



REPORT ON EU SURVEILLANCE
of an approved Quality System
pursuant to Regulation (EU) 2016/426, Annex III, Point 3.4 (MODULE D)
and
Directive 92/42/EEC, (Government Regulation 25/2003 Coll.)
No. 40-11668

Product: Hot water boilers burning gas

Type designation: see chapter I.

Versions: see chapter I.

Customer: AIC S.A.
ul. Rdestowa 41
81-577 Gdynia
POLAND

Manufacturer: AIC S.A.
ul. Rdestowa 41
81-577 Gdynia
POLAND

Manufacturing plant: AIC S.A.
ul. Tczewska 22
83-000 Pruszcz Gdański
Polsko – Poland

Report issue date: 2021-08-24
Audited period: 2019/09 ÷ 2021/08

Distribution list: 1 copy to the Customer
1 copy to the Engineering Test Institute



Verification of conformity of products with the type described in EU type-examination certificate has been carried out pursuant to Act 90/2016 Coll., on conformity assessment of products when made available on the market, as amended, and in accordance with the Manufacturer's choice pursuant to REGULATION (EU) 2016/426 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (procedure pursuant to Annex III, Point 3 – MODULE D) and Directive 92/42/EEC (procedure pursuant to Annex IV, module D, Point 3.3) hereinafter called BED.

I. Initial source materials for performance of audit

Product Identification Number (PIN)	Product	Type	Certificate no.
CE-1015CT0633	Hot-water boilers burning gas	Nesta 120 (N 120), Nesta 160 (N 160), Nesta 200 (N 200), Nesta 250 (N 250)	E-30-00473-18-rev.2 (GAR)
-	Hot-water boilers burning gas	Nesta 120 (N 120), Nesta 160 (N 160), Nesta 200 (N 200), Nesta 250 (N 250)	E-30-00474-18-rev.2 (BED)
CE-1015CU0746	Hot-water condensing boiler	Nesta Plus 280 (N 280), Nesta Plus 420 (N 420), Nesta Plus 570 (N 570), Nesta Plus 840 (N 840)	1015-GAR-02049-19 rev.2 (GAR)
-	Hot-water condensing boiler	Nesta Plus 280 (N 280),	1015-BED-02047-19-rev.2 (BED)
CE-1015 DL0796	Floor-standing condensing storage water heater	Texas 99 (TX 99), Texas 230 (TX 230)	1015-GAR-01799-20 rev. 01 (GAR)
063CU3550	Condensing central heating boilers	NESTA CHROME N 100 WH NESTA CHROME N 120 WH NESTA CHROME N 60 WH NESTA CHROME N 80 WH	19GR0387/00 (GAR) Issued by Kiwa*
0063CU3550	Condensing central heating boilers	NESTA CHROME N 100 WH NESTA CHROME N 120 WH NESTA CHROME N 60 WH NESTA CHROME N 80 WH	19BE0051/00 (BED) Issued by Kiwa*
	Floor-standing condensing boiler	Nesta Plus 280 (N 280 W), Nesta Plus 420 (N 420 W), Nesta Plus 570 (N 570 W), Nesta Plus 840 (N 840 W), Nesta Plus 350 (N 350 W), Nesta Plus 700 (N 700 W), Nesta Plus 1080 (N 1080 W), Nesta Plus 1260 (N 1260 W)	See previously conducted contract B-70955/30 (GAR, BED)

II. Objectives, method and scope of the quality system audit

The audit objective has been to ascertain whether the Manufacturer takes all actions necessary to assure that the production process including the final inspection, tests of finished product before shipment and the method of placing the products on the market ensures conformity of the appliances with the type described in the EU type-examination certificate and with the essential requirements of the EU Regulation, and whether the Manufacturer duly fulfills its obligations arising out of the approved quality system.

The Notified Body has carried out the audit of the production quality assurance system pursuant to Regulation (EU) 2016/426, procedure pursuant to Annex III, Point 3.4 and and Directive 92/42/EEC (procedure pursuant to Annex IV, module D, Point 3.3) at the manufacturing plant:, at the manufacturing plant: AIC S.A., ul. Tczewska 22, 83-000 Pruszcz Gdański , Poland



Person who performed the quality system audit:

Test Engineer of the SZU in Brno Heat and Environment-Friendly Equipment Test Station: Bc. Jan Hnilica

III. Quality system audit – Results

- Point 3.4, Annex III Module D, Regulation (EU) 2016/426

Required technical documentation	Submitted documentation	Evaluation *)		
		C	NC	O
Quality management system documentation:	<ul style="list-style-type: none"> Quality Manual Certificate to ISO 9001, issued by TÜV Rheinland, valid until 2022-05-29 Metrological rules, calibration sheets Declaration of conformity Organizational scheme Description of positions Drawing documentation + certificates issued for audited appliances Product accompanying technical documentation Quality goals, staff qualification requirements, used standards and other related documents Evaluation of suppliers Documents control manual, change of documents manual, education plans Control of documents Internal audits, plans, records and evaluation Technological procedures, checking and testing procedures, suppliers evaluation Internal information system + examples of usage of the system Systems in development (for example improving of already existing appliances) Manuals, packaging, service description 	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a) The quality system documentation		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) The quality records, such as inspection reports, and test data, calibration data, qualification reports on the personnel concerned, etc.		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Documentation relating to certified types		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*) Explanation for evaluation:

- C** – conformity (documentation is complete and satisfactory)
NC – nonconformity (documentation is incomplete and/or unsatisfactory)
O – omission (deviation), remove within the set deadline and no later than the next surveillance

If a nonconformity (NC) is detected, a Nonconformity / Nonconformities Record must be issued.

The system is evaluated as satisfactory if no requirement has been classified as „NC“ and if the occurrence of requirements classified as „O“ is less than 20% of all responses.

Notice:

Audit evidence is based on sampling of available information. Therefore, there is an element of uncertainty in the assessment and those acting on the conclusions of the assessment should be aware of this uncertainty. The long-distance audit may further deepen the uncertainty of sampling.



Evaluation:

Initial records from the audit are set out in Check-list no. 40-11668 of 2021-08-19.

All the regulations, documentation and requirements adopted by the manufacturer are documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programs, plans, manuals and records.

IV. Conclusion

The Notified Body has audited and assessed the quality system. The quality system **satisfies** the requirements laid down in Regulation (EU) 2016/426, Annex III, Point 3 (MODULE D) and Directive 92/42/EEC (Annex IV, module D, Point 3.3.).

The Manufacturer shall affix to each appliance the conformity mark completed with the identification number of the Notified Body responsible for EU surveillance and last 2 digits (XX) of the year in which the CE marking was affixed:



The Manufacturer shall keep informed the Notified Body, which has approved the quality system, of any updating of the quality system relating to changes induced, for instance, by new technologies and quality concepts. Also the manufacturer should obey these requirements:

- The manufacturer will fulfill the obligations arising out of the quality system as approved and will maintain it so that it remains adequate and efficient.
- The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

At least once in two years, the Notified Body performs an EU surveillance to make sure that the Manufacturer maintains and operates the approved system of quality. In addition, the Notified Body may pay unexpected visits to the Manufacturer.



V. A list of other relevant documentation

- Order D-60874/02 of 2019-09-05
- Contract D-60874/02/40 of 2019-11-11
- Amendment No. D-60874-02.D1
- Amendment No. D-60872-02.D2
- Act 90/2016 Coll., on conformity assessment of products when made available on the market, as amended
- REGULATION (EU) 2016/426 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC
- Council Directive 92/42/EEC on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels
- Check-list no. 40-11668 of 2021-08-19
- Documents mentioned in Chapters I and III

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