

L.N. 348 of 2007

**PRODUCT SAFETY ACT
(CAP. 427)**

**Efficiency Requirements for New Hot-Water Boilers Fired with
Liquid or Gaseous Fuels (Implementing Measures)
Regulations, 2007**

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, the Minister for Competitiveness and Communications, on the advice of the Malta Standards Authority, has made the following regulations:-

1. (1) The title of these regulations is the Efficiency Requirements for New Hot-Water Boilers Fired with Liquid or Gaseous Fuels (Implementing Measures) Regulations, 2007. Citation and commencement.

(2) These regulations shall be interpreted in terms of the Framework for the Setting of Ecodesign Requirements for Energy-Using Products Regulations, 2007, herein after referred to as “the Ecodesign Regulations”.

(3) (a) These regulations implement the requirements of Council Directive 92/42/EEC⁽¹⁾ of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels as amended by

i.) Directive 2004/8/EC on the promotion of cogeneration based on a useful heat demand in the internal energy market and amending Directive 92/42/EEC and,

ii.) Directive 2005/32/EC of the European Parliament and of the Council of 6th July 2005 Establishing a Framework for the Setting of Ecodesign Requirements for Energy-Using Products and Amending Council Directive 92/42/EEC and Directives 96/57/EC⁽²⁾ and 2000/55/EC⁽³⁾ of the European Parliament and of the Council.

¹ OJ No. L167, 22-06-1992, p. 17-28

² OJ No. L236, 18-09-1996, p. 36-43

³ OJ No. L279, 01-11-2000, p. 33-39

(b) Council Directive 92/42/EEC falls under the SAVE programme concerning the promotion of energy efficiency in the Community.

(4) These regulations constitute an implementing measure with in the meaning of the principal regulations with regard to energy efficiency during use of boilers.

(5) These regulations shall come into force on the 11th August, 2007.

Scope and application.

2. (1) These regulations determine the efficiency requirements applicable to new hot-water boilers fired by liquid or gaseous fuels with a rated output of no less than 4 kW and no more than 400 kW, hereinafter called “boilers”.

(2) The following shall be excluded from the scope of these regulations:

a) hot-water boilers capable of being fired by different fuels including solid fuels,

b) equipment for the instantaneous preparation of hot water,

c) boilers designed to be fired by fuels the properties of which differ appreciably from the properties of the liquid and gaseous fuels commonly marketed (industrial waste gas, biogas, etc),

d) cookers and appliances designed mainly to heat the premises in which they are installed and, as a subsidiary function, to supply hot water for central heating and sanitary hot water,

e) appliances with rated outputs of less than 6 kW using gravity circulation and designed solely for the production of stored sanitary hot water,

f) appliances with rated outputs of less than 6 kW using gravity circulation and designed solely for the production of stored sanitary hot water,

g) boilers manufactured on a one-off basis,

h) cogeneration units as defined in Directive 2004/8/EC of the European Parliament and of the Council of 11 February 2004

on the promotion of cogeneration based on useful heat demand in the internal energy market ⁽⁴⁾.

3. For the purposes of these regulations, the definitions of the Ecodesign Regulations as well as the following definitions shall apply: Definitions.

“Appliance” means the boiler body designed to have a burner fitted, or the burner designed to be fitted to a boiler body;

“Average temperature of the boiler water” means the average of the water temperatures at the entry and exit of the boiler;

“Back-boiler” means a boiler designed to supply a central-heating system and to be installed in a fireplace recess as part of a back boiler/gas fire combination,

“Boiler” means the combined boiler body-burner unit, designed to transmit to water the heat released from burning;

“Boiler to be installed in the living space” means a boiler with an effective rated output of less than 37 kW, designed to provide heat to the part of the living space in which it is installed by means of the emission of heat from the casing having an open expansion chamber, supplying hot water using gravity circulation; such boilers shall bear on their casings the explicit indication that they must be installed in living space;

“Effective rated output (expressed in kW)” means the maximum calorific output laid down and guaranteed by the manufacturer as being deliverable during continuous operation while complying with the useful efficiency indicated by the manufacturer;

“Gas condensing boiler” means a boiler designed to condense permanently a large part of the water vapour contained in the combustion gases;

“Low-temperature boiler” means a boiler which can work continuously with a water supply temperature of 35 to 40 °C, possibly producing condensation in certain circumstances, including condensing boilers using liquid fuel;

“Part load (expressed in %)” means the ratio between the effective output of a boiler operating intermittently or at an output lower than the effective rated output and the same effective rated output;

“Standard boiler” means a boiler for which the average water temperature can be restricted by design;

“Useful efficiency (expressed in %)” means the ratio between the heat output transmitted to the boiler water and the product of the net calorific value at constant fuel pressure and the consumption expressed as a quantity of fuel per unit time.

Placing on the market.

4. (1) With regard to placing on the market and putting into service mentioned in the principal regulations the following shall apply:

(a) Boilers shall satisfy the efficiency requirements set out in Schedule I section 1 hereto, and the conditions for entry into service laid down on the basis of local climatic conditions and the energy and the occupancy characteristics of the buildings;

(b) However, where back-boilers and/or boilers that are to be installed in the living space are widely installed at the date of the adoption of the Efficiency Requirements for New Hot-Water Boilers Fired with Liquid or Gaseous Fuels Regulations, 2002, the Malta Standards Authority shall authorise their entry into service, provided that their efficiency both at rated output and at 30% part load is not more than 4% below the requirements laid down in Schedule I section 1 hereto, for standard boilers;

(c) In the case of boilers with a dual function, that of heating premises and also providing sanitary hot water, the efficiency requirements referred to in Schedule I section 1 hereto, concern the heating function only;

(d) Where boilers are subject to other regulations concerning other aspects which also provide for the affixing of the ‘CE’ marking, the latter shall indicate that the boilers in question are also presumed to conform to the provisions of those regulations.

(2) Where one or more of these regulations allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those regulations applied by the manufacturer. In this case, particulars of the regulations applied, as published in the OJ, must be given in the documents, notices or instructions required by the regulations and accompanying the boilers.

Conformity assessment procedures.

5. (1) With regard to the conformity assessment procedures mentioned in the Ecodesign regulations the conformity of series-produced boilers shall be certified by:

- a) the examination of the efficiency of a boiler type in accordance with module B as described in Schedule II hereto, and
- b) a declaration of conformity to the approved type in accordance with module C, D or E as described in Schedule III hereto.

For boilers burning gaseous fuels, the procedures for assessing the conformity of their efficiency shall be those used to assess conformity to the safety requirements laid down in Directive 90/396/EEC⁴ on the approximation of the laws of the Member States relating to appliances burning gaseous fuels.

(2) Where appliances marketed separately are placed on the market, they must bear the CE marking and be accompanied by the declaration of conformity, which defines the parameters enabling them after assembly to achieve the useful efficiency levels laid down in Schedule I hereto.

6. With regard to notified bodies mentioned in the principal regulations a notified body shall also fulfil the criteria listed in Schedule IV hereto. Notified Bodies.

7. The Efficiency Requirements for New Hot-Water Boilers Fired with Liquid or Gaseous Fuels Regulations, 2002 are hereby being repealed. Repeals L.N. 62 of 2002.

⁴ L.N. 52 of 1996: Appliances Burning Gaseous Fuels, implementing Directive 90/396/EEC (OJ No. L 196, 26.07.90, p. 15-29).

Schedule I

Based on Article 5 of directive 92/42/EC

THE EFFICIENCY REQUIREMENTS

1. Boilers must comply with the following useful efficiency requirements:
 - at rated output, i.e. operating at rated output P_n expressed in kW, at an average boiler-water temperature of 70 °C , and
 - a part load, i.e. operating at 30 % part load, at an average boiler-water temperature which varies according to the type of the boiler.

The useful efficiency requirements to be complied with are set out in the following table:

Type of boiler	Range of power output	Efficiency at rated output		Efficiency at partload	
		Average boiler-water temperature (in °C)	Efficiency requirement expressed (in %)	Average boiler-water temperature (in °C)	Efficiency requirement expressed (in %)
Standard boilers	4 to 400	70	$\geq 84 + 2 \log P_n$	≥ 50	$\geq 80 + 3 \log P_n$
Low-temperature boilers (*)	4 to 400	70	$\geq 87,5 + 1,5 \log P_n$	40	$\geq 87,5 + 1,5 \log P_n$
Gas condensing boilers	4 to 400	70	$\geq 91 + 1 \log P_n$	30 (**)	$\geq 97 + 1 \log P_n$

(*) Including condensing boilers using liquid fuels

(**) Temperature of boiler water-supply

2. The harmonized standards relating to the requirements of these regulations drawn up under mandate from the Commission in accordance with directive 83/189/EEC⁵ and 88/182/EEC⁶ shall determine, *inter alia*, the verification methods valid for production and measurements.

⁵ OJ No. L 109, 26.04.83, P. 08-12.

⁶ OJ No. L 81, 26.03.88, P. 75.

Appropriate tolerances must be incorporated in the efficiency levels.

Schedule II

Based on Annex III of directive 92/42/EC

EC-TYPE EXAMINATION

Module B: EC type-examination

1. This module describes that part of the procedure by which a notified body ascertains and attests that an example, representative of the production envisaged, meets the relevant provisions of these regulations.
2. The application for EC type-examination is lodged by the manufacturer or his authorized representative with a notified body of his choice.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, the name and address in addition,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documents, as described in section 3 of this Module.

The applicant must place at the disposal of the notified body an example representative of the production envisaged, hereinafter called 'type'. The notified body may request further examples if needed for carrying out the test programme.

3. The technical documents must enable the conformity of the appliance with the requirements of these regulations to be assessed. They must, as far as is relevant for such assessment, cover the design, manufacture and operation of the appliance and contain as far as is relevant for assessment:
 - a general type-description,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

- descriptions and explanations necessary for the understanding of the drawings and diagrams and the operation of the product,
- a list of the standards referred to in Schedule I paragraph 2 hereto, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of these regulations where the standards referred to in Schedule I hereto, have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

4. The notified body must:

- 4.1. examine the technical documents, verify that the type has been manufactured in conformity with those documents and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in paragraph 2 of Schedule I hereto, as well as the components which have been designed without applying the relevant provisions of those standards;
- 4.2. perform or have performed the appropriate examinations and necessary tests to check whether, where the standards referred to in paragraph 2 of Schedule I hereto have not been applied, the solutions adopted by the manufacturer meet the essential requirements of these regulations;
- 4.3. perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;
- 4.4. agree with the applicant the location where the examinations and necessary tests are to be carried out.

5. Where the type meets the relevant provisions of these regulations, the notified body issues an EC type-examination certificate to the applicant. The certificate contains the name and address of the manufacturer, the conclusion of the examination and necessary data for identification of the approved type.

A list of the relevant parts of the technical documents is annexed to the certificate and a copy kept by the notified body.

If the manufacturer or his authorized representative is refused a type certificate, the notified body must provide detailed reasons for such refusal.

Provision must be made for an appeals procedure.

6. The applicant informs the notified body that holds the technical documents concerning the EC type-examination certificate of all modifications to the approved appliance which must receive additional approval where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC type-examination certificate.
7. Each notified body must communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.
8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The Annexes to the certificates must be kept at the disposal of the other notified bodies.
9. The manufacturer or his authorized representative must keep with the technical documents copies of EC type-examination certificates and their additions for a period of at least 10 years after the last date of manufacture of the product concerned.

Where neither the manufacturer nor his authorized representative is established in Malta, the obligation to keep the technical documents available is the responsibility of the person who places the product on the market.

Schedule III

Based on Annex IV of directive 92/42/EC

CONFORMITY TO TYPE AND QUALITY ASSURANCE

Module C: Conformity to type

1. This module describes that part of the procedure whereby the manufacturer or his authorized representative ensures and declares that the appliances concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of these regulations that apply to them. The manufacturer or his authorized representative shall affix the CE marking to each appliance and draw up a written declaration of conformity.
2. The manufacturer must take all measures necessary to ensure that the manufacturing process assures the conformity of the manufactured appliances with the type as described in the EC type-examination certificate and with the efficiency requirements of the regulations.
3. The manufacturer or his authorized representative must keep a copy of the declaration of conformity for a period of at least 10 years after the last date of manufacture of the product concerned.

Where neither the manufacturer nor his authorized representative is established in Malta, the obligation to keep the technical documents available is the responsibility of the person who places the product on the market.

4. A notified body chosen by the manufacturer must perform or have performed examinations of the product at random intervals. A suitable sample of the finished products, taken on the spot by the notified body, is examined and appropriate tests, defined in the applicable standard or standards referred to in Schedule I paragraph 2 hereto, or equivalent tests are carried out to check the conformity of the product with the requirements of the corresponding directive. In the event of one or more samples of the products examined not conforming, the notified body must take the appropriate measures.

Module D: Production quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 of this Module, ensures and declares that the appliances concerned are in conformity with the type as described in the EC type examination certificate and satisfy the requirements of these regulations. The manufacturer or his authorized representative shall affix the CE marking to each appliance and draw up a written declaration of conformity. The CE marking is accompanied by the identification number of the notified body responsible for the checks referred to in section 4 of this Module.
2. The manufacturer must operate an approved quality system for production, final appliance inspection and testing as specified in section 3 of this Module. He is subject to the checks referred to in section 4 of this Module.
3. *Quality system*
- 3.1. The manufacturer lodges an application for assessment of his quality system with a notified body of his choice, for the appliances concerned.

The application must include:

- all relevant information for the appliance category envisaged,
 - the documents concerning the quality system,
 - the technical documents pertaining to the approved type and a copy of the EC type-examination certificate.
- 3.2. The quality system must ensure conformity of appliances with the type as described in the EC type-examination certificate and with the requirements of these regulations that apply to them.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documents must permit a consistent interpretation of the quality programmes, plans, manuals and quality records.

It must contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to appliance quality,
- the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means of monitoring the achievement of the required appliance quality and the effective operation of the quality system.

- 3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2 of this Module. It must presume conformity with those requirements in respect of quality systems that implement the relevant harmonized standard. The auditing team must have at least one member with experience of assessing the relevant product technology.

The assessment procedure includes an inspection visit to the manufacturer's premises.

The decision is notified to the manufacturer. The notification must contain the conclusions of the examination and the duly substantiated assessment decision.

- 3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and maintain it at an adequate and efficient level.

The manufacturer or his authorized representative must keep the notified body that has approved the quality system informed of any proposed change in the quality system.

The notified body must assess the changes proposed and decide whether the altered quality system will still satisfy the requirements referred to in point 3.2 of this Module or whether reassessment is required.

It must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

4. *Monitoring under the responsibility of the notified body*

- 4.1. The purpose of monitoring is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer must allow the notified body access for inspection purposes to the manufacturing, inspection, testing and storage premises and provide it with all necessary information, in particular:

- the quality system documents,

- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc..
- 4.3. The notified body must periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and provides an audit report to the manufacturer.
 - 4.4. Additionally the notified body may pay unannounced visits to the manufacturer.

During such visits the notified body may carry out tests or have them carried out to verify that the quality system is functioning correctly; if necessary, the notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.
 5. The manufacturer must, for a period of at least 10 years after the last date of manufacture of the product, keep at the disposal of the national authorities:
 - the document referred to in the second indent of point 3.1 of this Module,
 - the updating referred to in the second paragraph of point 3.4 of this Module,
 - the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4, and in point 4.3 and point 4.4 of this Module.
 6. Each notified body must give the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

Module E: Product quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 of this Module ensures and declares that the boilers and appliances are in conformity with the type as described in the EC type examination certificate.

The manufacturer or his authorized representative shall affix the CE marking to each boiler and appliance and draw up a written declaration of conformity.

The CE marking must be accompanied by the identification number of the notified body responsible for the checks referred to in section 4 of this Module.

2. The manufacturer must operate an approved quality system for final boiler and appliance inspection and testing as specified in section 3 of this Module. He must be subject to the checks referred to in section 4 of this Module.

3. *Quality system*

- 3.1. The manufacturer lodges an application with a notified body of this choice for the assessment of the quality system for his boilers and appliances.

The application must include:

- all relevant information for the boiler or appliance category envisaged,
- the quality system's documentation,
- the technical documents pertaining to the approved type and a copy of the EC type-examination certificate.

- 3.2. Under the quality system, each boiler or appliance is examined and appropriate tests as defined in the relevant standard(s) referred to in out in Schedule I hereto, or equivalent tests are carried out in order to verify its conformity with the relevant requirements of these regulations. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.

This quality system documentation must enable the quality programmes, plans, manuals and records to be interpreted in a uniform manner.

It must in particular contain an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
- the examination and tests that will be carried out after manufacture,
- the means of monitoring the effective operation of the quality system,
- quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

- 3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2 of this Module. It must presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard.

The auditing team must have at least one member with experience of assessing the relevant product technology. The assessment procedure must include an inspection visit to the manufacturer's premises.

The manufacturer must be notified of the decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

- 3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and maintain it at an adequate and efficient level.

The manufacturer or his authorized representative must keep the notified body which has approved the quality system informed of any proposed change in the quality system.

The notified body must assess the changes proposed and decide whether the altered quality system will still satisfy the requirements referred to in section 3.2 of this Schedule or whether a reassessment is required.

It must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

4. *Monitoring under the responsibility of the notified body*

- 4.1. The purpose of monitoring is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer must allow the notified body access for inspection purposes to the inspection, testing and storage premises and provide it with all necessary information, in particular:

- the quality system documentation,
- the technical documents,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

- 4.3. The notified body must periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.

- 4.4. Additionally, the notified body may pay unannounced visits to the manufacturer.

During such visits the notified body may carry out tests or have them carried out to verify that the quality system is functioning correctly; if necessary, the notified body must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, for a period of at least 10 years after the last date of manufacture of the boiler or appliance, keep at the disposal of the national authorities:
 - the documents referred to in the third indent of point 3.1 of this Module,
 - the changes referred to in the second paragraph of point 3.4 of this Module,
 - the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4, and in point 4.3 and point 4.4 of this Module.
6. Each notified body must forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

Schedule IV

Based on Annex V of directive 92/42/EC

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT FOR THE NOTIFICATION OF BODIES

1. The body, its director and the staff responsible for carrying out the verification tests may not be the designer, manufacturer, supplier or installer of appliances which they inspect, nor the authorized representative of any of those parties. They may not become either involved directly or as authorized representatives in the design, construction, marketing or maintenance of such boilers and appliances. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
2. The body and its staff must carry out the verification tests with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgment of the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
3. The body must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it must also have access to the equipment required for special verification.
4. The staff responsible for inspection must have:
 - sound technical and professional training,
 - satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
 - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
5. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests carried out or on the results of such tests.
6. The body must take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.
7. The staff of the body must be bound to observe professional secrecy (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under these regulations or any provision of national law giving effect to it.

