signature <input type="checkbox"/> This report is an electronic report and is valid without signature	Signature <input type="checkbox"/> This report is an electronic report and is valid without signature
<input type="checkbox"/> For signature, see attached separate page	



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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:
	<input type="checkbox"/>	<input type="checkbox"/>	

Annex 1 Test Data Sheet – Routine Tests

<input type="checkbox"/> No production	
<input type="checkbox"/> 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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