

**CONTINUOUS SURVEILLANCE INSPECTION OF FACTORY PRODUCTION CONTROL
REPORT
n° EFR-17-003410**

CE MARKING FIRE DAMPERS

System of assessment and verification of constancy of performance level 1

Date of inspection	21 st and 22 nd November 2017	
Notified body	EFFECTIS France Route de l'orme des merisiers Espace technologique - Bâtiment Apollo F – 91193 SAINT-AUBIN	Identification n° : 1812
Inspection body	EFFECTIS France Voie Romaine F-57280 Maizières-lès-Metz	
Holder	KLIMAOPREMA Gradna 78A 10430 SAMOBOR	
Inspected Units	KLIMAOPREMA Gradna 78A 10430 SAMOBOR	KLIMAOPREMA Industrijska 19 35400 NOVA GRADISKA
Products ref.	Circular fire dampers ref. FDC25 and FDC40 <i>Certificate n° : 1812-CPR-1161</i> Rectangular fire dampers FD25 and FD40 <i>Certificate n° : 1812-CPR-1162</i>	

1. SUBJECT OF THE REPORT

Inspection of production facility and its subcontractors (if relevant) of factory production control in accordance with the harmonized technical specifications, in application of the EU Construction Products Regulation 305/2011 of March 9th, 2011.

Harmonized technical specifications	: EN 15650 (2010)
Certification rules	: General rules for issuing the CE marking attestation of conformity - DAP 08 F Specific rules for issuing the CE marking attestation of conformity of smoke control dampers ref. DAP 17 E
Specific documents	: Guidance Document TF N 548 rév. 1 Position Paper NB-CPR/AG/03/002r3 et NB-CPR/AG/03/004 Test and/or classification report(s) justifying declared performances
Product range concerned by the inspection	: Circular fire dampers ref. FDC25 and FDC40 Rectangular fire dampers FD25 and FD40
Inspection type	: Continuous surveillance of FPC 2018
Inspection date and duration	: 21 st and 22 nd November 2017 (1 day on each plant)

2. PERSONS PRESENT DURING THE INSPECTION

KLIMAOPREMA	Mr Robert OBRAZ – Quality Manager Mr Ivan DUNAJ – QC Engineer
	: Mr Josip VIDUK – Technical Office Mr Goran DOLENEC – Leader of Technical Sector
EFFECTIS France	: Mr REMOIVILLE Xavier – FPC Inspector

3. REPORT

3.1. CHANGES IN FACILITY SINCE PREVIOUS EVALUATION

- *Human resources : + 1 person on the HR service*
- *Product: No changes*
- *Purchasing: No changes*
- *Subcontracting: No changes*
- *Factory Production Control: No changes*
- *Manufacturing Equipments: New Opening/closing mechanism line in SAMOBOR*

3.2. TOPICS EVALUATED DURING INSPECTION

<i>Topic</i>	<i>Evaluated (E) / Non Evaluated (NE)</i>	<i>Comments (if any)</i>
Organisation and management		
Responsibilities et Authority	E	/
Direction review	E	/
Production		
Processes and Methods: job description and provisions (methods, equipment, environment, material, means), observation and interview	E	/
Means : maintenance of tools and equipments	E	/
Means : validity of tools and equipments	E	/
Production Control		
Provisions and results of components and raw materials reception controls (including collection of material certificates, certificate of compliance of incoming materials...)	E	/
Provisions and results of controls carried out during manufacture	E	/
Provisions and results of checks on finished products	E	/
Personnel		
Skills of management	E	/
Skills of support personnel (metrology, maintenance, ...)	E	/
Skills of production personnel	E	/
Metrology		
Processes and Methods: description of the tasks and provisions regarding the management of measurement, control and testing equipments	E	/
Validity of measurement, control and testing equipments	E	/
Conception		
Provisions regarding the control of the design means (configuration, performance management, derivatives and options, ...)	E	/
Validity of design means	E	/
Records and documentation of the quality management system		
Description of rules for document management (approval, modification, new documents' distribution, ...)	E	/
Description of rules regarding records management (duration and location of storage, external documents' management, ...)	E	/
Products' preservation		
Provisions regarding storage, delivery, handling, traceability	E	/
Purchasing, subcontracting		
Provisions regarding purchasing / components' subcontracting	E	/

Topic	Evaluated (E) / Non Evaluated (NE)	Comments (if any)
Non-compliances and Claims Provisions regarding non-compliances' and claims' management	E	/
Essential external documentation Presence of the potential certification rules, and of the technical specifications in force	E	/
Analyze and inclusion of the developments of the relevant external documentation	E	/
Compliance of the inspected product to the type testing	E	/

Referential	NF EN 15650	
Article	§ 6.3	Appendix E
Disposition checked	√	√

Referential	General EC certification rules ref. DAP 08	
Article	Appendix A	
Disposition checked	√	

3.3. DOCUMENTS EVALUATED DURING THE INSPECTION

The following documents were evaluated during the inspection.

Document ref.	Revision	Document title	Requirements of the standard and/or the certification rules
OB-6.2.0.3.01	03/2017	Organigramme	NF EN 15650 §6.3 DAP 08F Annexe A
-	-	ISO 9001v2015 certificate (valid until 03.03.2018) by DNV-GL	
-	18/04/17	Quality policy	
-	18/10/16	Quality documentation list	
-	22/02/16	Revue de direction	
-	H	Quality manual	
OP-8.3.0.1	C	Nonconformity procédure	
OP-8.5.2.1	C	Corrective action procedure	
OP-8.5.3.1	C	Preventive actions procédure	
OP-4.2.3.1	D	Documentation procédure	
OP-4.2.4.1	1	Recording procedure	
-	2017	Competencies Matrix	
OB-8.3.0.01	B	No conformity formular	
-	2016	General overview of non-conformity treatment	
OB-7.6.0.1	C	List of Measurement and control equipment	
-	-	External report of calibration (SISTEMSKA TECHNIKA)	

Document ref.	Revision	Document title	Requirements of the standard and/or the certification rules
-	-	Software INFRA (purchasing) and SMARTPROv2 (manufacturing)	NF EN 15650 §6.3
RU-8.2.4.14/5	A	Cutting machine instruction	DAP 08F Annexe A
RU-8.2.4.1	A	Incomings goods control	
RU-8.2.4.14/4	A	NAPER plate contrôle instruction on machine ROVER24 (BIESSE)	
RU-8.2.4.8/36	B	Work instruction (manufacturing and control) :FD25 and FD40	
RU-8.2.4.8/32	B	Work instruction (manufacturing and control) :FDC25	
RU-8.2.4.8/33	B	Work instruction (manufacturing and control) : FDC40	
-	-	Cycling test bench and Leakage test bench	
-	-	Purchasing order (NAPER)	
I-4040/16-1	-	Fire resistance test report (FDC40)	
I-4049/16-1	-	Fire resistance test report (FDC25)	
-	-	Cycling control report	
RU-8.2.4.1	B	Control procedure	
OP-8.2.2.1	1	Internal audit procedure	
-	-	Internal audit schedule	
-	2017	Training plan of the internal auditors	
RU-7.6.0.4	A	Calibration instruction of calipers	
RU-7.6.0.5	A	Calibration instruction of meter	
OB-7.6.0.2	2017	Internal calibration report	
-	2017	External calibration report	
RU-8.2.4.8/41->43	C	Mechanism assembly instruction	
-	01/02/17	List of people able to do the Mechanism assembly	
OP-7.4.0.1	E	Purchasing procedure	
RU-7.4.0.1	A	Supplier evaluation	
-	2017	List of evaluated supplier	
-	2017	Presentation of the manufacturing means, conception means, purchasing, no conformity treatment (internal/external) and final control test bench (cycling and leakage)	

Possible comments regarding the Declaration of Performance (DoP) and the CE-marking label (document under the responsibility of the holder / applicant): The allocated duration to this inspection has not allowed to perform a complete analyze of the accompanying documents.

3.4. DEVIATIONS

See the end of Factory Production Control (FPC) Inspection form in Appendix 2 of this report.

Comment: deviation not presenting particular risk towards the FPC, but which must be taken into account before the continuous surveillance of the FPC.

Minor deviation: deviation not presenting effective risk towards the FPC if corrective actions are engaged into a limited period.

Major deviation: deviation presenting an immediate influence towards the functioning and effectiveness of the FPC so that a non conformity product could be placed on the market, and/or with a requirement.

During the inspection, 4 deviations were found.

The corresponding forms of distance are listed by process of activity in the chapter 4 Conclusions and are reproduced in Appendix 3 of the present report.

3.5. ANALYSIS OF MANUFACTURER’S ANSWERS TO POSSIBLE DEVIATIONS OF THE PREVIOUS INSPECTION :

Reference of the previous evaluation report:

The answers to the deviations F1, F2, F3, F4, F5, F6 and F7 are satisfactory, see closed sheets dated 22.11.2017 in Appendix 1 to this report.

The implementation of corrective actions has been verified.

3.6. STRENGTHS AND SENSITIVE ISSUES OF THE INSPECTED COMPANY

Strengths:

- Material certificate of the steel systematically requested to the supplier and recorded
- Monthly report of the ongoing NC
- Human resources
- Manufacturing means
- After sales services and claims managed by France Air

Sensitive issues and improvement possibilities:

- Independence of the Quality Manager during his internal audits

4. CONCLUSIONS

During the inspection, the following deviations were found (see details on appendix):

Process of activity	Deviation n°		
	MAJOR deviation	MINOR deviation	Comment
Organisation and management	-	-	-
Production	-	-	-
Production control	-	D2	-
Personnel	-	D3	-
Metrology	-	D4	-
Design	-	-	-
Records, documentation of the quality system	-	D1	-
Products' preservation	-	-	-
Purchasing, subcontracting	-	-	-
Claims and non-compliances	-	-	-
Number of deviations (by type)	0	4	0
Total number of deviations		4	

5. APPRECIATION / DEVIATION(S) ANALYSIS

The responses to the deviations observed during this inspection, conducted in accordance with the requirements of harmonized technical specifications mentioned in chapter 1, under the EU Construction Products Regulation No. 305/2011, were not available at the time of writing this report, the conformity of factory production control system of the ranges of products listed in §1 requires the satisfaction of the deviations listed in chapter 4 of this report.

Maizières-lès-Metz, the 06th december 2017



Xavier REMOIVILLE
FPC Inspector