Conformity Evaluation Body METAS-Cert **METAS-Cert Guide**	**Document No** **6030B01_EN** First issue 17 August 2006/Ra Revised 25 February 2020/Couv Version 4.0 Released 17 February 2020/GLS Original in 6030B01_DE

METAS-Cert Guide

Contents

1 Scope

1.1 Scope of the document

This guide specifies the requirements and procedures for conformity assessment of measuring instruments and quality management systems pertaining to manufacturing processes as well as for the market introduction of measuring instruments by the notified conformity assessment body of the Federal Institute of Metrology METAS (METAS-Cert).

The guide is intended for use by manufacturers, importers or other entities that introduce measuring instruments into the Swiss or EU markets.

1.2 Objective of the conformity assessment body

METAS-Cert assesses the conformity of designs and types of measuring instruments and certifies products and management systems of measuring instrument manufacturers. It thus enables manufacturers to introduce measuring instruments into the Swiss and EU markets in accordance with the applicable legal requirements (Agreement between the European Community and the Swiss Confederation on Mutual Recognition in Relation to Conformity Assessment [37]).

The conformity assessment body METAS-Cert fulfils the requirements of Article 12 of the Measuring Instruments Ordinance and Article 27 of Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on Measuring Instruments (MID) [13] as well as Article 23 of Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on Non-automatic Weighing Instruments [14] for conformity assessments in accordance with the modules listed in Table 3 in section 2.1.

This guide provides information on the basic legal and normative principles and covers the procedures for conformity assessment and certification in the legally regulated area and in accordance with other procedures.

1.3 Basic principles

1.3.1 Basic principles for market introduction of measuring instruments

The requirements for the market introduction of measuring instruments in the legally regulated area are based on the following legal principles and standards:

	Swiss ordinance	**European directive**
Measuring instruments	Measuring Instruments Ordinance of 15 February 2006 (MIO; SR 941.210) [1] and measuring instrument-specific ordinances (see Table 4)	Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on Measuring Instruments (MID) [13]
Non-automatic weighing instruments	Ordinance of the FDJP of 16 April 2004 on Non-automatic Weighing Instruments (NSWV; SR 941.213) [7]	Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on Non-automatic Weighing Instruments [14]

Table 1: Legally regulated area

The requirements of the above-listed Swiss ordinances are equivalent to the requirements of the corresponding EU directives.

If a measuring instrument is introduced into the market in accordance with the ordinances or directives listed in Table 1 based on a conformity assessment by METAS-Cert, it must bear the following metrological CE marking:

CE M 20 1259

1.3.2 National conformity assessment

National conformity assessments apply to measuring instruments that are subject to this procedure for market introduction as set out in a measuring instrument-specific ordinance and which are not covered by the EU directives listed in Table 1 (NAWI, MID [13]).

When conducting a national conformity assessment, the conformity assessment procedures required under the relevant ordinance are applied based on the Blue Guide [31].

For a national conformity assessment, the conformity mark required under the relevant ordinance is used instead of the CE mark.

	Swiss ordinance
EMmV	Ordinance of the FDJP of 26 August 2015 on Measuring Instruments for Electrical Energy and Power (SR 941.251) [12]
VAMV	Ordinance of the FDJP of 19 March 2006 on Measuring Instruments for Exhaust Gases of Combustion Engines (SR 941.242) [11]
AlkBestV	Ordinance of the FDJP of 5 October 2010 on Measuring Instruments for Determining the Alcohol Content and Alcohol Quantity (Alcohol Determination Ordinance) (SR 941.210.2) [4]

Table 2: Legally regulated measuring instruments with national conformity assessment (these ordinances additionally apply to some extent to measuring instruments with EU conformity assessment)

The requirements of the above-listed Swiss ordinances are applicable only in the case of national conformity assessments.

If a measuring instrument is introduced into the market in accordance with the ordinances listed in Table 2 based on a conformity assessment by METAS-Cert, it must bear the following metrological CH marking:

1.3.3 Scope of validity of conformity assessments and certifications

Certifications performed in compliance with the ordinances listed in Table 1 are recognised in the EU and EFTA for the legally regulated area and authorise METAS-Cert's client to apply the conformity mark (CE mark) and the additional metrological marking. Certifications of measuring instruments in accordance with OIML-CS can be recognised worldwide. Certifications performed in compliance with the ordinances listed in Table 2 are recognised in Switzerland for the legally regulated area and authorise application of the conformity mark indicated in the measuring instrument-specific ordinance (e.g. CH conformity mark).

1.3.4 Organisational principles for operation of METAS-Cert

METAS-Cert is accredited by SAS in accordance with the standards ISO 17021 "Conformity assessment – Requirements for bodies providing audit and certification of management systems" [27], ISO 17065 "Conformity assessment – Requirements for bodies certifying products, processes and services" [29] and ISO 17020 "Conformity assessment – Requirements for the operation of various types of bodies performing inspection" [26].

2 Certification procedures

The following sections give details of the various conformity assessment procedures offered by METAS-Cert for the market introduction of measuring instruments.

For all of these services, the obligations of the client and METAS-Cert are regulated in the certification agreement [1].

For European conformity assessments, METAS-Cert relies on the provisions in the WELMEC guides [65] in addition to the requirements specified in the directives and standards.

2.1 Market introduction of measuring instruments based on conformity assessment procedures

Table 3 lists the possible modules for the declaration of conformity which must be evaluated by the conformity assessment body (CAB).

Passing the corresponding certification allows the manufacturer or its authorised representative to affix the conformity mark and the additional metrology mark to the measuring instrument.

	A2 =	Internal production control including supervised product checks at random intervals	
B = Type examination	+	C =	Conformity with type based on internal production control
		C2 =	Conformity with type based on internal production control including supervised product checks at random intervals
		D =	Conformity with type based on quality assurance for production
		E =	Conformity with type based on quality assurance for the product
		F =	Conformity with type based on product verification
	D1 =	Quality assurance for production	
	E1 =	Quality assurance for the product	
	F1 =	Conformity based on product verification	
	G =	Conformity based on unit verification	
	H =	Conformity based on full quality assurance	
	H1 =	Conformity based on full quality assurance plus design examination	

Table 3: Modules for attaining the conformity mark (e.g. CE) in accordance with MessMV

The modules may be divided into three categories: "Type examination", "Product verification" and "Examination of the quality management system"

A complete description of the modules is provided in MIO [2], MID [13] and NAWID [14].

Table 4 lists the services and conformity assessment modules that are offered by METAS-Cert. The available conformity assessment modules are given in the individual ordinances.

Swiss ordinance	MID annex or national	Measuring instrument	A2	B	C	C2	D	D1	E	E1	F	F1	G	H	H1
SR 941.231 [9]	MID III (MI-001)	Water meters		●			●				x				x
SR 941.241 [10]	MID IV (MI-002)	Gas meters and volume conversion devices		●			●				x				x
SR 941.251 [12]	MID V (MI-003)	Active electrical energy meters		●			●				●				●
SR 941.251 [12]	CH	Electricity meters for reactive energy, power and load profile		●			●				●				●
SR 941.231 [9]	MID VI (MI-004)	Heat meters		●			●				x				●
SR 941.212 [6]	MID VII (MI-005)	Measuring systems for continuous and dynamic measurement of quantities of liquids other than water		x			●				x		●		x
SR 941.213 [7]	NAWID	Non-automatic weighing instruments		●			●				●		●		
SR 941.214 [8]	MID VIII (MI-006)	Automatic weighing instruments		●			●	●	●		●	●	●		●
SR 941.201 [3] SR 941.211 [5]	MID X (MI-008)	Material measures - material measures of length - capacity serving measures	● ●	● ●			● ●	● ●	 ●	 ●		● ●	●	● ●	
SR 941.201 [3]	MID XI (MI-009)	Instruments for measuring dimensions and their combinations		●			●	●	●	●	●	●	●	●	●
SR 941.210.2 [4]	CH	Measuring instruments used to determine the alcohol content and alcohol quantity in alcohol/water mixtures		●		●									
SR 941.242 [11]	CH	Measuring instruments for nanoparticles from combustion engines		●							●				

● Conformity assessment procedure available from METAS-Cert
X Service not offered

Table 4: Measuring instruments and their conformity assessment modules

2.2 Procedures in accordance with OIML

2.2.1 OIML certification system (OIML-CS) for measuring instruments

In order to promote mutual recognition of type examinations of measuring instruments, the International Organization of Legal Metrology (OIML) has developed a certification system (www.oiml.org). The basic principles are defined in the document OIML B18 [15]. The OIML-CS is fully recognised around the world by over 30 countries[1] where it serves as the basis for national authorisation. An OIML certification is generally carried out in combination with an EU type examination. The system provides two different schemes:

Scheme A: Both the issuing authority and the testing laboratory demonstrate their competence based on a peer audit or accreditation. Certificates issued under scheme A enjoy greater recognition.

Scheme B: The issuing authority and the testing laboratory provide a self-declaration as evidence of their competence.

Under the OIML-CS, METAS-Cert can offer the following certifications:

[1] Declared users of OIML certificates; further countries that are not listed may also recognise the OIML certificates.

OIML recommendation	Scheme
R 50 (Continuous totalizing automatic weighing instruments) [16]	**B**
R 51 (Automatic catch weighing instruments) [17]	**B**
R 60 (Load cells) [18]	**A**
R 61 (Automatic gravimetric filling instruments) [19]	**B**
R 76 (Non automatic weighing instruments) [20]	**A**
R 106 (Automatic rail weighbridges) [21]	**B**
R 107 (Discontinuous totalizing automatic weighing instruments) [22]	**B**
R 117 (Measuring systems for liquids other than water) [23]	**B**
R 134 (Automatic instruments for weighing road vehicles in motion) [24]	**B**

Table 5: Measuring instrument categories for which METAS-Cert issues OIML documents

2.3 NTEP Verified Conformity Assessment Program Procedures (VCAP)

VCAP is an American procedure that requires the manufacturer to verify that it performs a statistical control procedure in production for testing the measuring instruments in relation to any influence factors. To maintain the NTEP type approval, manufacturers that introduce measuring instruments falling under the VCAP programme into the American market must be able to verify that they have been audited by an authorised body in this respect. METAS-Cert is authorised to perform VCAP audits.

VCAP encompasses the following: Weighing cells, indicators and evaluation units for weighing instruments, complete weighing instruments, automatic weighing instruments, automatic conveyor type weighers, automatic hopper scales

2.4 Other procedures

METAS-Cert also offers conformity assessments and inspections of measuring instruments and other products in accordance with Swiss regulations and other requirements (e.g. standards). The verifications are typically performed by METAS laboratories.

3 Conformity assessment and certification procedures

Conformity assessment procedures are managed by METAS-Cert, and METAS specialist laboratories, third-party laboratories and external experts may be involved. In cases where external laboratories or experts are involved, the client shall be duly informed. External parties must pledge to METAS-Cert to meet the requirements relating to confidentiality and impartiality as described in section 5.2.

3.1 Parties involved

The following roles matrix shows the possible combinations of parties that can be involved in a conformity assessment.

	Type examinations	Audits	Product verifications
METAS-Cert	Project management	Lead auditor	Tester
METAS specialist laboratory	Verification	Technical expert (if relevant)	Tester (if relevant)
Third-party laboratory	Verification (if relevant)	-	-
External experts	-	Technical expert (if relevant)	-

Table 6 Roles matrix

METAS-Cert is the primary contact for each of these relationships. METAS-Cert must be included in any communication between the client and the testing laboratory.

3.1.1 Project manager

The project manager is responsible for the following:

- Communication and coordination with the client
- Designation of required laboratories (internal and external), scheduling and coordination during the verifications
- Validation of the certification scope
- Timely and technically correct handling of the certification
- Creation / adaptation and editing of certificates, document lists and, if relevant, assessment reports
- Submission of the complete certification file to the CC [68] for the final decision on certification

3.1.2 Lead auditor

The lead auditor is responsible for the following:

- Communication and coordination with the client
- Determination of deadlines and planning with the client
- Assembly of the audit team
- Creation of the audit programme and invitation of participants to the audit
- Timely and technically correct handling of the audit
- Creation of the audit report and preparation of the certificate
- Submission of the certification file to the CC [68] for the final decision on certification

3.1.3 Tester

Duties of a tester (product and unit verifications)

The tester is responsible for planning and correctly performing the verification on-site. The tester briefs the customer about the necessary preparations (e.g. provision of support staff and materials). The tester organises the necessary references for the verification. The tester creates the test reports and the certificate of conformity and submits the certification application to the CC [68].

3.1.4 Technical expert

This person is generally an employee of the testing laboratory within METAS or an external testing laboratory.

3.2 Application for certification

Upon receiving an application for certification of a product, a type or a management system, METAS-Cert informs the applicant about the corresponding procedure.

For product verifications, an application form can be directly filled in and sent to METAS-Cert according to the instructions on the form.

For all other procedures, additional information is required in order to prepare a quotation.

For type examinations, METAS-Cert provides a list of module B descriptive documents (6030.xxF21) that the manufacturer must complete and return to METAS-Cert for the verification. This list summarizes all of the relevant information and documents for the measuring instrument. It is used in condensed form to prepare the quotation.

Order forms can be found on the METAS website
www.metas.ch/METAS-Cert

For each certification, an order or application form must be filled in and signed by the applicant. When submitting an order form, a quotation number must be provided. In case of third-party billing, the designated invoice recipient must also sign the form.

In justified cases, METAS-Cert may refuse an application for certification and shall inform the applicant in writing.

3.3 Certificate renewal

Prior to the expiration of a type examination certificate, the client should submit, in good time, a new application for certification in order to renew the certificate. The project manager must check whether the supporting documents are complete. If necessary, additional documents as well as inspections and checks can be required.

Prior to the expiration of a certificate for a quality management system, a re-certification audit is automatically initiated in order to renew the certificate.

3.4 Change request

According to certification agreement 6030B03 [1], section 13, the client is obliged to immediately report in writing any changes in the scope of the certification to METAS-Cert.

In case of modification of a type (extension, revision or correction of faults), the applicant must submit a change request using the change request form available on the METAS website.

3.5 Certification agreement

Certification agreement 6030B03 [1] serves as the basis for the order. It is published on the METAS website under METAS-Cert and is binding for certification. Furthermore, the METAS general terms and conditions (METAS GTCs [38]) apply.

The version of the certification agreement that is published on the METAS website is applicable.

3.6 Technical documents

For every conformity assessment, the manufacturer must provide the technical documents on the design, manufacture and operation of the product and take all necessary steps to ensure that the production process guarantees conformity of the products with the technical documents and the applicable requirements (i.e. it shall operate a quality assurance system).

3.7 Conformity assessment procedures

3.7.1 Type examination

Type examination (MID: "EU type examination") is the part of a conformity assessment procedure in which METAS-Cert examines and evaluates the type of a measuring instrument and declares whether or not the technical design meets the requirements that apply to the measuring instrument.

METAS-Cert offers three categories of type examinations:

1. Type examination in accordance with module B based on a European directive
2. Type examination in accordance with module B based on a national ordinance[2]
3. Type examination in accordance with OIML-CS

An OIML-CS certification (section 2.2) can be simultaneously combined with a type examination.

The obligations of the economic players in connection with measuring instruments that are introduced into the market based on a conformity assessment procedure are governed by Annex 2, Module B of MIO [1] or Annex 3, Section 1 of NSWV [7].

3.7.2 Examination of quality management systems

This group includes the modules D, D1, E, E1, H and H1. The examinations carried out by METAS-Cert relate to the manufacturer's quality management system.

The manufacturer shall operate an approved quality assurance system for production, final product inspection and testing that includes the preparation of technical documents (i.e. mandatory information on the intended product category, documentation of the quality assurance system and its updating, technical documentation of the approved type, a copy of the type examination certificate and the decisions and reports from the notified body).

METAS-Cert evaluates the manufacturer's (or the client's) management system in terms of its capability to ensure the production of measuring instruments that comply with legal requirements. METAS-Cert carries out periodic audits in order to make sure that the management system can effectively guarantee fulfilment of these requirements.

First-time audits shall be performed in two stages (unless the manufacturer was previously certified and is switching to METAS-Cert).

In addition, METAS-Cert may pay the manufacturer unannounced visits. During these visits, it may carry out any necessary product verifications, or have them carried out, to check the correct functioning of the management system.

Two-stage procedure

The audit for initial certification of a management system is carried out in two stages.

Stage 1 can be performed on METAS premises or on-site. The lead auditor shall decide on the appropriate procedure.

The stage 1 audit serves as orientation and preparation for the stage 2 main audit. It is intended to ensure that the quality management system has all of the necessary elements to proceed with certification. The audited entity shall be informed of any non-conformities. A pre-audit is not a consultation. It is performed on the basis of the same principles as a certification audit.

The stage 2 audit shall be performed in accordance with an audit plan agreed in writing with the applicant. This audit plan shall be based on ISO/IEC 19011 [30] and take into consideration the information gathered during the stage 1 audit.

Audit report and decision on certification

At the final meeting, the audit team communicates the relevant observations, conditions and actions to the manufacturer by means of a conditions check list. The manufacturer is obliged to rectify the non-conformities within the agreed time interval.

After completion of the audit, the audit team shall use the gathered information to draft its audit report. This report indicates the status of the manufacturer's management system, provides information on the course of the audit and describes the major and minor conditions imposed as well as the areas with potential for improvement.

It includes a recommendation on the granting of certification, observations to support the recommendation and, if required, conditions to be complied with during the period of validity. The audit report is provided to the applicant for comment.

[2] As a prerequisite, module B must be applicable to the measuring instrument and not harmonised at the European level.

In case of substantial non-conformities, a certificate cannot be issued until the non-conformities have been rectified. If necessary, section 5.4, Cancellation of the certification procedure, shall be applied.

At the end, the CC [68] makes its decision on certification based on the audit report and the provided verifications.

Supervisory audit

During the certificate's period of validity, a supervisory audit shall be performed annually. For each audit, an audit report is prepared and provided to the holder of the certificate.

For manufacturers with ISO 9001 certification, the audit period may be extended to one and a half years. However, this is subject to approval by the head of METAS-Cert and requires that no major complaints have been recorded by market supervisory authorities and that the ISO 9001 certification body is monitoring the manufacturer on an annual basis.

For manufacturers under licence [51] that do not manipulate their measuring instruments in any way and whose supplier (original equipment manufacturer [57]) is certified in accordance with module D, an audit is performed only when the certificate is to be renewed.

For organisations that are already certified by another notified body in accordance with MID, a document audit may be performed instead of an on-site audit if:

- The manufacturer is certified under MID/MI003 and, additionally, a national conformity assessment is performed by METAS-Cert.
- The manufacturer is a manufacturer under licence, receives pre-sealed instruments from the original equipment manufacturer and does not manipulate the measuring instrument in any way.

If, during a supervisory audit, any non-conformity with the requirements for certification is detected, the head of METAS-Cert may respond as follows:

- The change in situation is justifiable: the certification may be extended or renewed, possibly after fulfilment of relevant conditions
- The situation is unacceptable: this calls for a temporary suspension or withdrawal of certification (procedure as described in section 5.4)

The head of METAS-Cert may, if necessary, stipulate a shorter period for the supervisory audits or arrange an audit at short notice.

Further details are regulated by the certification agreement [1].

3.7.3 Product verification

This group includes the modules A, A2, F, F1 and G.

The verifications carried out or supervised by METAS-Cert relate to the manufactured product. METAS-Cert issues a certificate of conformity and supervises the affixing of its identification number on the product.

For module F verifications (and especially when the verification truck is used), the device under test must be ready and clean and the necessary tools and support staff must be available during the entire verification process in order to avoid additional charges.

In order to avoid extra effort and expenses, the specialist from METAS-Cert affixes the identification number upon successful conclusion of the verification (unless otherwise agreed) and secures the measuring instrument. The conformity assessment procedure is not completed until after approval by the CC [68] and after the certificate of conformity is signed.

Conformity based on unit verification, module G

For a module G verification, the instrument is generally inspected at the installation site. The manufacturer shall provide METAS-Cert with all relevant technical documents, specifications, unit certificates and software specifications in advance.

4 Certificates

The manufacturer may affix the CE marking (based on an EU directive) or the CH marking (in the case of a national conformity assessment) solely on the basis of a certificate of conformity. At the same time, it issues a declaration of conformity (see also section 5.6).

4.1 Types of certificates and additional documents

METAS-Cert issues various types of certificates with different formats for the numbering. Some types of certificates include additional documents. Each certificate or document number is unique. A certificate can be reissued with the same number only by means of a new revision.

4.1.1 Type examination certificates

Upon successful conclusion of a type examination, a type examination certificate is issued. The following numbering format is used: CH-KK-YYNNN-RR

KK: Measuring instrument category

MI001	Water meters
MI002	Gas meters and volume conversion devices
MI003	Electricity meters (active energy meters)
MI004	Heat meters
MI005	Measuring systems for liquids other than water
MI006	Automatic weighing instruments
MI008	Material measures
MI009	Instruments for measuring dimensions and their combinations
MI010	Exhaust gas analysers
CH003	Electricity meters with the exception of active energy meters
W1	Non-automatic weighing instruments
K4	Nanoparticle measuring instruments
DS	Elements of intelligent measuring systems (data security)

YY: Year of initial certification

NNN: Reference number within category

RR: Revision number (not indicated on type plate)

The period of validity is specified in the statutory regulations.

Type examination certificates may be amended as needed and each revision is shown in the revision history. In case of renewal, the revision number is incremented.

As part of revisions, the content is supplemented; elements can be deleted only for renewals.

The client is provided with a separate document list (Doc_List_TEC) that accompanies the type examination certificate.

4.1.2 Certificates of evaluation, unit certificates

These certificates are handled like type examination certificates. Numbering format: 6030-NNNNN (revision R)

NNNNN: Unique base number

R Revision number (appears starting with 1st revision only) The file name is supplemented with –RR.

4.1.3 Certificates of conformity for quality management systems

Numbering format: 6030-NNNNN (revision R)

NNNNN: Unique base number

R Revision number (appears starting with 1st revision only) The file name is supplemented with –RR.

A revision of a certificate for a QMS is treated as a completely new certificate; the base number remains the same. Since the manufacturer lists the certificate number without revision in its doc-

uments (declaration of conformity), it does not have to revise the documents in case of certificate renewal.

The certification agreement [1] regulates the period of validity.

An audit report is issued for a QMS certificate.

4.1.4 Certificates of conformity for product and unit verifications

Numbering format: 6030-NNNNN

NNNNN: Unique base number

The certificate corresponds to a state at the time of verification (inspection) and has no validity period.

METAS-Cert creates a test report. For product verifications, it is kept only for internal purposes. For unit verifications, a numbered test report is prepared.

4.1.5 Test reports

Numbering format: 6030-NNNNN

NNNNN: Unique base number

The certificate corresponds to a state at the time of verification (inspection) and has no validity period.

4.1.6 OIML certificates

Content and numbering in accordance with OIML requirements

Numbering format: RXXX/YYYY-S-CH1-yyyy.NN (revision R)

RXXX: Number of OIML recommendation

YYYY: Year of OIML recommendation

S: Scheme: A or B

CH1: Number of issuing authority METAS-Cert

yyyy: Year of certification

NN: Unique base number of year for corresponding recommendation

R: Revision number (starting with 1st revision only)

All of the listed documents are included with the OIML certificate:

- OIML type evaluation report
- Test reports from laboratory
- Document list

An OIML certificate does not have a period of validity.

4.1.7 Other certificates

For justified purposes, METAS-Cert may issue other certificates. Such certificates must fall within the area of responsibility of METAS-Cert. They may be issued only on the basis of standards, directives, ordinances and other documents of a normative nature.

Numbering format: 6030-NNNNN

NNNNN: Unique base number

4.1.8 Document list (Doc_List_TEC)

A document list is created for type examination, evaluation, unit and OIML certificates. The document list includes the underlying test reports, technical documents and firmware versions.

A document list may be revised without having to revise the certificate in case of technical changes that do not impact the content of the certificate.

4.1.9 OIML type evaluation report

Content in accordance with OIML requirements

Numbering format: 6030-NNNNN (revision R)

NNNNN: Unique base number

R Revision number (appears starting with 1st revision only) The file name is supplemented with –RR.

4.1.10 Audit and inspection reports

Numbering format: YYYY-MM-DD-NNN

YYYY-MM-DD Date of audit or inspection

(N)NNN Unique serial number

Inspection reports are issued only for weather stations.

4.2 Publication of certificates

The manufacturer is in possession of the original certificate that was issued while METAS-Cert keeps a list of issued certificates that it publishes on its website (www.metas.ch/certsearch).

Certificates issued on the basis of NAWID [14] are also sent to the EMeTAS database for publication.

OIML-CS certificates are sent to the OIML for publication. The OIML charges the cost of publishing and maintaining these certificates to the manufacturer.

4.2.1 E-certificates

METAS-Cert only issues electronically signed certificates in the form of PDF files. The certificates feature a digital ID for the Federal Institute of Metrology METAS. The certificates can only be examined in electronic form and are valid only in this form.

4.2.2 Access restriction

Type examination certificates can be viewed in full only by registered persons, in particular market supervisory authorities. Unregistered persons can view a brief description of the certificate.

Certificates for quality management systems are not subject to any access restrictions.

Certificates for product verifications and internal production control are available only upon request by market supervisory authorities.

4.3 Extension and withdrawal of a certificate

4.3.1 Extension

If a manufacturer requests an extension of the scope of certification, the evaluation shall be carried out following the same procedures as described above. If all of the requirements are fulfilled, a new certificate shall be issued.

4.3.2 Replacement of a certificate

If there is a valid reason for replacing a certificate (issuance of a new certificate number), the phrase "Replaces certificate no.", followed by the old certificate number, shall appear on the new certificate directly under the certificate number.

4.3.3 Suspension or withdrawal of a certificate

Relevant details are regulated by the certification agreement [1].

5 General information

5.1 Technical documents

The manufacturer is obliged to keep the technical documents relating to the type as well as the production, inspection and certification verifications available for the individual national authorities for a period of ten years following the market introduction of the measuring instrument.

5.2 Confidentiality and secrecy

In accordance with Article 20 Paragraph 1 of PV-METAS (obligation of secrecy) [36], METAS employees are obliged to maintain secrecy on professional and business matters that, as a function of their nature as well as the applicable legal provisions or directives, must be kept confidential. External auditors and technical experts shall be bound by a non-disclosure agreement. If it becomes necessary to divulge information for legitimate legal reasons, the affected parties shall be informed.

5.3 Impartiality

METAS-Cert is obliged to treat its customers in an impartial manner. Accordingly, employees of METAS-Cert as well as other persons involved in the certification process are not allowed to provide consulting or suggestions relating to verifications and documentation (e.g. document preparation, drafting, etc.).

5.4 Cancellation of the certification procedure

If the applicant does not fulfil the conditions that are imposed or fails to submit the required documentation on schedule, the head of METAS-Cert is entitled to postpone or cancel the certification.

Relevant details are regulated by the certification agreement [1].

In case of product verifications, the responsible verification office shall be informed.

5.5 Complaints, appeals and civil actions

Complaints relating to conformity assessments shall be addressed to METAS-Cert. They shall be handled in accordance with the METAS internal process for dealing with complaints and non-conformities. The conditions that apply to appeals and civil actions are regulated by the certification agreement [1].

5.6 Content of a declaration of conformity (DoC)

Upon conclusion of every conformity assessment, the manufacturer or its authorised representative must issue a declaration of conformity (DoC).

The form and content of the DoC are specified in MIO [2] Art. 10, NSWV Art. 10 [7], MID [13] Annex XIII and NAWID [14] Annex IV.

The following points explain what has to be included in a declaration of conformity.

5.6.1 Title

For declarations of conformity in accordance with an EU directive:

EU declaration of conformity

For declarations of conformity based on a national conformity assessment (e.g. CH or DE):

CH declaration of conformity

DE declaration of conformity

The manufacturer may voluntarily assign a number to each declaration of conformity.

5.6.2 Identification

The instrument or instrument model must be indicated in the same form as in the type examination certificate or certificate of conformity, as relevant.

Furthermore, identification is required on the basis of an instrument, serial or batch number. It is possible to specify the number at which validity of the DoC begins. This number must be adjusted each time the DoC is revised.

5.6.3 Manufacturer

The name and address of the manufacturer and, where applicable, its authorised representative must be specified.

The manufacturer or its representative must be in possession of a certificate of conformity (e.g. module D or F) in order to declare conformity (except for module A, which is based on a self-declaration by the manufacturer).

5.6.4 Confirmation

The following declaration must appear verbatim:

"This declaration of conformity is issued under the sole responsibility of the manufacturer."

5.6.5 Object

It is necessary to indicate what kind of measuring instrument is covered by the DoC, e.g. water meter, meter for active electrical energy, non-automatic weighing instrument, etc.

An illustration can be provided for identification purposes.

5.6.6 Regulations

The DoC contains information on the applicable directives, e.g.:

- Directive 2014/31/EU on Non-automatic Weighing Instruments, or
- Measuring Instruments Directive 2014/32/EU (MID)

And/or the applicable ordinances and/or laws in case of a national conformity assessment:

- MIO 941.210 Annexes 1 and 2
- EMmV 941.251 Annex 2

5.6.7 Standards

The DoC contains a list of the relevant harmonised standards or normative documents which form the basis, or a reference to other normative documents or other technical specifications in relation to which conformity is declared.

5.6.8 Notified body

The DoC must list all relevant information for the involved notified bodies as well as which certificates were issued (both for module B and for module D or F):

Type examination certificate (module B) no. CH-MI003-YYNNN, issued by METAS-Cert (no. 1259)

Certificate of conformity (module D) no. 6030-NNNNN, issued by METAS-Cert (no. 1259)

Note: The number of the notified body must be indicated on every certificate. For conformity assessments in accordance with EU directives, the number of METAS-Cert is 1259. For national conformity assessments, the number is CH01.

5.6.9 Additional information / signature

The DoC must be signed by a person with signing authority (according to the commercial register) who is associated with the manufacturer or its representative.

Signed for and on behalf of:

(place and date of issue):

(name, job title) (signature):

5.6.10 Languages

The language of the DoC and the accompanying documents must conform to the national provisions of the country where the measuring instrument is introduced into the market.

For Switzerland, the DoC must be drawn up in one of Switzerland's official languages or in English.

5.6.11 Further information

The manufacturer or its representative shall retain the original of the DoC. A copy thereof shall be enclosed with the measuring instrument or the batch. The DoC may also be published on a website. However, it must be easy to find the correct DoC based on information provided on or with the measuring instrument.

Annex I Index of references

[1]	6030B03	Certification agreement
[2]	MIO	Measuring Instruments Ordinance of 15 February 2006 (SR 941.210)[3]
[3]		Ordinance of the FDJP of 19 March 2006 on Dimensional Measuring Instruments (SR 941.201)
[4]	AlkBestV	Ordinance of the FDJP of 5 October 2010 on Measuring Instruments for Determining the Alcohol Content and Alcohol Quantity (Alcohol Determination Ordinance) (SR 941.210.2)
[5]		Ordinance of the FDJP of 19 March 2006 on Measurement of Volume (SR 941.211)
[6]		Ordinance of the FDJP of 19 March 2006 on Measuring Systems for Liquids other than Water (SR 941.212)
[7]	NSWV	Ordinance of the FDJP of 16 April 2004 on Non-automatic Weighing Instruments (SR 941.213)
[8]	SWV	Ordinance of the FDJP of 19 March 2006 on Automatic Weighing Instruments (SR 941.214)
[9]		Ordinance of the FDJP of 19 March 2006 on Measuring Instruments for Thermal Energy (SR 941.231)
[10]		Ordinance of the FDJP of 19 March 2006 on Gas Meters (SR 941.241)
[11]	VAMV	Ordinance of the FDJP of 19 March 2006 on Measuring Instruments for Exhaust Gases of Combustion Engines (SR 941.242)
[12]	EMmV	Ordinance of the FDJP of 26 August 2015 on Measuring Instruments for Electrical Energy and Power (SR 941.251)
[13]	MID	Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast)
[14]	NAWID	Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (recast)
[15]	OIML B18	Framework for the OIML Certification System (OIML-CS), Edition 2018
[16]	OIML R 50	International Recommendation OIML R50, Edition 2014, Continuous totalizing automatic weighing instruments
[17]	OIML R 51	International Recommendation OIML R51, Edition 2006, Automatic catch weighing instruments
[18]	OIML R 60	International Recommendation OIML R60, Edition 2017, Metrological regulation for load cells
[19]	OIML R 61	International Recommendation OIML R61, Edition 2017, Automatic gravimetric filling instruments
[20]	OIML R 76	International Recommendation OIML R76, Edition 2006, Non-automatic weighing instruments
[21]	OIML R 106	International Recommendation OIML R106, Edition 2011, Automatic rail weighbridges
[22]	OIML R 107	International Recommendation OIML R107, Edition 2007, Discontinuous totalizing automatic weighing instruments
[23]	OIML R 126	International Recommendation OIML R126, Edition 2012, Evidential breath analyzers

[3] Swiss Ordinances are only available in German, French and Italian languages

[24]	OIML R 134	International Recommendation OIML R134-1, Edition 2006, Automatic instruments for weighing road vehicles in motion and measuring axle loads
[25]	ISO 9001	Quality Management Systems – Requirements (SN EN ISO 9001:2015)
[26]	ISO/IEC 17020	Conformity assessment – Requirements for the operation of various types of bodies performing inspection (ISO/IEC 17020:2012)
[27]	ISO/IEC 17021	Conformity assessment – Requirements for bodies providing audit and certification of management systems (ISO/IEC 17021-1:2015)
[28]	ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories (SN EN ISO/IEC 17025:2005)
[29]	ISO/IEC 17065	Conformity assessment – Requirements for bodies certifying products, processes and services (ISO/IEC 17065:2012)
[30]	ISO/IEC 19011	Guidelines for auditing management systems (ISO 19011:2011)
[31]	Blue Guide	"Blue Guide" on the implementation of EU product rules 2016
[32]	Metrology Act	Swiss Federal Law of 17 June 2011 on Metrology (SR 941.20)
[33]	EIMG	Swiss Federal Law of 17 June 2011 on the Federal Institute of Metrology (SR 941.27)
[34]	THG	Swiss Federal Law of 6 October 1995 on Technical Barriers to Trade (SR 946.51)
[35]	BPG	Swiss Federal Personnel Act (SR 172.220.1)
[36]	PV-METAS	METAS Personnel Ordinance (SR 941.273)
[37]	0.946.526.81	Agreement between the European Community and the Swiss Confederation on Mutual Recognition in Relation to Conformity Assessment (entered into force on 1 June 2002)
[38]	METAS GTCs	METAS general terms and conditions

Annex II Index of key terms

[39]	**Audit**	Systematic, independent and documented examination procedure to ascertain whether organisations and processes comply with specified requirements and guidelines.
[40]	**Type examination certificate (TEC)**	See section 4.1.1
[41]	**Certificate**	See Certification
[42]	**FDJP**	Federal Department of Justice and Police
[43]	**EMeTAS**	European Metrology Type Approval Service (www.emetas.eu)
[44]	**Evaluation certificate**	See WELMEC guide 8.8
[45]	**Distributor**	According to section 3.4 of the Blue Guide: Any natural or a legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.
[46]	**Manufacturer**	According to section 3.1 of the Blue Guide: Any natural or legal person who manufactures a product or has a product designed or manufactured, and places it on the market under his own name or trademark.
[47]	**CAB**	Conformity assessment body
[48]	**Conformity assessment**	Conformity assessment is an umbrella term for the activities of selection, determination (of characteristics), evaluation (e.g. of conformity with specified or general requirements) and confirmation (e.g. based on a manufacturer's declaration or a certificate from a certification body that a product complies with certain standards). Such activities include, for example, sampling, verification, inspection, declaration, certification and accreditation. The subjects of the conformity assessment are not restricted.
[49]	**Declaration of conformity (DoC)**	Document issued by the manufacturer or its representative declaring the conformity of the measuring instrument in accordance with the applicable directives, ordinances and harmonised standards (see also section 5.6).
[50]	**Certificate of conformity**	Certificate verifying that a measuring instrument is in compliance with the legal requirements.
[51]	**Manufacturer under licence (MUL)**	A manufacturer under licence places a measuring instrument from another manufacturer on the market under its own name. The corresponding responsibilities are mutually agreed on a contractual basis.
[52]	**Management system (MS)**	Description of management duties and combination of methods in order to successfully handle the management duties and set, regulate and control the objectives.
[53]	**Nando**	Information System of the European Commission (New Approach Notified and Designated Organisations) https://ec.europa.eu/growth/tools-databases/nando/
[54]	**NAWI**	Non-automatic weighing instrument (German: NSW)
[55]	**Non-conformity**	Non-compliance with an applicable requirement of a standard
[56]	**NSW**	German abbreviation for "non-automatic weighing instrument"
[57]	**Original equipment manufacturer (OEM)**	An original equipment manufacturer produces measuring instruments in its own manufacturing organisations but places a different name on them and does not handle their retail marketing. See also manufacturer under licence (MUL)

[58]	**OIML**	International Organization of Legal Metrology www.oiml.org
[59]	**Parallel certificate**	The term "parallel certificate" refers to a type examination certificate issued to a manufacturer under licence on the basis of an original certificate from an original equipment manufacturer. The measuring instrument specified in the parallel certificate may not differ from the original apart from the labelling, the type designation and the decoration (e.g. colour).
[60]	**Quality**	All of the characteristics of an entity that bear on its ability to fulfil stipulated requirements. (ISO 9000:2015) An entity can be a product, a service, an activity, a process, a system, a person, an organisation, etc.
[61]	**Quality policy**	Broad intentions and objectives of an organisation in relation to quality, as formally expressed by top management.
[62]	**Quality assurance**	All planned and systematic activities that are implemented as part of the QM system and are demonstrated, as required, to provide a sufficient level of confidence that an entity fulfils the quality requirements.
[63]	**RNSW (NAWID)**	German (English) abbreviation for the European Non-automatic Weighing Instruments Directive [14]
[64]	**System audit**	Assessment of a management system by an independent third party in relation to its ability to ensure the declared quality of products or services.
[65]	**WELMEC**	European Cooperation in Legal Metrology www.welmec.org
[66]	**Economic player**	Natural or legal person established in the EU[4] who introduces a measuring instrument into the market that falls under the provisions of the Directive 2014/31/EU or 2014/32/EU.
[67]	**Certification**	Process by which a certification organisation declares that a measuring instrument complies with the legal requirements, that a management system fulfils all of the requirements stipulated in the standard and that the applicant meets the internally defined specifications.
[68]	**CC**	Certification Commission

[4] Also applicable to CH (Blue Guide section 9.2.2), EEA/EFTA countries and TR.