Bundesamt
für Eich- und
Vermessungswesen

Notifizierte Stelle NB 0445

bev.gv.at

Bundesamt für Eich- und Vermessungswesen

Notifizierte Stelle NB 0445

notifizierte.stelle@bev.gv.at
+43 1 211 76-826361
Fax +43 1 211 10-82996000

Arltgasse 35, 1160 Wien, Österreich

Leaflet on the requirements for conformity assessment according to the

Ordinance on Measuring Instruments, Federal Gazette II No 31/2016 (corresponds to MID 2014/32/EU) and the

Ordinance on Conformity Assessment of Non-automatic Weighing Instruments, Federal Gazette II No 30/2016 (corresponds to NAWI 2014/31/EU)

1 General provisions

1.1 Application on approval

The application is to be lodged

- by the manufacturer himself or
- by the authorised representation resident in a member state*

For the audit – which is not a task of the public authority – by the Physico-technical Testing Service (PTP) of the BEV, an explicit order in the application has to be given to the PTP of the BEV.

In case of an authorisation, the information listed below is necessary:

- authorisation of the manufacturer given to a company (or person) resident in a member state
- withdrawal of a former authorisation
- declaration of the authorised applicant to pay all costs of the conformity assessment procedure(s).

The authorised company (person) is the applicant and has to assume the duties laid down in the Ordinance on measuring instruments 2016 (corresponds to MID 2014/32/EU) or in the Ordinance on non-automatic weighing instruments (corresponds to NAWI 2014/31/EU). If not a person, but a company is authorised, the company must name a natural person as the authorised recipient.

* Member states are member states of the European Union, signatory states of the EEA and Switzerland

The application contains:

- information about the manufacturer
- scope of the certification
- information as stated in 2.1 and 2.2
- agreement to meet the certification requirements and to provide all relevant information

1.2 Fees

The fees mentioned are to be paid according to the Fees and Duty Act 1957, Federal gazette no. 267/1957 as amended and the ordinance on verification fees 1999, Federal gazette no. II 467/1998 amended through ordinance Federal gazette no. II 311/2013.

Application and authorisation (§ 14 of the Fees and Duty Act): 14.30 € each.

Enclosures (§§ 5, 14 of Fees and Duty Act): 3.90 € per sheet, maximum 21.80 € per enclosure.

Rating Fee (ordinance on verification fees, tariff A, 1, tariff F): 12 € per 15 minutes

The costs of auditing will be calculated separately by PTP

1.3 Enclosures

Depending on the scope of certification, all relevant documents are to be enclosed to the application. The BEV may ask for further documentation if necessary (without any fees).

According to Article 14 of the ordinance on measuring instruments 2016 (corresponds to MID 2014/32/EU) enclosures have to meet the following requirements:

(1) The technical documentation shall render the design, manufacture and operation of the measuring instrument intelligible and shall permit an assessment of its conformity with the appropriate requirements of this ordinance.

(2) The technical documentation shall be sufficiently detailed to ensure the following:

1. the definition of the metrological characteristics,

2. the reproducibility of the metrological performances of produced measuring instruments when properly adjusted using appropriate intended means, and

3. the integrity of the measuring instrument.

(3) The technical documentation shall include insofar as relevant for assessment and identification of the type and/or measuring instrument:

1. a general description of the measuring instrument;

2. conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits, etc;

3. manufacturing procedures to ensure consistent production;

4. if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;

5. descriptions and explanations necessary for the understanding of paragraphs 2, 3 and 4, including the operation of the measuring instrument;

6. a list of the standards and/or normative documents referred to in Article 12, applied in full or in part, published in the Official Journal of the EU

7. descriptions of the solutions adopted to meet the essential requirements where the standards and/or normative documents referred to in Article 12 have not been applied, including a list of other relevant technical specifications applied.

8. results of design calculations, examinations, etc;

9. the appropriate test results, where necessary, to demonstrate that the type and/or measuring instruments comply with:

   – the requirements of this Ordinance under declared rated operating conditions and under specified environmental disturbances,
   – the durability specifications for gas-, water-, heat-meters as well as for liquids other than water as laid down in the requirements concerning the verification of measuring instruments

10. the EU-type examination certificates or EU-design examination certificates in respect of measuring instruments containing parts identical to those in the design.

(4) The manufacturer shall specify where seals and markings have to be applied.

(5) The manufacturer shall indicate the conditions for compatibility with interfaces and sub-assemblies, where relevant.

According to Annex I of the ordinance on non-automatic weighing instruments (corresponds to NAWI 2014/31/EU) enclosures have to meet the following requirements:

- a general description of the measuring instrument,
- conceptual designs and manufacturing drawings and plans of components, sub-assemblies, circuits, etc.,

- descriptions and explanations necessary for the understanding of the above, including the operation of the measuring instrument,
- a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- results of design calculations, examinations, etc.,
- test reports

2 Module-depending requirements

2.1 EU-Type examination and EU-Design examination

According to Annex 2 module B, 3. und H1, 4.2 of the ordinance on measuring instruments 2016 (corresponds to MID 2014/32/EU) and Annex 1, module B, 1.3 of the ordinance on non-automatic weighing instruments (corresponds to NAWI 2014/31/EU) the application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;
- a written declaration that the same application has not been lodged with any other NB;
- the technical documentation as described in Article 14. The technical documentation shall make it possible to assess the instrument's conformity with the applicable requirements of this ordinance and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.
- the specimens, representative of the production envisaged. The Notified Body may request further specimens if needed for carrying out the test programme;
- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards, and/or normative documents have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

EU-type examination certificate and revisions issues by the Notified Body are published in the Official Bulletin (Journal) of the Metrology Service.

2.2 Quality management

2.2.1 Application

According to Annex 3 module D, D1, E and H1 of of the ordinance on measuring instruments 2016 (corresponds to MID 2014/32/EU) and Annex 1, module D 2,3 Ordinance on non-automatic weighing instruments (corresponds to NAWI 2014/31/EU) the application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- a written declaration that the same application has not been lodged with any other NB;
- all relevant information for the instrument category envisaged;
- the documentation concerning the quality system;
- the technical documentation of the approved type and a copy of the EU type examination certificate (except for H1);

For module D and D1 Annex 3 module D, 3.2 and module D1 5.2 of the ordinance on measuring instruments 2016 (corresponds to MID 2014/32/EU) and Annex 1, module D, 2.3. and module D1, 3.5. Ordinance on non-automatic weighing instruments (corresponds to NAWI 2014/31/EU) additionally

- the corresponding 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;

For module E, Annex 3 module E, 3.2, of the ordinance on measuring instruments 2016 (corresponds to MID 2014/32/EU) additionally

- the examinations and tests that will be carried out after manufacture;

For module H1, Annex 3 module H1, 3.2, of the ordinance on measuring instruments 2016 (corresponds to MID 2014/32/EU) additionally

- the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents will not be applied in full, the means that will be used to ensure that the essential requirements of this Ordinance that apply to the measuring instruments will be met, applying other relevant technical specifications;
- the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered;
- the corresponding 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;

2.2.2 Documentation

The documentation is to be provided essentially in the form of

- Quality management handbook
- Documented procedures
- Checklist ISO 9001:2015, completed by the applicant
- EU type examination certificates or EU type approval certificates
- Template for forms and template for declaration of conformity
- Scope of certification requested
- List of personnel involved
- List of measuring instruments
- List of documents

2.2.3 The documentation of the Quality System:

The documentation of the QM system has to have an adequate description of the following points:

- Quality objectives as well as organisational structure, responsibilities and powers of the management with regard to the product quality;
- quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc;
- means to monitor the achievement of the required product quality and the effective operation of the quality system.

For module D and D1 Annex 3 module D, 3.2 and module D1 5.2. of the ordinance on measuring instruments 2016 (corresponds to MID 2014/32/EU) and Annex 1, module D, 2.3. and module D1, 3.5. Ordinance on non-automatic weighing instruments (corresponds to NAWI 2014/31/EU) additionally

- 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;

For module E, Annex 3 module E, 3.2, of the ordinance on measuring instruments 2016 (corresponds to MID 2014/32/EU) additionally

- the examinations and tests carried out after manufacture;

For module H1, Annex 3 module H1, 3.2, of the ordinance on measuring instruments 2016 (corresponds to MID 2014/32/EU) additionally

- the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents will not be applied in full, the means

that will be used to ensure that the essential requirements of this Ordinance that apply to the measuring instruments will be met, applying other relevant technical specifications;
- the design control and design verification techniques, processes and systematic actions that will be used when designing the instruments pertaining to the instrument category covered;
- the corresponding 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;

2.2.4 Procedure

The approval procedure is basically performed as follows:

1. Application on approval of the QM-System and transmission of the documents

2. Examination of the application

3. Transmission of the surveillance agreement and information about the audit team

4. Assignment of the audit team (usually two experts covering the organisation of the audit, the QM, the working field and the implementation of the directive)

5. If necessary, additional documents will be requested by the experts

6. Examination of the documents

7. Sending of an audit plan

8. Stage 1
   The audit of stage 1 provides a basis for orientation and preparation of the main audit of stage 2. In particular the following shall be clarified:

- Provision of sufficient information about the company and its management system for the planning of the extent and the focus of the audit of stage 2.
- What is the extent of the management system? Which processes and locations are covered by this system? Are there statutory and regulatory aspects? How are they complied with?
- Do the business processes at the different locations and the site-specific conditions meet the standard requirements?
- Do the condition of the enterprise and the understanding of the standard requirements meet the expectations, especially as far as the identification of important activities, processes and objectives as well as the operation of the management system is concerned?
- Is the documentation of the management system in good order?

- Do the planning and execution of the internal audits and the management review meet the standard requirements? Is the introduction of the management system advanced sufficiently enough in order to execute the main audit of stage 2?
- Are the personnel ready for the execution of the main audit (stage 2) and are the necessary resources available?

The result of the audit of stage 1 is documented in writing and communicated to the applicant.It characterizes the areas that could yet give rise to reservations and be found not conform in the audit of stage 2.

9. Stage 2
   The audit of stage 2 is carried out according to an audit plan agreed upon in writing with the applicant.
   The main audit plan is based on ISO/IEC 19011 [17] and takes the information gained at the audit at stage 1 into account.
   The audit of stage 2 provides prove if the management system is implemented and if the intended effect is achieved. It is carried out at the site of the applicant and comprises the following aspects as a minimum:

   - information and evidence about conformity to all requirements of the applicable management system standard or other normative document;
   - Monitoring of the performance, i.e. measurement, report and assessment with regard to the most important performance goals (in agreement with the applicable standard requirements or other normative document);
   - the client's management system and performance as regards legal compliance;
   - operational control of the processes;
   - internal auditing and management review;
   - management responsibility for the client's policies;
   - Evidence of accordance between the normative requirements, policy, performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document), any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions.

   The main audit stage 2 is documented by an audit report.

10. The approval is valid for a period of 3 years beginning with the decision of the approval. Annual supervising audits take place.

The auditors are chosen in such a way, that an impartial approval procedure is ensured. You have the possibility to disagree on the nomination of auditors.

Information from the approval procedure is kept confidentially and protected against unauthorised access. Such information is communicated only after prior consent by you. You will be informed about any information published by us.

2.2.5 Maintaining and extending the approval

The Notified Body carries out an announced audit each year and a re-approval audit before the expiration of the approval in order to ascertain that the manufacturer updates and applies the quality assurance system and prepares an audit report which is provided to the manufacturer and kept ready for the Federal Ministry for Digital and Economic Affairs (BMDW). The first audit has to take place within 12 months after the approval.

Furthermore, surveillance can be held unannounced. It can be carried out as full or partial audits. The manufacturer receives a short report and if applicable an audit report.

At minor deficiencies a dead-line is given for the correction. At serious and/or numerous non-conformities in the documentation, doubts in the competence of the personnel, as well as non-conformities of the produced measuring instruments the approval is suspended until the non-conformities are remedied.

The approval is suspended if:

1. the quality management of the manufacturer does not meet the approval requirements persistently or gravely;
2. the manufacturer does not permit the execution of the surveillance or re-approval audit;
3. the manufacturer asked for a temporary suspension voluntarily.

The withholding of the approval is carried out by notice with dead-line; the related requirements are communicated in the conditions.

The examination of the correction of the non-conformity which led to the suspension is carried out by control of the documents or audit, respectively.

If the deficiencies mentioned above arise repeatedly or the non-conformities which led to a suspension are not corrected within the dead-line given, the approval will be limited or withdrawn.

If you apply for the extension of the scope of the recognized QM system a new audit is necessary in order to be able to decide if this extension can be granted.

3 Obligations due to approval

The applicant assures:

- that all necessary arrangements for the conduct of the assessment, including provision for examining documentation and the access to all areas, locations, records (including internal audit reports), client`s subcontractors and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints are provided;
- eg. observers can take part on the audits and surveillance;
- claiming of certification with respect to those activities only for which it has been certified;
- that its certification is not used in such a manner as to bring the NB into disrepute, and that there is no statement regarding its certification which the NB may consider misleading or unauthorized;
- that upon suspension or withdrawal of its certification (however determined), use of all advertising matter that contains any reference thereto will be discontinued and any certification documents will be returned as required by the NB;
- that certification is only used to indicate that the quality system is in conformity with specified standards or other normative documents, and does not use its certification to imply that a product or service is approved by the NB;
- that no certification document, mark or report, or any part thereof, is used in a misleading manner;
- copies of certification documents are only valid as a whole to be distributed to third parties
- that making reference to its certification in communication media such as documents, brochures or advertising, complies with the requirements of the NB.
- corrective actions are taken whenever the conformity of products is injured.
- that the records of all complaints and corrective actions taken in accordance with the requirements of the quality system standards or other normative documents are available for the NB.
- That the NB is informed about all relevant changes, e.g. modification of products, procedures, quality management system, which may lead to influence on product conformity. The NB will decide whether further investigations are necessary. Modified products may be brought on the market after release by the NB.

4 Confidentiality

The certification body is responsible, through legally commitments, to treat all information obtained or created during the performance of certification activities in the framework of EU directives, as confidential.

The information from certification procedures are given to third parties only after prior consent of the applicant(s). Applicants are also informed in writing about the information which the NB has to give by obligation to law to the public.

5 Dealing with objections and complaints

Objections in the conformity assessment procedure are dealt with according to the Allgemeines Verwaltungsverfahrensgesetz (General administration procedure act, AVG). The receipt of the objection is confirmed in writing.

6 Withdrawal of EU type examination certificates

If the state of the respective measuring instruments will not be corrected in time despite order of the NB by systematic non-compliance with the requirements of the measuring instruments directive or the directive for conformity assessment for non-automatic weighing instruments, the NB can withdraw the design approval or the EU type examination certificate. The withdrawal will be published in the Official Bulletin of Metrology Service.

7 Notes

Certificates and changes concerning the certificates are published in the Official Bulletin of the Metrology Service and on the Website www.bev.gv.at.

The documents forming the base of the approval have to be provided to the member state by the notified body of BEV on request.

You will be informed in writing about changes of requirements by the Notified Body of BEV.