



Conformity Evaluation Body METAS-Cert

Guide for the market introduction of measuring instruments

Document No	6030B01_EN
First issue	17 August 2006/Ra
Revised	6 March 2017/Couv
Version	3.0
Released	20 February 2017/GLS
Original in	6030B01_EN

Guide for the market introduction of measuring instruments

Contents

1	Scope	3
1.1	Scope of the document	3
1.2	Objective of the notified body (NB)	3
1.3	Basic principles	3
1.3.1	Basic principles for market introduction of measuring instruments	3
1.3.2	National conformity assessment	4
1.3.3	Scope of validity of the certification of management systems for the manufacture of measuring instruments	4
1.3.4	Organisational principles for operation of METAS-Cert	4
2	Conformity assessment procedures	5
2.1	Market introduction of measuring instruments in accordance with Annex II of the MeasIO [1] (equivalent to MID procedures)	5
2.1.1	Category "Type examination"	7
2.1.2	Category "Product verification"	8
2.1.3	Category "Assessment of the quality management system"	11
2.2	Market introduction of non-automatic weighing instruments (NAWI)	16
2.3	<i>Procedures in accordance with OIML</i>	17
2.3.1	OIML certification system for measuring instruments	17
2.3.2	OIML framework agreement (Mutual Acceptance Arrangement, MAA)	18
2.4	NTEP Verified Conformity Assessment Program Procedures (VCAP)	18
2.5	Other procedures	18
3	Certification of types and management systems	18
3.1	Application for certification	18
3.2	Certification agreement, commission	18
3.3	Appointment of auditors and technical experts	19
3.4	Duties of the lead auditor	19
3.5	Confidentiality	19
3.6	Audit report and decision on certification	19
3.6.1	Non-fulfilment of the non-conformities	19
3.7	Scope of validity of the certificate and period of validity	19
3.8	Surveillance audit	20
3.9	Extension and withdrawal of a certificate	20
3.9.1	Extension	20
3.9.2	Suspension and withdrawal of a certificate	20
3.10	Publication of certificates	20
3.10.1	Access restriction	21
3.11	Cancellation of the certification procedure	21
3.12	Complaints, appeals and civil action	21
3.13	Performance of a management system audit	21
3.13.1	Preparation	21
3.13.2	Two-stage procedure	21
3.13.3	Stage 1	21
3.13.4	Stage 2	22
3.14	Performance of a type examination	22
3.14.1	Preparation	22
3.14.2	Tests	23
3.14.3	Type examination or type approval certificate	23
3.14.4	Final steps	23
3.15	Generalities	23
Annex I	Index of references	25
Annex II	Index of key terms	27
Annex III	Certification agreement METAS-Cert	29

1 Scope

1.1 Scope of the document

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

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

1.2 Objective of the notified body (NB)

METAS-Cert evaluates 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 [42]). The notified body METAS-Cert functions as a notified body in the EC and EFTA (EU states plus Norway, Iceland, Liechtenstein, Switzerland) as well as Turkey and the United Arab Emirates in accordance with Article 27 of Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on Measuring Instruments (MID) [12] and handles conformity assessments in accordance with the modules listed in Table 4 in Section 1.3.4.

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 (SR 941.210) [1] and relevant specific ordinances (see Table 5)	Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on Measuring Instruments (MID) [12]
Non-automatic weighing instruments	Ordinance of the FDJP of 16 April 2004 on Non-automatic Weighing Instruments (SR 941.213) [6]	Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on non-automatic Weighing Instruments (NAWI) [13]

Table 1: Legally regulated area

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

The requirements for certification of measuring instruments in accordance with other procedures are based on the following principles:

	International directive, standard
--	-----------------------------------

Measuring instruments in accordance with other procedures	International Organization of Legal Metrology (OIML), OIML Recommendation Rxxx ¹ (directive corresponding to measuring instrument categories in Section 2.3.1 Table 7 and Section 2.3.2 Table 8), SN EN ISO/IEC 17025 [33]
---	---

Table 2: Other procedures

1.3.2 National conformity assessment

National conformity assessment applies to measuring instruments that are subject to a procedure for market introduction that is envisaged in a measuring instrument-specific ordinance, and that are not, or only partially, covered by the European directives listed in Table 1 (NAWI, MID [12]).

When conducting a national conformity assessment, the conformity assessment procedures required under the relevant ordinance are applied based on the Blue Guide [35].

	Swiss ordinance
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) [2]
VAMV	Ordinance of the FDJP of 19 March 2006 on Measuring Instruments for Exhaust Gases of Combustion Engines (SR 941.242) [8]
EMmV	Ordinance of the FDJP of 19 March 2006 on Measuring Instruments for Electrical Energy and Power (SR 941.251) [11]

Table 3: Legally regulated measuring instruments with national conformity assessment

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

1.3.3 Scope of validity of the certification of management systems for the manufacture of measuring instruments

Certifications performed in compliance with the ordinances listed in Table 1 are recognised in the EC and EFTA for the legally regulated area and authorise METAS-Cert's customer to apply the conformity mark (CE mark) and the additional metrology marking. Certifications of measuring instruments in accordance with Table 2 can be recognised worldwide. Certifications performed in compliance with the ordinances listed in Table 3 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

The requirements for METAS-Cert are based on ISO standard 17021 "Conformity assessment – Requirements for bodies providing audit and certification of management systems" [32] and ISO standard 17065 "Conformity assessment – Requirements for bodies certifying products, processes and services" [34] along with the corresponding WELMEC guidelines.

¹ xxx stands for the number of the OIML Recommendation

2 Conformity assessment procedures

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

2.1 Market introduction of measuring instruments in accordance with Annex II of the MeasIO [1] (equivalent to MID procedures)

Table 4 lists the possible modules for the declaration of conformity; these modules must be evaluated by the notified body (NB).

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.

A = Internal Production control	
A2 = Internal production control plus supervised instrument checks at random intervals	
B = Type examination	C = Conformity to type based on internal production control
	C2 = Conformity to type based on internal production control plus supervised instrument checks at random interval
	D = Conformity to type based on quality assurance of the production process
	E = Conformity to type based on instrument quality assurance
	F = Conformity to type based on product verification
D1 = Quality assurance of the production process	
E1 = Quality assurance of final product inspection and testing	
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 4: Modules for attaining the conformity mark (e.g. CE) in accordance with the MeasIO

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 the MEASIO [1] and the MID [12].

Guide for the market introduction of measuring instruments

Table 5 lists the modules that are offered by METAS-Cert.

Conformity assessments in accordance with modules A1, D1, E1, F1, G, H and H1 may only be performed by a single NB.

Conformity assessments in accordance with combinations B+D, B+E and B+F may be carried out by two different CEBs.

Swiss ordinance (see Annex I)	MID Annex or national	Measuring instrument	A2	B+C	B+C2	B+D	B+E	B+F	D1	E1	F1	G	H	H1
SR 941.231 [8]	III (MI-001)	Water meters				●		●						●
SR 941.241 [9]	IV (MI-002)	Gas meters and volume conversion devices				●		●						●
SR 941.251 [11]	V (MI-003)	Active electrical energy meters				●		●						●
SR 941.251 [11]	CH	Reactive electrical energy meters, power and load profile				●		●						●
SR 941.231 [8]	VI (MI-004)	Heat meters				●		●						●
SR 941.212 [5]	VII (MI-005)	Measuring systems for continuous and dynamic measurement of quantities of liquids other than water				●		●				●		●
SR 941.213 [6]	EU - EEE	Non-automatic weighing instruments				●		●				●		
SR 941.214 [7]	VIII (MI-006)	Automatic weighing instruments - mechanical devices - electromechanical devices - electronic devices or devices that contain software				● ● ●	● ●	● ● ●	●		●	● ● ●		● ● ●
SR 941.201 [2] SR 941.211 [4]	X (MI-008)	Material measures - material measures of length - capacity serving measures	●			● ●	●		● ●	●	● ●	●	● ●	
SR 941.201 [2]	XI (MI-009)	Dimensional measuring instruments - mechanical or electromechanical devices - electronic devices or devices that contain software				● ●	●	● ●	● ●	●	●	● ●	● ●	● ●
SR 941.242 [10]	XII (MI-010)	Exhaust gas analysers				●		●						●
SR 941.210.2 [3]	CH	Measuring instruments used to determine the alcohol content and alcohol quantity in alcohol-water mixtures			●									
SR 941.242 [10]	CH	Measuring instruments for nanoparticles from combustion engines						●						

Table 5: Measuring instruments and their conformity assessment modules

2.1.1 Category “Type examination”

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 that the technical design meets the requirements that apply to the measuring instrument.

Outlined below are the tasks for which the manufacturer or its authorised representative is responsible, along with the tasks that METAS-Cert (hereafter “notified body”) is expected to perform:

2.1.1.1 Type examination, module B

The manufacturer shall

- prepare technical documentation on the design, manufacture and operation of the product.

The manufacturer or its authorised representative shall

- submit an application for type examination,
- provide the notified body with one or several specimens that are representative of the planned production,
- inform the notified body of any modifications made to the approved product,
- keep the technical documentation and a copy of the type examination certificate available for the supervisory authorities.

METAS-Cert shall

- carry out the relevant examinations and necessary tests, or have them carried out, to determine whether the specimen or specimens fulfil the specified requirements and have been manufactured in compliance with the technical documentation,
- issue a type examination certificate,
- keep a copy of the certificate and a list of other important technical documents,
- provide other notified bodies, upon their request, with the required information on the type examination certificates.

2.1.2 Category “Product verification”

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

The examinations 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.

2.1.2.1 Internal production control plus supervised instrument checks at random intervals, module A1

The manufacturer shall

- prepare technical documentation on the design, manufacture and operation of the product,
- 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),
- perform one or several random inspections of the manufactured product, or have them carried out at its expense,
- appoint a notified body that shall be responsible for the handling of the tests.

The manufacturer or its authorised representative shall

- ensure and declare that the relevant products fulfil the requirements,
- affix the conformity mark and the metrology marking to each product,
- affix the identification number of the notified body,
- issue a declaration of conformity to the fulfilled directives (e.g. 2004/22/EC) and provide a copy for the measuring instrument (or set of measuring instruments),
- keep the original of the declaration of conformity and the technical documentation available for the supervisory authorities.

METAS-Cert shall

- monitor the inspections performed by the manufacturer,
- supervise the affixing of its identification number,
- keep any mandatory information,
- provide other notified bodies, upon their request, with the required information.

2.1.2.2 *Conformity to type based on product verification, module F*

The manufacturer shall

- take all necessary steps to ensure that the production process guarantees conformity of the manufactured products with the type described in the type examination certificate and the applicable requirements (i.e. it shall operate a quality assurance system and prepare the necessary documents),
- in the case of a statistical examination, present its products in homogeneous lots and take all necessary steps to ensure the homogeneity of each lot produced in the manufacturing process.

The manufacturer or its authorised representative shall

- submit an application for a conformity assessment,
- guarantee and declare that the applicable products are in compliance with the type described in the type examination certificate and fulfil the applicable requirements,
- affix the conformity mark and the metrology marking to each product,
- affix the identification number of the notified body,
- issue a declaration of conformity to the directives complied with (e.g. 2014/32/EU) and provide a copy for the measuring instrument (or set of measuring instruments),
- keep the technical information (i.e. the certificate of conformity from the notified body with the listed supplementary documents) and the declaration of conformity available for the supervisory authorities.

METAS-Cert shall

- carry out appropriate evaluations and tests, either by examining and testing each individual product or by examining and testing the products on a statistical basis, to check the conformity of the product to the relevant requirements,
- supervise the affixing of its identification number,
- issue a certificate of conformity for the examinations performed,
- if a lot is rejected, take appropriate measures to prevent the market introduction of that lot,
- keep a list of important technical documents,
- provide other notified bodies, upon their request, with the required information.

2.1.2.3 *Conformity based on product verification, module F1*

The manufacturer shall

- prepare technical documentation on the design, manufacture and operation of the product,
- take all necessary steps to ensure that the production process guarantees conformity of the manufactured products to the applicable requirements (i.e. it shall operate a quality assurance system),
- in the case of a statistical examination, present its products in homogeneous lots and take all necessary steps to ensure the homogeneity of each lot produced in the manufacturing process.

The manufacturer or its authorised representative shall

- submit an application for a conformity assessment,
- ensure and declare that the relevant products fulfil the applicable requirements,
- affix the conformity mark and the metrology marking to each product,
- affix the identification number of the notified body,
- issue a declaration of conformity to the directives complied with (e.g. 2014/32/EU) and provide a copy for the measuring instrument (or set of measuring instruments),
- keep the declaration of conformity, the technical documentation and the certificate of conformity from the notified body available for the supervisory authorities.

METAS-Cert shall

- carry out appropriate evaluations and tests, either by examining and testing each individual product or by examining and testing the products on a statistical basis, to check the conformity of the product to the relevant requirements,
- supervise the affixing of its identification number,
- issue a certificate of conformity for the examinations performed,
- if a lot is rejected, take appropriate measures to prevent the market introduction of that lot,
- keep a list of important technical documents,
- provide other notified bodies, upon their request, with the required information.

2.1.2.4 Conformity based on unit verification, module G

The manufacturer shall

- prepare technical documentation on the design, manufacture and operation of the product,
- ensure and declare that the relevant product fulfils the specified requirements.

The manufacturer or its authorised representative shall

- submit an application for a conformity assessment,
- affix the conformity mark and the metrology marking to each product,
- affix the identification number of the notified body,
- issue a declaration of conformity to the directives complied with (e.g. 2014/32/EU) and provide a copy for the measuring instrument (or set of measuring instruments),
- keep the declaration of conformity, the technical documentation and the certificate of conformity from the notified body available for the supervisory authorities.

METAS-Cert shall

- examine the product and carry out appropriate tests to check the conformity of the product to the specified requirements,
- supervise the affixing of its identification number,
- keep a list of important technical documents,
- issue a certificate of conformity for the examinations performed,
- provide other notified bodies, upon their request, with the required information.

2.1.3 Category “Assessment of the quality management system”

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.

METAS-Cert evaluates the manufacturer’s (or the customer’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.

In addition, METAS-Cert may also 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.

2.1.3.1 Conformity to type based on quality assurance of the production process, module D

The manufacturer shall

- operate an approved quality assurance system for production, final product inspection and testing that includes the preparation of technical documentation (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),
- submit an application for assessment of the quality assurance system for the applicable products,
- ensure and declare that the applicable products are in compliance with the type examination certificate and fulfil the relevant requirements,
- undertake to fulfil the obligations associated with the quality assurance system in its approved form and to guarantee its correct and efficient functioning at all times,
- support the notified body in its supervisory activities,
- keep the documentation of the quality assurance system, details of its updating as well as the decisions and reports from the notified body available for the supervisory authorities.

The manufacturer or its authorised representative shall

- affix the conformity mark and the metrology marking to each product,
- affix the identification number of the notified body,
- issue a declaration of conformity to the directives complied with (e.g. 2014/32/EU) and provide a copy for the measuring instrument (or set of measuring instruments),
- inform the notified body of its intention to update the quality assurance system,
- keep the declaration of conformity available for the supervisory authority.

METAS-Cert shall

- evaluate the quality assurance system in order to establish whether it fulfils the relevant requirements and reach a decision on this matter,
- supervise the affixing of its identification number,
- monitor the manufacturer by paying both periodic and unannounced visits,
- keep a list of important technical documents,
- provide other notified bodies, upon their request, with the required information on issued or withdrawn approvals of quality assurance systems.

2.1.3.2 *Quality assurance of the production process, module D1*

The manufacturer shall

- prepare technical documentation on the design, manufacture and operation of the product,
- operate an approved quality assurance system for production, final product inspection and testing that includes the preparation of technical documentation (i.e. mandatory information on the intended product category, documentation of the quality assurance system and its updating as well as the decisions and reports from the notified body),
- submit an application for assessment of the quality assurance system for the applicable products,
- ensure and declare that the relevant products fulfil the requirements,
- undertake to fulfil the obligations associated with the quality assurance system in its approved form and to guarantee its correct and efficient functioning at all times,
- support the notified body in its supervisory activities,
- keep the documentation of the quality assurance system, details of any updating as well as the decisions and reports from the notified body available for the supervisory authorities.

The manufacturer or its authorised representative shall

- affix the conformity mark and the metrology marking to each product,
- affix the identification number of the notified body,
- issue a declaration of conformity to the directives complied with (e.g. 2014/32/EU) and provide a copy for the measuring instrument (or set of measuring instruments),
- inform the notified body of its intention to update the quality assurance system,
- keep a copy of the declaration of conformity available for the supervisory authority.

METAS-Cert shall

- evaluate the quality assurance system in order to establish whether it fulfils the relevant requirements and reach a decision on this matter,
- supervise the affixing of its identification number,
- monitor the manufacturer by paying both periodic and unannounced visits,
- keep a list of important technical documents,
- provide other notified bodies, upon their request, with the required information on issued or withdrawn approvals of quality assurance systems.

2.1.3.3 Conformity to type based on instrument quality assurance, module E

The manufacturer shall

- Fulfil the obligations as in module D; the operated and approved quality assurance system applies solely to final product inspection and testing.

The manufacturer or its authorised representative shall

- Fulfil the obligations as in module D.

METAS-Cert shall

- Fulfil the obligations as in module D.

2.1.3.4 Quality assurance of final product inspection and testing, module E1

The manufacturer shall

- Fulfil the obligations as in module D1; the operated and approved quality assurance system applies solely to final product inspection and testing.

The manufacturer or its authorised representative shall

- Fulfil the obligations as in module D.

METAS-Cert shall

- Fulfil the obligations as in module D.

2.1.3.5 Conformity based on full quality assurance, module H

The manufacturer shall

- operate an approved quality assurance system for design, production, final product inspection and testing that includes the preparation of technical documentation (i.e. mandatory information on the design, intended product category, documentation of the quality assurance system and its updating as well as the decisions and reports from the notified body),
- submit an application for assessment of the quality assurance system for the applicable products,
- ensure and declare that the relevant products fulfil the specified requirements (declaration of conformity, conformity mark, etc.),
- undertake to fulfil the obligations associated with the quality assurance system in its approved form and to guarantee its correct and efficient functioning at all times,
- support the notified body in its supervisory activities,
- keep the documentation of the quality assurance system, details of any updating as well as the decisions and reports from the notified body available for the supervisory authorities.

The manufacturer or its authorised representative shall

- fulfil the obligations as in module D.

METAS-Cert shall

- fulfil the obligations as in module D.

2.1.3.6 Conformity based on full quality assurance plus design examination, module H1

The manufacturer shall

- operate an approved quality assurance system for design, production, final product inspection and testing that includes the preparation of technical documentation (i.e. mandatory information on the design, intended product category, documentation of the quality assurance system and its updating as well as the decisions and reports from the notified body),
- submit an application for assessment of the quality assurance system for the applicable products,
- ensure and declare that the relevant products fulfil the specified requirements (declaration of conformity, conformity mark, etc.),
- undertake to fulfil the obligations associated with the quality assurance system in its approved form and to guarantee its correct and efficient functioning at all times,
- support the notified body in its supervisory surveillance activities,
- keep the documentation of the quality assurance system, details of any updating as well as the decisions and reports from the notified body available for the supervisory authorities,
- submit an application for examination of the design,
- keep the notified body informed of any modifications made to the approved design.

The manufacturer or its authorised representative shall

- fulfil the obligations as in module D.

METAS-Cert shall

- evaluate the quality assurance system in order to establish whether it fulfils the relevant requirements and reach a decision on this matter,
- supervise the affixing of its identification number,
- monitor the manufacturer by paying both periodic and unannounced visits,
- keep a list of important technical documents,
- provide other notified bodies, upon their request, with the required information on issued or withdrawn approvals of quality assurance systems,
- examine the design,
- issue a design examination certificate if the design fulfils the requirements,
- keep a list of design examination certificates,
- provide other notified bodies, upon their request, with the required information on the design examination certificates.

2.2 Market introduction of non-automatic weighing instruments (NAWI)

The market introduction of non-automatic weighing instruments is regulated in the Ordinance of the FDJP of 16 April 2004 on Non-automatic Weighing Instruments ([SR 941.213](#)) [5].

Table 6 lists the possible modules for the declaration of conformity; these modules must be evaluated by the notified body.

Passing the corresponding certification authorises the manufacturer or its representative to affix the conformity mark (CE or CH) and the metrology marking to the measuring instrument and, where applicable, to issue a declaration of conformity to the NAWI directive.

B = Type examination	+	D = Conformity to type based on quality assurance of the production process
		F = Conformity to type based on product verification
D1 = Quality assurance of the production process		
F1 = Conformity based on product verification		
G = Unit verification		

Table 6: Modules for attaining the CE marking in accordance with the Ordinance of the FDJP of 16 April 2004 on Non-automatic Weighing Instruments

Non-automatic weighing instruments without electronic equipment whose load-measuring device does not use a spring to balance the applied load, do not require a Module B procedure (Annex 3, Paragraph 1 of the NAWIO [6]). For those instruments where Module B is not required, Module D1 (Annex 3, Paragraph 3 of the NAWIO [6]) or module F1 (Annex 3, Paragraph 4 of the NAWIO [6]) is applicable.

If the manufacturer submits an application to METAS-Cert for assessment of its management system, METAS-Cert shall perform periodic audits as described in Section 3 of this guide in order to ensure that the manufacturer possesses an adequate management system and is using it correctly.

A simplified audit procedure may be used for applicants who are performing only the second stage of the conformity assessment procedure (Annex 3 Paragraph 5 NAWIO [6]).

2.3 Procedures in accordance with OIML

2.3.1 OIML certification system 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 (see also OIML publication [OIML B 3](#) [14]) and reached an agreement on mutual recognition.

Under this agreement, internationally recognised type examinations, OIML test reports, test results and certificates can be issued for the following measuring instrument categories:

OIML Recommendation R 16 (Non-invasive sphygmomanometers) [16]
OIML Recommendation R 49 (Water meters) [17]
OIML Recommendation R 50 (Continuous totalizing automatic weighing instruments) [18]
OIML Recommendation R 51 (Automatic catch weighing instruments) [19]
OIML Recommendation R 61 (Automatic gravimetric filling instruments) [21]
OIML Recommendation R 97 (Barometers) [23]
OIML Recommendation R 98 (High precision line measures of length) [24]
OIML Recommendation R 106 (Automatic rail weighbridges) [25]
OIML Recommendation R 107 (Discontinuous totalizing automatic weighing instruments) [26]
OIML Recommendation R 117 (Measuring systems for liquids other than water) [27]
OIML Recommendation R 134 (Automatic instruments for weighing road vehicles in motion) [28]
OIML Recommendation R 137 (Gas meters) [29]

Table 7: Measuring instrument categories for which METAS-Cert issues OIML documents

The signatories to the agreement undertake to recognise OIML test reports, test results and certificates and to use them for their national approvals.

2.3.2 OIML framework agreement (Mutual Acceptance Arrangement, MAA)

The OIML certification system has been supplemented by a framework agreement on the mutual recognition of OIML type evaluations (see also OIML publication [OIML B 10](#) [12]). Certificates of conformity issued by member states within this certification system confirm that the tests were carried out in accordance with the internationally harmonised procedures and that the examined types fulfil the requirements specified in the recommendations.

Type examinations in accordance with OIML Recommendation R 60 (Load cells) [20]
Type examinations in accordance with OIML Recommendation R 76 (Non-automatic weighing instruments) [22]

Table 8: Measuring instrument categories for which METAS-Cert issues OIML certificates of conformity within the context of the MAA

After successful testing, an OIML certificate of conformity is issued. Recognition of these certificates is mandatory for the MAA signatories.

2.4 NTEP Verified Conformity Assessment Program Procedures (VCAP)

VCAP is an American procedure, where the manufacturer must prove, that he performs a statistical control procedure for testing the measuring instruments on influence factors. To maintain the NTEP-Type approval, manufactures that bring measuring instruments on the market that fall under the VCAP program must prove that they are audited by an authorized body. METAS-Cert has such authorization to perform VCAP audits.

Following instrument categories fall under VCAP

- Load cells
- Weighing Indicators
- Complete weighing instruments
- Automatic weighing instruments
- Automatic belt weigher
- Automatic hopper scales

2.5 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 tests are typically performed by METAS laboratories.

3 Certification of types and management systems

3.1 Application for certification

Upon receiving a request for certification of a type or a management system, METAS-Cert shall inform the applicant of the procedure and provide an application form ([application forms are available on the METAS-Cert Internet page](#)).

On the application form, the applicant shall state the requirements (directives) under which the product or management system is to be certified.

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

3.2 Certification agreement, commission

The order is based on the certification agreement between the applicant and METAS-Cert. This agreement consists of the METAS-Cert order form related to the certification agreement (see Annex III) and the [Terms and conditions METAS](#) and based on the quotation from METAS-Cert (except the product verification where a quotation is only made on demand, the amount is communicated with the order confirmation).

The applicant is obliged to inform METAS-Cert without delay in writing of any modifications to the product or the management system that are of consequence for the certification.

3.3 Appointment of auditors and technical experts

Once the application for certification has been submitted, the head of METAS-Cert appoints a lead auditor and, depending on the size and complexity of the certification, additional auditors and technical experts. The minimum personnel requirement is one lead auditor.

METAS-Cert may, if required, engage external auditors and/or technical experts.

3.4 Duties of the lead auditor

The lead auditor is responsible for the audit and draws up the audit programme together with the auditors and technical experts. He ensures proper coordination of the work between the applicant, the audit team and the head of METAS-Cert. Furthermore, he is responsible for the timely preparation of the audit report.

First-time audits shall be performed in two stages: the stage 1 audit and the stage 2 audit (see Sections 3.13.3 and 3.13.4).

3.5 Confidentiality

In accordance with Article 20 Paragraph 1 of PV-METAS [41], METAS employees are obliged to maintain secrecy and confidentiality 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. The 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.

3.6 Audit report and decision on certification

After completion of the initial 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 requirements as well as the areas with potential for improvement.

It shall include a recommendation on the granting of certification, observations to support the recommendation and, if required, restrictions to be observed during the period of validity. The audit report shall be forwarded to the applicant for comments and to the Certification Commission (CC) for evaluation. After evaluation, the report shall be passed on by the CC to the head of METAS-Cert. On the basis of the audit report, the applicant's comments and the CC's recommendation, the head of METAS-Cert then decides on the granting of certification.

In case of a non-conformity or a minor non-conformity, the applicant shall be requested to eliminate the deficiencies in its management system within an agreed period. For each non-conformity, a check sheet is completed for the certification requirement and submitted, ideally at the audit's final meeting.

3.6.1 *Non-fulfilment of the non-conformities*

If the non-conformities are not solved within the agreed period, the agreement between METAS-Cert and the applicant may be terminated. The costs incurred up to this point shall be charged to the applicant.

3.7 Scope of validity of the certificate and period of validity

Once all of the requirements have been fulfilled, the applicant shall receive a numbered certificate for operation of the quality management system.

The certificate is individually numbered and includes a reference to the mandatory measuring instrument category. It may also contain an annex specifying a scope of validity with the applicable measuring instrument categories and a list of the recognised representatives affiliated with the manufacturer.

The certificate for the quality management system is valid for a period of 3 years. If requested by the applicant and following successful renewal of certification, validity may be extended by a further 3 years.

Certificates for type examination in accordance with module B are valid for 10 years.

Certificates for product verification in accordance with modules F, F1 and G confirm the conformity of the measuring instrument at the time of market introduction and do not have a specified period of validity.

Certificates for internal production control in accordance with module A2 confirm the conformity of a product batch and do not have a specified period of validity.

3.8 Surveillance audit

During periods between renewals of certification, a supervisory audit shall be carried out by METAS-Cert at least once a year in the first certification period. For each audit, an audit report is prepared and provided to the holder of the certification.

For manufacturers with ISO 9001 certification, the head of METAS-Cert may decide, at the earliest three years after initial certification by METAS-Cert, to extend the audit period by 1 1/2 years subject to the condition that the ISO 9001 certification authority will monitor the manufacturer on an annual basis.

For OEM manufacturers that do not manipulate their measuring instruments in any way and whose supplier is certified in accordance with module D, an audit is performed only when the certificate is renewed.

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 requirements,
- the situation is unacceptable: this calls for a temporary suspension or withdrawal of certification.

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

3.9 Extension and withdrawal of a certificate

3.9.1 Extension

If a company 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.

3.9.2 Suspension and withdrawal of a certificate

If any non-conformity to the conditions of certification is detected during a supervisory audit, renewal of certification or for any other reason, the certificate may be suspended or its scope restricted during this period.

The imposed measure may be lifted once an audit confirms that the non-conformity has been eliminated.

The applicant may appeal the decision to suspend the certificate (see Section 3.12).

3.10 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 the NAWI Directive Directive [11] are also sent to the EMeTAS database for publication.

3.10.1 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 surveillance authorities.

3.11 Cancellation of the certification procedure

If the applicant fails to submit the required documentation on schedule, the head of METAS-Cert is entitled to postpone certification or to cancel the certification agreement, stating the grounds for doing so.

3.12 Complaints, appeals and civil action

Complaints have to be addressed to the notified body. They are handled in accordance with the METAS "Internal instructions on the processing of complaints and non-conformities" (W004) procedure.

The conditions and rules in case of a contestation and civil action are defined in the METAS general terms and conditions.

3.13 Performance of a management system audit

3.13.1 Preparation

The lead auditor shall forward the scheduled audit programme to the applicant for comments.

The time required for the audit depends, among other things, on the following factors:

- previous certification (e.g. ISO 9001 [30]),
- language in which the handbook and the work instructions are written (English, French, German and Italian are accepted for the handbook),
- number of personnel within the scope to be assessed,
- complexity of the measuring instrument and the management system,
- number of the company's branches that must be assessed.

3.13.2 Two-stage procedure

The first certification audit of a management system is carried out in two stages: stage 1 and stage 2.

Parts of the management system that are audited during audit stage 1 and have been established as complete, effective and in compliance with the requirements do not necessitate further assessment during audit stage 2.

METAS-Cert shall verify that the previously audited parts of the management system continue to satisfy the certification requirements. The report on audit stage 2 shall contain such verification and clearly indicate that conformity was established during audit stage 1.

3.13.3 Stage 1

The stage 1 audit serves as orientation and preparation for the stage 2 main audit. In particular, the following investigations shall be made:

1. Gathering of sufficient information about the business and its management system in order to plan the scope as well as the focal points of the stage 2 audit.
2. What is the scope of the management system? Which processes and locations does it cover? Are there any applicable legal regulations or internal company specifications? How is compliance with them ensured?

3. Do the company's processes at the various locations and the location-specific conditions satisfy the standard requirements?
4. Do the state of the company and the understanding of the standard requirements meet expectations, particularly in terms of recognition of essential services, processes and objectives as well as operation of the management system? Measuring instrument management? Metrological traceability (monitoring and calibration of measuring instruments)?
5. Is the documentation of the management system in good order?
6. Do planning and execution of the internal audits and of the management review assessment satisfy the standard requirements? Is the introduction of the management system sufficiently advanced to carry out the stage 2 audit?
7. Are staff members adequately prepared for the main audit? Are the resources that are necessary to perform the main audit (stage 2) available?

The results of the stage 1 audit shall be documented in writing and communicated to the applicant. The report shall indicate the areas that still give cause for concern and could be found inadequate in the stage 2 audit.

The date for the stage 2 audit shall be set such that it gives the applicant enough time to improve the areas that were determined to be problematic in the stage 1 audit.

3.13.4 Stage 2

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 [35] and take into consideration the information gathered during the stage 1 audit.

The stage 2 audit examines whether the management system has been implemented and whether it achieves the intended effect. The audit shall be performed at the applicant's premises and comprise at least the following aspects:

1. gathering of information and verification of conformity to all requirements of the applicable normative documents;
2. monitoring of performance, i.e. measurement, reporting and evaluation related to the primary performance objectives (in agreement with the applicable standard requirements);
3. management system and its effectiveness in relation to all of the legal requirements;
4. process control;
5. internal auditing and management review;
6. management responsibility for the essential operational regulations;
7. verification of agreement between the results of the internal audit(s) and the normative requirements, internal rules, performance objectives, legal requirements, responsibilities, personnel expertise, processes, procedures and specifications.

The stage 2 audit shall be documented in an audit report. The further procedure shall be as described in Section 3.6.

3.14 Performance of a type examination

3.14.1 Preparation

Once the manufacturer has submitted an application for type examination, METAS-Cert shall prepare a detailed quotation that reflects the costs incurred by METAS-Cert as well as the laboratories involved.

Based on the quotation, the manufacturer may order the type examination.

METAS-Cert provides a list of the descriptive documents for module B (6030.10F21_EN) that the manufacturer must supply to METAS-Cert for the examination process.

Based on the submitted documents, METAS-Cert coordinates the tests and scheduling with the laboratories and informs the applicant about the types (test specimens) that must be supplied for the certification process.

3.14.2 Tests

The tests are performed on the scheduled dates at the various laboratories. The laboratories examine the test specimens in terms of the requirements of the applicable standards, and then METAS-Cert examines their conformity to the requirements of the applicable ordinances or, where applicable, the European directive.

3.14.3 Type examination or type approval certificate

Once the testing process has been completed, METAS-Cert works with the laboratories to draft the type examination or type approval certificate. The finalised draft is forwarded to the manufacturer (customer) for checking.

3.14.4 Final steps

By way of conclusion, METAS-Cert works with the laboratories to prepare a consolidation report for type examination (6030T02), which identifies the type, describes the examination process, lists the underlying test reports, identifies the software classification in accordance with WELMEC Guide 7.2, where applicable, and mentions any existing non-conformities.

Along with the test reports and type examination or type approval certificate, the report is submitted to the Certification Commission (CC) for the final decision on certification.

After evaluation, the report shall be passed on by the CC to the head of METAS-Cert. On the basis of the test reports, the applicant's comments and the CC's recommendation, the head of METAS-Cert then decides on the granting of certification.

3.15 Generalities

The manufacturer is obliged to keep the measuring instrument's technical documentation, reports and test results of the production and certificates during a period of ten years from the date of the market introduction available on request for the national authorities.



Conformity Evaluation Body METAS-Cert

Guide for the market introduction of measuring instruments

Document No	6030B01_EN
First issue	17 August 2006/Ra
Revised	6 March 2017/Couv
Version	3.0
Released	20 February 2017/GLS
Original in	6030B01_EN

Annex I Index of references

- [1] [MeasIO](#) Measuring Instruments Ordinance of 15 February 2006 ([SR 941.210](#))
- [2] Ordinance of the FDJP of 19 March 2006 on Dimensional Measuring Instruments ([SR 941.201](#))
- [3] [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] Ordinance of the FDJP of 19 March 2006 on Measurement of Volume ([SR 941.211](#))
- [5] Ordinance of the FDJP of 19 March 2006 on Measuring Systems for Liquids other than Water ([SR 941.212](#))
- [6] [NAWIO](#) Ordinance of the FDJP of 16 April 2004 on Non-automatic Weighing Instruments ([SR 941.213](#))
- [7] [AWIO](#) Ordinance of the FDJP of 19 March 2006 on Automatic Weighing Instruments ([SR 941.214](#))
- [8] Ordinance of the FDJP of 19 March 2006 on Measuring Instruments for Thermal Energy ([SR 941.231](#))
- [9] Ordinance of the FDJP of 19 March 2006 on Gas Meters ([SR 941.241](#))
- [10] [VAMV](#) Ordinance of the FDJP of 19 March 2006 on Measuring Instruments for Exhaust Gases of Combustion Engines ([SR 941.242](#))
- [11] [EMmV](#) Ordinance of the FDJP of 19 March 2006 on Measuring Instruments for Electrical Energy and Power ([SR 941.251](#))
- [12] [2014/32/EU](#) 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.
- [13] [2014/31/EU](#) 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
- [14] [OIML B3](#) OIML Certificate System for Measuring Instruments (Edition 2003), formerly OIML P 1
- [15] [OIML B 10](#) Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations (Edition 2011, amended 2012)
- [16] [OIML R 16](#) International Recommendation OIML R16, Edition 2002, Non-invasive sphygmomanometers
- [17] [OIML R 49-1](#) International Recommendation OIML R49-1, Edition 2006, Water meters
- [18] [OIML R 50-1](#) International Recommendation OIML R50, Edition 1997, Continuous totalizing automatic weighing instruments
- [19] [OIML R 51-1](#) International Recommendation OIML R51, Edition 2006, Automatic catch weighing instruments
- [20] [OIML R 60](#) International Recommendation OIML R60, Edition 2000, Metrological regulation for load cells
- [21] [OIML R 61-1](#) International Recommendation OIML R61, Edition 2004, Automatic gravimetric filling instruments

- [22] [OIML R 76-1](#) International Recommendation OIML R76, Edition 2006, Non-automatic weighing instruments
- [23] [OIML R 97](#) International Recommendation OIML R97, Edition 1990, Barometers
- [24] [OIML R 98](#) International Recommendation OIML R98, Edition 1991, High precision line measures of length
- [25] [OIML R 106-1](#) International Recommendation OIML R106, Edition 2011, Automatic rail weighbridges
- [26] [OIML R 107-1](#) International Recommendation OIML R107, Edition 2007, Discontinuous totalizing automatic weighing instruments
- [27] [OIML R 117-1](#) International Recommendation OIML R117-1, Edition 2007, Dynamic measuring systems for liquids other than water
- [28] [OIML R 134-1](#) International Recommendation OIML R134-1, Edition 2006, Automatic instruments for weighing road vehicles in motion and measuring axle loads
- [29] [OIML R 137-1&2](#) International Recommendation OIML R137-1&2, Edition 2012, Gas meters
- [30] ISO 9001 Quality Management Systems – Requirements (SN EN ISO 9001:2015)
- [31] ISO/IEC 17020 General criteria for the operation of various types of bodies performing inspection (ISO/IEC 17020:2012)
- [32] ISO/IEC 17021 Conformity assessment – Requirements for bodies providing audit and certification of management systems (ISO/IEC 17021:2015)
- [33] ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories (SN EN ISO/IEC 17025:2005)
- [34] ISO/IEC 17065 Conformity assessment – Requirements for bodies certifying products, processes and services (ISO/IEC 17065:2012)
- [35] ISO/IEC 19011 Guidelines for quality and/or environmental management systems auditing (SN EN ISO 19011:2002)
- [36] [Blue Guide](#) Guidelines for the implementation of EU product rules (Blue Guide 2016)
- [37] [Metrology Act](#) Swiss Federal Law of 17 June 2011 on Metrology (SR 941.20)
- [38] [EIMG](#) Swiss Federal Law of 17 June 2011 on the Federal Institute of Metrology (SR 941.27)
- [39] [THG](#) Swiss Federal Law of 6 October 1995 on Technical Barriers to Trade (SR 946.51)
- [40] [BPG](#) Federal Personnel Act (SR 172.220.1)
- [41] [PV-METAS](#) METAS Personnel Ordinance (SR 941.273)
- [42] [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)



Conformity Evaluation Body METAS-Cert Guide for the market introduction of measuring instruments	Document No	6030B01_EN
	First issue	17 August 2006/Ra
	Revised	6 March 2017/Couv
	Version	3.0
	Released	20 February 2017/GLS
	Original in	6030B01_EN

Annex II Index of key terms

Audit	Systematic, independent and documented examination procedure to ascertain whether organisations and processes comply with specified requirements and guidelines.
Certificate of conformity	Certificate that provides the evidence, that a measuring instrument is in conformity with the legal requirements.
Certification	Process by which a certification organisation declares that a measuring instrument complies with the legal requirements, a management system fulfils all of the requirements stipulated in the standard and the applicant meets the internally defined specifications.
DEC	Design examination certificate / EC design examination certificate .See Section 2.1.3.6
EMeTAS	European Metrology Type Approval Service (www.emetas.eu)
Evaluation Certificate	See WELMEC guide 8.8
FDJP	Federal Department of Justice and Police
MAA	OIML Mutual Acceptance Arrangement
Management system / MS	Management system; organisational structure, procedures, processes and means required for the purpose of quality management.
MID	European Measuring Instrument Directive [12]
NAWI	Non-automatic weighing instrument
NAWI Directive	European Non-automatic Weighing Instruments Directive [13]
NB	Notified Body (Conformity evaluation body)
Non-conformity	Non-compliance with an applicable requirement of a standard
OEM	Original equipment manufacturer, i.e. a manufacturer that sells a measuring instrument under its own name; the measuring instrument has a parallel certificate.
OIML	International Organization of Legal Metrology (Organisation Internationale de la Métrologie Légale)
Parallel certificate	Certificate issued in the name of an original equipment manufacturer (OEM) based on an original certificate. The measuring instrument specified in the parallel certificate may not differ from the original apart from the labelling and type designation.
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.

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 requirement.
Quality policy	Broad intentions and objectives of an organisation in relation to quality, as formally expressed by top management.
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.
TEC	Type examination certificate / EC type examination certificate. See Section 2.1.1
WELMEC	European Cooperation in Legal Metrology (www.welmec.org)



Conformity Evaluation Body METAS-Cert

Guide for the market introduction of measuring instruments

Document No	6030B01_EN
First issue	17 August 2006/Ra
Revised	6 March 2017/Couv
Version	3.0
Released	20 February 2017/GLS
Original in	6030B01_EN

Annex III Certification agreement METAS-Cert

1 Preamble

- 1.1 The conformity assessment body of the Federal Institute of Metrology METAS (METAS-Cert) performs conformity assessments 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 Swiss Confederation and the European Community on Mutual Recognition in Relation to Conformity Assessment; SR 0.946.526.81 [42]).
- 1.2 The designating authority of METAS-Cert is the General Secretariat of the Federal Department of Justice and Police (GS-FDJP). As evidence of its competence, METAS-Cert holds accreditation in accordance with ISO/IEC 17020 [31] (inspection body), ISO/IEC 17021 [32] (certification body for management systems) and ISO/IEC 17065 [34] (certification body for products).
- 1.3 This agreement lays out the relevant general conditions and the services to be rendered by METAS-Cert and the client to ensure that conformity assessments are carried out appropriately and in accordance with the applicable standards. This agreement is subject to Swiss law.

2 Contractual agreement

- 2.1 The client is aware of the general and domain-specific certification principles of METAS-Cert. The client has submitted a written application to METAS-Cert.
- 2.2 In order to perform a conformity assessment procedure for a measuring instrument or quality management system, the client engages METAS-Cert, via the order form, to perform the conformity assessment as a general contractor. The order form specifies the nature of the certification.
- 2.3 METAS-Cert shall inform the client in good time of any changes to the agreement that are made necessary by changes in the certification requirements or procedures. It shall maintain the client's freedom of contract.
- 2.4 METAS-Cert shall ensure that due discretion is maintained with respect to third parties for all of the observations and experience gathered in connection with the certification.

3 Scope of the certification (3.2 Type examination, 3.3 Production quality assurance or 3.4 Product verification)

3.1 General terms and conditions

- 3.1.1 In order to ensure the impartiality of the conformity assessment, only technical experts and auditors who have not had an employment or consulting relationship with the client for at least 3 years may be engaged.

3.2 Type examination by test laboratories and test results

- 3.2.1 The client shall designate a contact person who is responsible for the certification, and shall forward to METAS-Cert all of the technical documentation, descriptions, files and pictures required to assess the conformity of the type.

- 3.2.2 Tests that were performed by recognised bodies or test laboratories can be included in the conformity assessment. The client shall forward the relevant authentic test reports and certificates to METAS-Cert to enable METAS-Cert to take the test results into consideration before submitting its quotation.
- 3.2.3 METAS-Cert may recognise test results from a client's laboratory accredited in accordance with ISO/IEC 17025 [33]. A specific agreement between METAS-Cert and the client shall be drawn up for this purpose.
- 3.2.4 The client shall forward to METAS-Cert a type specimen that is representative for production and that may not be a prototype.
- 3.2.5 METAS-Cert shall designate both a technical expert (Project Manager) who is responsible for coordination and the test laboratories involved in examining the type specimen (hereafter the "certification team"), with preference given to the METAS technical laboratories.
- 3.2.6 If necessitated by circumstances, and with the client's consent, METAS-Cert can pass on the test order to external technical laboratories.
- 3.3 Production quality assurance
 - 3.3.1 The client shall designate a contact person who is responsible for the certification, and shall forward to METAS-Cert all of the documentation required to assess the conformity of the quality management system.
 - 3.3.2 METAS-Cert shall designate a chief auditor (Project Manager) responsible for the conformity assessment who shall assemble an appropriate audit team in line with the conceptual criteria.
 - 3.3.3 The employees of the audited client shall strive to create the greatest possible transparency and participate actively in the entire process so that the audit can be productive for the client.
 - 3.3.4 The client shall ensure that the audit team has access to the appropriate equipment, location(s), department(s) and personnel, as well as to its subcontractors. It shall openly inform the audit team of events, problems and projects which may have any bearing whatsoever on the conformity assessment.
 - 3.3.5 The audit team shall perform an impartial assessment of the client's quality management system and its practical implementation.
 - 3.3.6 Observers may participate in the audit for purposes named by METAS-Cert as designated body. The head of METAS-Cert shall ensure that such parties comply with the obligation to maintain confidentiality.
- 3.4 Product verification
 - 3.4.1 The client shall designate a contact person who is responsible for the certification, and shall forward to METAS-Cert all the technical documentation, descriptions, files and pictures required to assess the conformity of the product.
 - 3.4.2 Tests that were performed by recognised bodies or test laboratories can be included in the conformity assessment. The client shall forward the relevant authentic test reports and certificates to METAS-Cert in good time.
 - 3.4.3 METAS-Cert shall designate a technical expert (Project Manager) who is responsible for the testing.
 - 3.4.4 The client shall prepare the measuring instrument and the environment for the testing and ensure that the materials and auxiliary personnel specified in the order confirmation are provided.

Guide for the market introduction of measuring instruments

- 3.4.5 The client shall ensure that the measuring instrument is correctly marked and that the necessary documentation is to hand.
- 3.4.6 In the event of a cancellation or postponement of the test date by the client, the costs incurred as a result shall be chargeable.
- 3.4.7 If necessitated by circumstances, and with the client's consent, METAS-Cert can pass on the test order to external technical laboratories.
- 4 Dates
- 4.1 The procedure, the dates and the determination of the tests or audits to be performed are defined during a preliminary discussion between the METAS-Cert Project Manager and the client's contact person. They are binding upon both parties.
- 5 Requirements
- 5.1 If the measuring instrument or the quality management system fails the examination, the certification team shall inform the client in writing about the non-compliant items, making reference to the test results attained by the tester.
- 5.2 The client shall analyse the specified requirements and make any necessary corrections.
- 5.3 The certification team shall work with the technical expert to analyse the corrective measures proposed by the client and shall determine the tests that are to be repeated. Depending on the correction, it may be necessary for all of the tests or the audit to be repeated.
- 5.4 In case of uncertainty, the Head of METAS-Cert can be involved.
- 6 Settlement of costs
- 6.1 The client agrees to the cost and payment conditions contained in the METAS General Terms and Conditions² and undertakes to bear the calculated certification costs.
- 6.2 The costs shall be compiled by METAS-Cert on receipt of the request for certification and submitted to the client in the form of a written quotation. The relevant quotation, or in case of product verifications the order confirmation, forms an integral part of this agreement and is binding upon the parties.
- 6.3 Any expenses incurred for re-examinations, document checking, clarification meetings and complaint proceedings are invoiced separately at cost.
- 6.4 Expenses incurred in connection with notifications or complaints from authorities concerning the client's measuring equipment will be charged to the client at cost.
- 7 After the testing
- 7.1 In case of type examinations or complex certifications, the client shall receive the draft of the certificate to make any necessary factual corrections. Such corrections are discussed between the client and the certification team and adopted as relevant. If required, the management of METAS-Cert can be involved for clarification purposes.
- 7.2 Once the certificate has been finalised, the certification team shall prepare a consolidation report or a test report for product verifications and submit the certification file to the Certification Commission (CC).
- 8 Certification Commission (CC)
- 8.1 CC members are not permitted to be involved in the certification of the conformity assessment.

² METAS GTC: www.metas.ch/AGB

- 8.2 The CC members are persons from METAS-Cert or METAS who possess the requisite technical expertise for the assessment.
- 8.3 The CC announces its decision in written form by means of the consolidation report or the test report.
- 9 Certification
- 9.1 The validity of the certificate is 10 years for type examinations and 3 years for quality management systems. For product and individual verifications, the certificate retains its validity for as long as the measuring instrument remains on sale and no new conformity assessment is carried out. The client is authorised to make the certificate public during this period of time. The client agrees to respect the guidelines on the validity and usage of the certificate.
- 9.2 The Head of METAS-Cert takes the CC's decision into account and decides on the award of the certification. Should the head of METAS-Cert reject the certification, he or she shall inform the client, the CC and the certification team of the reasons. In case of a positive decision, the Head of METAS-Cert shall sign the certificate.
- 9.3 METAS registers the certificates for publication on the METAS website, for registration with OIML or the EMETAS database, if applicable, and for despatch of the original to the client.
- 9.4 Certificates are published on the METAS website www.metas.ch/certsearch.
- 9.5 Certificates of conformity for management systems can be viewed publicly. In case of type examination and type approval certificates, full access is limited to market supervisory authorities and notified bodies; the information on the first page of such certificates can be viewed publicly. Certificates for product verifications are not published.
- 9.6 If a certificate is suspended or withdrawn, the client must inform its customers accordingly.
- 9.7 In the event of serious deficiencies or grievances, the certification is deferred or refused, or suspended and cancelled, respectively. In addition, an appropriate notification is delivered to the responsible bodies.
- 10 Invoicing
- 10.1 Invoicing of METAS services is handled exclusively by METAS-Cert.
- 11 Usage of certificates and conformity marks
- 11.1 After the certificate has been issued, the client may publish it on its own authority.
- 11.2 Usage of conformity marks is stipulated in the corresponding directives and ordinances.
- 11.3 The METAS logo or the METAS-Cert name may be used in communications media such as the Internet as well as in brochures and marketing materials.
- 11.4 The client may not communicate any information about the status of the certification.
- 11.5 The METAS logo may not appear in the declaration of conformity, on the measuring instrument, in the manual or on the test certificate; instead, the METAS-Cert identification number must be used.
- 11.6 The Head of METAS-Cert shall decide about any exceptions and inform the client in writing of the decision.
- 11.7 In case of suspension, withdrawal or termination of the certification, the client shall cease using all marketing materials that make reference to the certification.
- 12 Complaints

Guide for the market introduction of measuring instruments

- 12.1 The client shall keep records of all complaints that were made known in connection with compliance with the certification requirements; upon request, it shall make these records available to METAS-Cert.
- 12.2 The client shall take suitable measures in relation to such complaints as well as any deficiencies that were discovered in the products and that influence compliance with the certification requirements, and shall document the measures that were taken.
- 13 Revisions and changes
 - 13.1 The client agrees to inform METAS-Cert promptly of any deficiencies and complaints affecting the certification.
 - 13.2 The client shall inform METAS-Cert promptly in the event of any changes to the certified products and areas (product, type, organisational structure or quality assurance system).
 - 13.3 In case of such changes, the client agrees to bear any costs incurred for tests and the revision of the files with the technical documentation or of the type examination or type approval certificate, or for an additional audit that may be required.
 - 13.4 In case of a revision, a new certification process shall be performed but only the affected parts of the measuring instrument shall be examined. Upon successful conclusion, METAS-Cert shall issue a revised certificate. Certificates of conformity for quality management systems or products can only be replaced.
- 14 Validity period of the certification agreement
 - 14.1 This agreement ends upon expiration of the validity of the issued certificate. In case of certificates for quality management systems, the agreement is tacitly extended starting from the moment when METAS-Cert commences a recertification audit. In case of product verifications, the agreement is valid until the first calibration.
 - 14.2 In the event of complaints after termination of the agreement, the client will be required to provide METAS-Cert with a mandate for the clarifications.
- 15 Termination
 - 15.1 The agreement may be terminated by either party at any time.
 - 15.2 If the termination occurs at an inopportune moment, the terminating party is obliged to provide compensation for the damage caused to the other party (Article 404 Paragraph 2 of the Swiss Code of Obligations).
 - 15.3 The client agrees to provide compensation for the services rendered by METAS-Cert up to that time.
 - 15.4 In the event of disputes relating to this agreement or any other objections, the parties to the agreement undertake to follow the procedure defined in the "Guide for the market introduction of measuring instruments", i.e. to clarify the situation first in direct talks as well as through voluntary mediation. If this proves unsuccessful, the client is entitled to contest the METAS-Cert decision with the METAS management within 30 days. Should there be any unresolved differences, the place of jurisdiction and applicable law shall be determined in accordance with the METAS GTC.
- 16 METAS GTC
 - 16.1 The METAS GTC, supplemented by this METAS-Cert certification agreement, are deemed to be the certification agreement.
 - 16.2 The METAS GTC and the METAS-Cert certification agreement can be called up on the Internet at www.metas.ch, which makes them accessible to the partner to the agreement.

- 17 By returning the signed order form to METAS-Cert, accepting a quotation in writing, receiving an order confirmation from METAS-Cert, in writing or sending an order with reference to a METAS-Cert quotation, the client agrees to the terms of this agreement as well as the METAS General Terms and Conditions.