PrincipleDecision
by the
“CentralExperienceExchangeCircle
of the Notified Bodies and the GS Bodies according to the
ProductSafetyAct”
– ZEK –
about Defining theRequirements for a
GSMarkApproval according to Section 5 ProductSafetyAct
(ProdSG)
ZEK-GB-2017-01 rev. 1
(Replaces ZEK-GB-2006-01 rev.1 and ZEK-GB-2017-01)
at 26. September 2018

1. Introduction / Preface / Preamble

The GS Mark (GS = geprüfte Sicherheit [tested safety]) is a recognized safety mark that is known beyond the borders of Germany. It signals that an independent GS Body has verified compliance of a certain product with the safety-related requirements and is monitoring the production of this product on a regular basis. The value of the GS Mark depends to a great extent on the trust and confidence of the market players. This trust can only be maintained by a thorough approval process and by consistent actions against the misuse of the GS Mark. Therefore, based on and in accordance with the provisions of the Product Safety Act, this Principle Decision specifies the requirements that ensure a consistent GS Mark approval process, and that must be followed by the GS Bodies.

2. Definitions
a GS Mark Certificate Certificate according to § 21 Sec. 2 ProdSG
b Initial Factory Inspection Procedure by which the GS Body ensures that the manufacturer has taken care to ensure that the ready-to-use products correspond to the type, cf. § 21 Sec. 1 No. 4 ProdSG. Other English equivalent terms: First Factory Inspection, First Inspection, etc.

c Production control Measures by which the GS Body ensures that the products placed on the market by the manufacturer correspond to the type that was submitted and tested at the time of GS mark approval, cf. § 21 Sec 5 ProdSG.
d GS Mark Holder A manufacturer or his representative based in the European Economic Area (EEC), who was awarded a GS Mark certificate.
3. Suspension

Notification of the GS Mark certificate holder by the GS Body that starting immediately, the GS Mark may no longer be attached to newly manufactured products. Products that already have the GS Mark and are about to be placed on the market (e.g. that are in the manufacturer's warehouse) may still be brought on the market. Once the cause for the suspension has been rectified and the GS Mark certificate holder is informed about this by the GS Body, the affected products may be labeled with the GS Mark again. When assessing whether the cause of the non-conformity was rectified, the GS Body can focus primarily on the issues of complaint. The validity period of the GS Mark certificate will remain the same as in the original certificate, at the maximum.

3. Withdrawal

Notification of the GS Mark certificate holder by the GS Body that starting immediately, the GS Mark may no longer be attached to newly manufactured products, and that products that already have the GS Mark and are about to be placed on the market (e.g. that are in the manufacturer's warehouse) may no longer be placed in circulation. The ZLS and other GS Bodies must be notified about the withdrawal of the GS Mark. Once the cause for the withdrawal of the GS Mark has been rectified, the manufacturer may reapply for a GS Mark approval. A new GS Mark approval procedure according to § 21 ProdSG is required.

3. Type examination

A type examination is the prerequisite for a GS Mark approval, see § 21 Sec. 1 No. 1 -3 ProdSG. The following special cases must be considered:

3.1. GS Mark approval for manufacturers who are not based in the EEC

§ 21 Sec. 1 No. 1 ProdSG specifies that the GS Mark may only be awarded if the tested type complies with the requirements specified in § 3 ProdSG and, for consumer products, also with the requirements specified in § 6 ProdSG.

§ 6 Sec. 1 Clause 1 No. 2 ProdSG specifies that as part of their business activities of placing a consumer product on the market, manufacturers have the obligation to "affix the name and contact address of the manufacturer, or the name and contact address of the authorized representative or the importer if the manufacturer is not based in the European Economic Area (EEC)". This requirement is directly based on the General Product Safety Directive 2001/95/EC (see. Art. 5 Sec. 1 Subsec. 4 lit. a) in conjunction with Art. 2 lit. e). It enables the tracing of consumer products and it is a prerequisite for the marketability of a product. It is not a directly safety-related or safety-relevant requirement. This means that it is not relevant for a GS Mark approval, i.e. the name and contact address of the authorized representative or the importer need not yet to be known at the time a manufacturer who is not based in the European Economic Area (EEC) is awarded a GS Mark certificate.

Note: At the same time, the GS Body must notify the manufacturer that according to § 6 ProdSG, the product may only be imported into the European Economic Area if the name and the contact
3.2. GS Mark approval based on an existing GS Mark certificate by another GS Mark certificate holder

If a product already has a GS Mark and another application for a product that is identical in construction was submitted to the GS Body, a type examination must generally be conducted for that product as well. A GS Mark may not be issued solely based on the statement by the manufacturer that the affected product is unchanged and still consistent with the previously tested type.

A new full type examination may be waived if the GS Body itself conducts the verification and documents that the new type is identical to the original type carrying a GS Mark, in all safety-related aspects.

Any changes to the legal/normative requirements that happened in the meantime, including testing requirements, which are relevant to the product must be taken into account.

3.3. GS Mark re-approval after expiration of the validity period of a GS Mark certificate

Same as Section 3.2

4. Initial Factory Inspection

Another prerequisite for a GS Mark approval is that in accordance with § 21 Sec. 1 Clause 1 No. 4 ProdSG measures were taken to ensure that the ready-to-use products are consistent with the tested type. This must be verified by the GS Body during an initial factory inspection of the manufacturing facility/facilities. During this inspection,

- Technical equipment
- Personnel resources
- Production processes
- Qualified incoming inspection
- Control of production, such as interim and final product inspections

and

- Special product-specific requirements

must be reviewed. The result must be documented with reference to the individual manufacturing sites.

Manufacturers who do not conduct qualified incoming inspections (also for prefabricated assemblies and components) and final product inspections for conformity with the GS-certified type must be excluded from GS Mark approval.

If a manufacturer already received a GS Mark by the same GS Body for a product of the same product group (= same manufacturing process) and for the same manufacturing facility, or if the

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1 A justified exceptional case for foregoing an initial factory inspection is e.g. a large-scale machine that is assembled for the first time not at the manufacturer's facilities but at the client's premises. In this case, the GS Mark certificate will be issued per lot (if several identical products are being manufactured) or for each individual product.
In the event of any conflict between the English and German versions, the German version shall prevail.

A manufacturing facility is already being monitored by the same GS Body in the same product group and in the same way, the report about the most recent factory inspection that was conducted as part of the surveillance for that product can be used as documentation for the initial factory inspection for the new GS-certified product, if

- this factory inspection was conducted within the past 12 months
- no deviations were detected or any established deviations were verifiably remedied
- there is no information about the manufacturer, which would raise doubt about his trustworthiness.

Monitoring activities other than factory inspections (see Chapter 6.d) may not serve as initial factory inspection.

The initial factory inspection must be documented in a suitable way; for electrical equipment for example, CIG inspection reports have been proven to be a good way of documentation.

5. GS Mark Certificate / Documentation

a) The test specifications that formed the basis for the type examination must be documented. When listing standards, regulations and technical specifications, the year those were issued must always be indicated.

b) The documentation, which forms the foundation for a GS Mark approval, must enable a clear identification of the product and its components (photos, drawings, parts lists etc.)

c) Generally, all documents for the GS Mark approval must be in German. The GS Body may accept documents in different languages. For documents written in other languages, the ZLS may require that important paragraphs be submitted in German.

d) The GS Body must archive all documents required for the GS Mark approval for at least 10 years after the GS Mark certificate becomes invalid.

e) Upon request by a market surveillance authority or the ZLS, the following documents must be submitted within the period of time indicated:
   - Copy of the GS Mark certificate within one business day,
   - Test reports and documentation on the initial factory inspection, and documentation on the production control and on the legitimate use of the GS Mark within two business days, and
   - All other documents and any documents specified in this Principle Decision within an adequate time limit. This also applies to responses to additional inquiries and to the request of additional documents or clarifications.

f) The original GS Mark certificate must be issued in German. Additional versions in other languages may be issued as well.

g) The validity period for a GS Mark certificate is 5 years maximum or must be limited to a specific contingent or lot.
A GS Mark certificate must at least contain the information listed in the following table. This information must be listed on the front page (= first page) of the certificate. If applicable, the front page must also contain a reference to additional pages (e.g. by a clear numbering of the pages, 1 to 3 etc.) or to attachments to the certificate.

Content of the GS Mark certificate

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>a</td>
<td>Name of the GS Body that issued the GS Mark certificate</td>
</tr>
<tr>
<td>b</td>
<td>Certificate holder</td>
</tr>
<tr>
<td>c</td>
<td>Certificate number</td>
</tr>
<tr>
<td>d</td>
<td>Date of issue of the GS Mark certificate and validity period&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>e</td>
<td>Product, type designation; identification of the production lot, part number, if applicable&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>f</td>
<td>Technical information about the product in order to clearly match the product with the certificate, e.g. protection class, voltage, power, dimensions etc.&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td>g</td>
<td>Statement that the product (tested type) meets the requirements with regard to ensuring safety and health (§ 21 Sec. 1 Nos. 1 to 3 ProdSG) and that measures have been taken to ensure that the ready-to-use products are consistent with the tested type (§ 21 Sec. 1 No. 4 ProdSG).</td>
</tr>
<tr>
<td>h</td>
<td>Test specifications with year of the date of issue (&quot;Using...&quot; and/or &quot;Referring to...&quot;) and a note in case a test specification was applied only in part&lt;sup&gt;5&lt;/sup&gt;.</td>
</tr>
<tr>
<td>i</td>
<td>A note that the certificate holder is entitled to use the GS Mark (in the form shown) on the product described, plus a display of the GS Mark to be used.</td>
</tr>
</tbody>
</table>

If a GS Mark certificate is withdrawn by the GS Body because of a violation of § 21 Sec. 1 ProdSG, in particular because of:

- Errors during the GS mark approval, e.g. inaccurate type examination
- Detection of irregularities during the manufacturing of the product (e.g. in the production process at the manufacturer's) with regard to the consistency of the product with the tested type
- Safeguard clause procedure or RAPEX notification according to EU law
- Market control, reports or notifications by authorities, GS Bodies and consumer organizations etc. about safety-related defects of products,

or if a GS Mark certificate holder preempts a withdrawal of a GS Mark certificate based on the aforementioned reasons, the other GS bodies and the ZLS must be informed about this withdrawal via the respective experience exchange circle. This is currently done via a reporting form.

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<sup>2</sup> The validity period does not apply to a GS certificate that is restricted to specified lots.
<sup>3</sup> In case of a large number of types, in exceptional cases additional types may be listed not on the front page but on the back page (= second page) or in attachments.
<sup>4</sup> If this part becomes too large, the front page of the certificate should contain only essential information and include a reference to more detailed information on subsequent pages or attachments.
<sup>5</sup> A clear specification of the sections of the test specifications that were applied is mandatory.
<sup>6</sup> If there was no laboratory test and the requirements/test specifications were only evaluated, this test specification may not be named on the GS Mark certificate as such.
6. Production Control

a) As specified in § 21 Section 5 ProdSG, the GS Body must monitor the production of a GS-certified product. This control of production is generally done on an annual basis but must be modified or adapted depending on the manufacturer, production, product and in particular based on the experiences with previous follow-up inspections, product-specific publications, information by market surveillance authorities, consumer organizations, and other relevant information. The time intervals and methods used in the follow-up inspections are determined by the GS Body and must be adjusted as needed. The decision about the specified time intervals for the monitoring measures to be conducted must be documented in a traceable way.

b) Follow-up inspections are being conducted to verify that the manufacturer's quality assurance system continues to ensure the consistency of the manufactured products with the certified type. During these inspections, the quality assurance measures specific for the product that was awarded the GS Mark must be reviewed for their effectiveness. Therefore, an ISO 9001 or an equivalent quality management system certification may not replace the monitoring activities by the GS Body.

c) As part of the inspection, the packaging and the user manual must also be reviewed with regard to GS Mark images and other labeling requirements.

d) Specifically, the following methods may be used for the inspection:
   - Periodic factory inspections
   - Pre-shipment control
   - Inspections restricted to specified lots / During-Production-Inspections (DUPRO)
   - Withdrawal of products from the market or a warehouse
   - Withdrawal of products from production
   The GS Body shall explain and document its method chosen for the inspection.

e) If the product to be controlled was not found at the last two factory inspections, despite it being produced during the inspection interval, the GS Body must immediately arrange for check tests of products in the market or in a warehouse.

f) The inspection must be documented in a suitable way. For electrical equipment for example, CIG inspection reports have been proven to be a good way of documentation.

g) Subcontracting is possible only for factory inspections. It must be noted however, that the GS Body remains fully responsible for the monitoring measures and for their control and analysis. If these monitoring measures are delegated in part to third parties, appropriate measures must ensure that these third parties:
   - have all the necessary information about the GS certified product (configuration, parts lists, test report(s) etc.),
   - have the necessary competence in this area,
   - are involved in the work of the GS Body through relevant information, and
   - are independent for the purpose of §13 Section 2 ProdSG.

The third party must prepare a comprehensive documentation for these monitoring measures so that the GS Body is able to get a clear picture of the production of the product consistent with the GS-certified type, and of the legitimate use of the GS Mark.

Upon request, the GS Body must provide proof about the qualification of the third party to the Central Authority of the Federal States for Safety (ZLS).
7. Measures in Case of Non-Conformities

a) If during an inspection, deviations are detected (e.g. deviations from the test results of the type examination), the GS Body shall take measures depending on the severity of the deviation(s) found and on their evaluation.

<table>
<thead>
<tr>
<th>No:</th>
<th>Observed deviation</th>
<th>Measures to be taken by the GS Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Minor non-conformities <em>Non-conformities that do not affect the safety of the product.</em></td>
<td>Notification of the manufacturer and any additional certificate holders, if indicated. Review of the effectiveness of the implemented corrective measures at the next on-site inspection.</td>
</tr>
<tr>
<td></td>
<td>Examples for minor non-conformities: Incoming inspection is performed but inadequately documented; measuring instruments are calibrated but inadequately labeled, etc.</td>
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<tr>
<td>B</td>
<td>Non-conformities with a need for clarification <em>Non-conformities that are suspected of being safety-related.</em></td>
<td>The GS Body examines whether a non-conformity with the need for clarification is a safety-related or a minor non-conformity. The GS Mark certificate might be suspended until clarification, if indicated.</td>
</tr>
<tr>
<td></td>
<td>Examples for non-conformities with a need for clarification: Deficiencies in the calibration of measuring instruments, expiration of required qualifications of employees (e.g. welding certifications), changes to the product, unclear material specifications, etc.</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Safety-related non-conformities</td>
<td>Generally, the GS Body must withdraw the GS Mark certificate.</td>
</tr>
<tr>
<td></td>
<td>Examples for safety-related non-conformities: Changes to safety-relevant components, incoming inspection is not performed, no/inadequate verification checks on the product, undocumented production steps, missing final inspection of production, etc.</td>
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</tbody>
</table>

b) In addition, the GS Body must assess and determine whether the detected non-conformities at the manufacturing facility in question also affect the other manufacturing sites or other GS-certified products manufactured at the same facility. Depending on this evaluation or decision, additional appropriate measures must be initiated immediately by the GS Body, such as a suspension or withdrawal of the GS Mark certificate, if necessary. The evaluation and decision must be documented accordingly.