Regulation (EU) 2016/426 on appliances burning gaseous fuels (GAR)

Guidance Document: Questions & Answers on the transition from the Gas Appliances Directive to the Gas Appliances Regulation and on the GAR implementation

Glossary of terms and acronyms:

- GAD -Directive 2009/142/EC on appliances burning gaseous fuels (GAD);
- GAR -Regulation (EU) 2016/426/ on appliances burning gaseous fuels (GAR);
- NB - Notified Body;
- GAD-AC - Gas Appliances Directive -Advisory Committee;
- GAR-AC - Gas Appliances Regulation-Advisory Committee *(to be established);*
- EN - 'European standard' means a standard adopted by a European standardisation organization;
- hEN 'harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation (Note: A harmonised standard starts to give the legal effect called 'presumption of conformity' only once its reference has been published in the *OJEU*);
- ER - Essential Requirements;
- DoC - manufacturer's Declaration of Conformity;
- OJEU - *Official Journal of the European Union.*

Section 1: Certificates:

1. **Question: Will existing GAD EC type-examination certificates become invalid when the GAR applies?**

   Answer: Yes, for products to be placed on the market as from 21 April 2018.

   All GAD EC type-examination certificates will expire on 21 April 2018. This means that they will not be valid for the production of new appliances and fittings. The lack of time-limit of their validity is not relevant as GAD (on which they are based) will cease to exist on 21 April 2018 and GAR provides for some changes in relation to GAD.

   However, the GAD EC type-examination certificates will be relevant for appliances and fittings designed, constructed and placed on the market until 20 April 2018 under the GAD provisions.

2. **Question: Do GAD EC type-examination test reports stay valid?**

   Answer: Yes.

   GAD EC type-examination test reports remain valid provided that the design of the product tested remains unchanged. The GAD EC type-examination test reports can be used by a GAR notified body in the framework of the EU type-examination under the GAR to cover ERs which have remained unchanged in the GAR. This has to be checked by the GAR notified body, on a case-by-case basis.

3. **Question: Which ERs have changed and what is the impact**?

Answer:
It must be examined on a case-by-case basis which ERs applicable to an appliance/fitting have changed.

Most of the ER did not change in such a way that this affects the design and construction of the appliance and/or fitting. Some ERs of the GAD are reworded, some are new and some of them are updated in the GAR. It must be taken into account also that GAR introduces ERs on risk assessment and design principles requiring that the technical file referred to in point 1.3.1(c) of Annex III to GAR enables verification of compliance with e.g. ERs 1.2 and 1.3.

This could affect specific types of appliances/fittings certified under the GAD in their construction and design.

The manufacturer shall examine the relevance of the ERs to his products. The notified body has to examine this on a case-by-case basis.

4. **Question: Is a risk analysis needed?**

Answer: Yes.

ER 1.2 of Annex I to GAR requires explicitly the manufacturer to carry out a risk analysis in order to identify all possible risks that the appliance/fitting may pose for the safety and health of persons and domestic animals and for property and determine the applicable requirements so as to design and construct the appliance/fitting taking into account the results of this risk assessment and in accordance with the principles set out in ER 1.3.

In accordance with point 1.3.1c) of Annex III to GAR, an adequate analysis and assessment of the risks shall be part of the technical documentation to be submitted to the notified body by the manufacturer when lodging an application for EU type-examination.

The manufacturer must document the assessment on how he has addressed the risks identified during the risk analysis so as to ensure that the appliance/fitting complies with the essential requirements applicable to it and that it can operate safely and present no danger to persons, domestic animals and property when normally used.

Risks relevant to the risk analysis related to the GAR are (non-exhaustive list):

I: Safety:
- Explosion (gas or steam),
- Fire,
- Hot surface temperatures,
- Poisoning (combustion gases, water and food),
- Suffocation.
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II: Health of persons and domestic animals:
- Long term exposure to substances harmful to health

When designing and constructing the appliance, and when drafting the instructions, the manufacturer shall envisage not only the intended use of the appliance, but also the reasonably foreseeable use (as stated in GAR, Annex I, ER 1.4).

Following the risk analysis, the manufacturer shall select the most appropriate solution to cover the risk (as stated in GAR, Annex I ER 1.3), being either:

(a) eliminate or reduce risks as far as possible (inherently safe design and construction);
(b) take the necessary protection measures in relation to risks that cannot be eliminated;
(c) inform users of the residual risks due to any shortcomings of the protection measures adopted and indicate whether any particular precautions are required.

Existing technical specifications (e.g. hENs, if applicable) can be used to proof the most appropriate solution.

The above is also reflected in the Blue Guide 2016 which states on page 42: After this assessment (e.g.: meaning risk assessment) a manufacturer may then choose to apply specifications given in harmonised standards to implement "*risk reduction measures*" which are specified by harmonised standards. It is further stated that in risk related harmonization legislation, harmonized standards most commonly provide certain means to reduce or remove risks while manufacturers remain fully responsible for risk assessment to identify applicable risks and to identify applicable essential requirements in order to select suitable harmonized standards or other specifications.

5. **Question: Can a GAD certificate be used to cover Annex III, clause 1 (module B) of the GAR?**

Answer: No.

GAD will be repealed with effect from April 21st 2018. An EU type-examination certificate as required from 21 April 2018 on has to refer to the GAR.

6. **Question: can an EU DoC for the GAR be based upon a GAD module B certificate?**

Answer: No (see previous answer).

7. **Question: Does a new GAR EU type-examination certificate need to be issued from April 21st 2018?**

Answer: Yes.

Any previous certificate making reference to the GAD will cease to be valid with effect from 21 April 2018 for products to be placed on the market as from that date. From this date, EU type-examination certificates issued must only refer to the GAR.

However, it should be noted that a GAR notified body can begin issuing EU type-examination certificates before 21 April 2018 as soon as it appears in the NANDO.

8. **Question: Is an initial production inspection / audit performed by a notified body needed prior to issuing the EU type-examination certificate even if the EU type-examination certificate has a significant validity period?**

Answer: No.

An initial inspection is not part of the requirements listed under point 1 of Annex III (module B).

It has to be noted that Module B is an independent conformity assessment module taking place prior to production of the concerned type. Only if the type succeeds to pass the EU type-examination, the manufacturer can start manufacturing that product type. Modules C2, D and E

(production phase surveillance) require the notified body to perform periodic assessments.

9. **Question: When will the validity of the EU type-examination certificate count from?**

Answer:
The validity period of the EU type-examination certificates starts from the date of issue of the certificate. To facilitate the transition to the GAR, the answer to question 18 is relevant.

10. **Question: Can a notified body issue an EU type-examination certificate having a finite validity period without performing surveillance for this product according to module C2, D or E?**

Answer:
Yes, such an EU type-examination certificate can be issued as it is not necessary that the same NB performs the type examination and the surveillance control phase. There is no change to this regard between GAR and GAD.

The manufacturer has to inform the notified body who issued the EU type-examination certificate on modifications of the product design. This notified body should assess the impact of the modifications and determine if re-testing / updating of the EU type-examination certificate is needed.

Additionally, the notified body who issued the EU type-examination certificate must keep itself appraised of any changes in the generally acknowledges state of the art and take the necessary actions, if needed, in accordance with point 1.7 of Annex III to GAR.

Section 2: Harmonized Standards - Technical Knowledge:

11. **Question: Is the use of hENs that are cited in the *OJEU* under the GAR mandatory?**

Answer: No.

The use of any technical specification as a means to ensure compliance with the GAR requirements is voluntary. The application of a hEN whose references have been published in the *OJEU* and provide therefore the presumption of conformity to the GAR requirements (as far as covered by them) is always a possibility for the manufacturer of the appliance/fitting, who can in any case to apply any other technical means so as to ensure that his appliance/fitting complies with GAR.

The basis for EU type-examination as part of the conformity assessment by a notified body which examines the technical design of an appliance/fitting representative of the production envisaged and notes that the type meets the GAR provisions which apply to it, are the ERs, laid down in Annex I of the GAR. See also Blue Guide 2016, clause 4.1.2.2 for further explanation of the role of harmonized standards and clause 4.1.3 of the Blue Guide on the other possibilities/technical means for the assessment of the conformity of an appliance/fitting to the essential requirements.

12. **Question: What is meant by state of art?**

Answer:
State of art is a common understanding about technical and scientific knowledge and expertise on the minimum requirements needed to achieve a level of safety (or performance level) which is

considered to satisfy the ER of a directive / regulation at a particular time.

The state of art is mentioned in the GAR in:

- Recital (30);
- Annex I: points 2 (preliminary observation) and 3.5 (rational use of energy);
- Annex III, point 1.7 - responsibility of Notified Bodies.

According to point 2 of Annex I to GAR, the essential requirements are to be interpreted and applied in such a way as to take into account the state of the art and current practice at the time of design and manufacture as well as technical and economic considerations which are consistent with a high degree of energy efficiency and of health and safety protection.

Although GAD does not contain any explicit such requirement, also under GAD, the essential requirements have been applied and interpreted so as to take into account the state of scientific and technical knowledge at the time of design and manufacturer of the appliance/fitting and also at the time of its placing on the market.

13. **Question: which publicly available documents describe the state of art?**

Answer:
In case a hEN is available, such a document is considered to reflect the generally acknowledged state of art at the time of the adoption of the standard concerned as far as the ERs it aims to cover are concerned (hEN provides presumption of conformity after its reference numbers have been published in the *OJEU*).

In case a standard is available as a revised /amended document agreed upon by the experts e.g. as EN standard but its reference numbers have not been published in the *OJEU*, this document could be used as a reference document to reflect the state of the art.

In exceptional cases, in the absence for example of a hEN or another European or international standard, a guidance document approved by GAR-AC and accepted by the GAR WG, could also be used as a reference document to reflect the state of the art.

14. **Question: Which notified body is responsible to cover Annex III, point 1.7 (information responsibility) on changes of the technical knowledge relevant for the product?**

Answer:
According to point 1.7 of Annex III to GAR, the notified body who issued the EU type-examination certificate shall keep itself appraisal of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the GAR and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

However, also the notified body involved in the production control phase must follow the evolution of the state of the art and in case it detects an issue, it must inform the manufacturer and the notified body which issued the EU type-examination certificate and as far as necessary, take the appropriate actions towards the concerned appliances or fittings.

15. **Question: How should a manufacturer fulfill his responsibilities as described under GAR Annex III, point 1.7 2nd paragraph?**

Answer:
According to GAR Annex III point 1.7 2nd paragraph, the manufacturer shall inform the notified body that holds the technical documentation relating to the EU type- examination certificate of all modifications to the approved type that may affect the conformity of the appliance or the fitting with the essential requirements or the conditions for validity of the certificate.

Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate in case, following examination by the notified body, they are indeed considered to affect the conformity of the appliance/fitting of the conditions for validity of the certificate.

In addition the manufacturer must understand both the design and construction of this appliance/fitting in order to be able to take the responsibility that his appliance/fitting complies with GAR and the other applicable legislation.

16. **Question: How should a manufacturer fulfill its responsibilities that each individual product complies with the requirements of the GAR in such a way that this takes into account *"the state of the art and current practice at the time of design and manufacture"* (see Annex I, point 2 of GAR) and which notified body is responsible for supervising this?**

Answer:
The manufacturer has -as a part of the production process- to ensure that each individual product is in conformity with the type described in the EU type-examination certificate and complies with the requirements of the GAR.

The manufacturer, after the design of a product, has to keep himself apprised on the changes in the state of the art applicable to his product and take appropriate actions if required.

The manufacturer must therefore have procedures in place to ensure this. The notified body for the production surveillance will assess the suitability of these procedures.

Although the main responsibility to follow the evolution of the state of the art is for the notified body that performed the EU type-examination, in case the notified body involved in the production control phase discovers a potential non-conformity due to the evolution of the state of the art, it has to take the necessary measures and inform the manufacturer and the notified body who issued the EU type-examination certificate.

17. **Question: How can a notified body fulfil his responsibilities as described under Annex III, point 1.7, 1 paragraph?**

Answer:
Notified Bodies must follow the evolution of the generally acknowledged state of the art (see question 14). To this regard, the examples below intend to provide an indication on how this obligation can be fulfilled:

- Regular attendance at GAR-AC meetings
- Regular attendance at GAR notified bodies meetings;
- Regular review of available revisions of (h)ENs in the working field of the NB;
- Regular meeting with authorities / stakeholders in its member state (e.g. harmonization of accreditations, obtain market surveillance information).

- Regular review of trends in the non-conformities found during surveillance audits at manufacturers' sites.

Section 3: Practical Implementation:

18. **Question: Can notified bodies issue a GAR EU type-examination certificate before April 21 2018 having a starting date later than April 20st 2018?**

Answer: Yes.

According to Article 46(2a) of GAR, the Regulation shall apply from 21 April 2018, with the exception of Articles (inter alia) 19 to 35, which apply from 21 October 2016. According to Article 31(1), notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex III.

It results that a GAR notified body may perform all necessary tests and examinations so as to ensure compliance of an appliance/fitting with the GAR. A GAR notified body is therefore allowed to issue an EU type-examination certificate before 21 April 2018, as from the date it appears in NANDO. However, it will be valid only for products to be placed on the market as from 21 April 2018 under GAR. In accordance with point 1.6 of Annex III, the 10 year maximum validity of such EU type-examination certificates will start from the date of their issue.

19. **Question: Can a DoC be issued referring to the GAD after April 21st 2018?**

Answer: No.

An EC DoC issued before 21 April 2018 and declaring compliance to GAD remains valid for appliances placed on the market before until 20 April 2018, in accordance with GAD. The same applies for the certificates issued under GAD and declaring conformity of a fitting to the GAD (and which accompany the fittings placed on the market). Appliances and fittings placed on the market until 20 April 2018 under the GAD provisions will continue to be on the market, in accordance with GAR Article 44.

20. **Question: Can a DoC be issued referring to the GAR (additionally to the reference to the GAD) before 21st April 2018?**

Answer: Yes.

The GAR applies as from 21 April 2018. Before that date, all products must comply to the GAD and the DoC must refer it. Only products covered by a DoC under the GAD may be placed on the market and put into service.

As from 21 April 2018, only products complying with the GAR (and therefore covered by an EU Declaration of Conformity under the GAR) will be allowed to be placed on the market.

However, in order to facilitate transition and provided that the conformity of the product has been verified also under the GAR (see point 19), manufacturers may make use of flexibility and refer to both legal acts (the GAD and the GAR) in their Declaration of Conformity, indicating the corresponding periods of application for each of them. They could use for example the following formulation based on the new model structure of EU Declaration of Conformity: *"The object of*

the declaration described above is in conformity with the relevant Union harmonization legislation: Directive 2009/142/EC (until 20 April 2018) and Regulation (EU) 2016/426 (from 21 April 2018)".

21. **Question: Point 2.3 of Annex III (Module C2) mentions product checks once a year (or less) while point 3.4.3 (Module D) production check is to be performed (at least once) every 2 years. Are both required?**

Answer: No.

Article 14(2) of GAR clearly states:
The conformity of series-manufactured appliances and fittings with the requirements of this Regulation shall be assessed by means of the EU type-examination (Module B — production type) set out in point 1 of Annex III, combined with one of the following modules, at the choice of the manufacturer:

a) conformity to type based on internal production control plus supervised product checks at random intervals (Module C2), set out in point 2 of Annex III;

b) conformity to type based on quality assurance of the production process (Module D), set out in point 3 of Annex III;

c) conformity to type based on product quality assurance (Module E), set out in point 4 of Annex III;

d) conformity to type based on product verification (Module F), set out in point 5 of Annex III. 3.

22. **Question: What should a DoC contain for the GAR?**

Answer: See article 15 and Annex V of the GAR.

In particular, the EU DoC shall state that the fulfillment of the GAR requirements has been demonstrated. By drawing up and signing the EU DoC, the manufacturer assumes responsibility for the compliance of the appliance/fitting to GAR.

The EU DoC shall have the model structure set out in Annex V of GAR, shall contain the elements specified in the relevant modules set out in Annex III of GAR and shall be continuously updated.

Where the appliance/fitting is subject to more than one Union acts requiring an EU DoC, a single DoC shall be drawn in respect of all such Union acts.

Under GAR, a DoC is required also for fittings.

In comparison to the GAD DoC, the GAR format for DoCs is about the same with some additional points to be added, in accordance with Annex V to GAR.

23. **Question: How is the situation with spare parts for gas appliances or fittings, certified according GAD when GAR applies?**

Answer:
Neither GAD nor GAR covers spare parts. So, spare parts are outside the GAR scope.

In paragraph 2.1 the Blue Guide provides clear guidance for this. As a general rule it is stated in the Blue Guide that spare parts need to comply with the regulations that were in place when the

final product containing the original part was put on the market.

24. **Question: Is the definition of a fitting changed from the GAD to the GAR?**

Answer: No.

The GAR has slightly modified, updated the definition of fittings, without however, changing the scope of the notion. More particularly,

GAD art 2(2) ‘fittings’ means safety devices, controlling devices or regulating devices and sub-assemblies, *other than forced draught burners and heating bodies to be equipped with such burners, separately marketed for trade use* and designed to be incorporated into an appliance burning gaseous fuel or assembled to constitute such an appliance*;*

GAR art: 2 (2) 'fittings’ means safety devices, controlling devices or regulating devices and sub-assemblies *thereof,* designed to be incorporated into an appliance or to be assembled to constitute an appliance;

The major difference, without any legal consequence as it is a legal issue drafting, is that the new definition of fittings does not contain the underlined words in the GAD definition.

a) In particular, the part "*other than forced draught burners and heating bodies to be equipped with such burners*" was deleted as those products are considered as appliances both under GAD and GAR and there was no need to repeat in the definition of fittings something what was already explicitly and clearly stipulated in the appliance definition, as follows:

   - GAD Article 2(a), stipulates that "appliances means appliances burning gaseous fuels used for cooking, heating, hot-water production, refrigeration, lighting or washing and having, having where applicable, a normal water temperature not exceeding 105°C. Forced *draught burners and heating bodies to be equipped with such burners shall also be considered as appliances".*

   - GAR Article 2(1) stipulates that "appliances means appliances burning gaseous fuels used for cooking, refrigeration, air-conditioning, space heating, hot water production, lighting or washing, *and also forced draught burners and heating bodies to be equipped with such burners".*

b) The part "*separately marketed for trade use*" has also been deleted, as it was redundant. Of course fittings are covered by GAD and GAR only if they are placed on the market as separate products, if there is a transfer of the fitting at least between the fitting manufacturer and the appliance manufacturer. Fittings, under both GAD and GAR, are intended to be incorporated into an appliance in the meaning of GAD or GAR (a new appliance). As a result, there was no reason to keep a wording that was adding only confusion.

   In case there is no transfer between a fitting manufacturer and an appliance manufacturer, e.g. because the appliance manufacturer designs and constructs himself the fitting (which includes the cases that he has subcontracted this task under his whole responsibility), there is no placing on the market and therefore, such a product is not considered as a fitting, but as component of the appliance, for which the appliance manufacturer takes the full responsibility (see also question 26).

Notwithstanding the above, it is noted that although GAR did not change the fitting definition, it introduced changes with regard specifically for fittings, as it is the CE marking (under GAD

fittings are not CE marked) and the EU DoC which replaces the fitting certificate provided for by GAD.

25. **Question: Should a fitting which is made available on the market comply with the GAR?**

Answer: Yes

GAR art 3(2): Fittings shall only be made available on the market if they comply with this Regulation.

GAR art: 2 (15): '*placing on the market'* means the first making available of an appliance or a fitting on the Union market.

26. **Question: Should a fitting which is designed and produced at request of a specific appliance manufacturer comply with the GAR? Should a component which is designed and produced as a sub-contracted task by the appliance manufacturer and under his full responsibility comply with GAR?**

Answer:
From the moment there is a transfer between the fitting manufacturer and the appliance manufacturer, there is placing on the market of the fitting. In that case the GAR requirements apply to the fitting as such (see also question 24).

Even if an appliance manufacturer orders a specific fitting for his appliance, there is a (first) making available on the market of the fitting, in the meaning of GAR Article 2(14) according to which *"making available on the market means any supply of an appliance or a fitting for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge"*.

However, if the fitting is designed and produced within the internal manufacturing process of the appliance manufacturer, there is no legal transfer of the product and therefore no placing on the market. Consequently, the product is not considered formally as a "*fitting*" within the meaning of GAR (and of GAD) and therefore in that case, it is not subject to the GAR requirements. It is considered as a component of the appliance, and therefore its conformity to GAR will be examined and assessed as part of the appliance and under the full responsibility of the appliance manufacturer.

This covers for example the case of sub-contracting or cases of in-house design and construction under the full responsibility of the appliance manufacturer.

Of course, the appliance which incorporates a component which would be qualified as a "*fitting"* in case of placing on the market must comply with the GAR.

As a consequence:

- An EU Declaration of Conformity (GAR art 15) is not relevant for this component only (but for the appliance as a whole). By drawing up the EU declaration of conformity of the appliance, the manufacturer of the appliance is responsible for the compliance of the appliance including this component.
- CE marking (GAR art 17) and inscriptions (GAR art 18) is not relevant to be placed on the component. By CE marking and inscription of the appliance, the manufacturer of the appliance is responsible of the CE marking and inscriptions of the appliance including this

component**.**

- The appliance manufacturers shall draw up the technical documentation according to Annex III of the GAR which includes the documentation of the component too, as far as relevant.
- The appliance manufacturer shall have carried out the relevant conformity assessment procedure referred to in Article 14 (e.g. Module B — production type in combination with Module C2, D, E or F) of the appliance only which includes the component at stake.

27. **Question: can a general purpose component which is not specially designed and intended to be incorporated into an appliance be used by the appliance manufacturer?**

Answer: Yes.

The appliance manufacturer in order to construct the appliance needs to use not only fittings (in the meaning of GAR) but also other products/components to be incorporated into the appliance so as to constitute a finished appliance. The appliance including such (a) component(s) shall comply with the requirements of the GAR.