Application for Assessment of a full quality assurance system regarding Measuring Instruments in accordance with MID

Company (applicant):

hereby applies to RISE Research Institutes of Sweden AB, as Notified Body, in accordance with the MID-directive 2014/32/EU (Measuring Instruments Directive) for assessment of a quality system (module) registered below

Conformity Assessment Module in accordance with MID

Module ☐ H ☐ H1

The application is regarding

☐ New certificate:

☐ Revision of certificate No.:

☐ Renewal of certificate No. (extension of validity time):

Type of instrument:

☐ MI-001 Water meters ☐ MI-003 Electric meters ☐ MI-004 Heat meters

☐ MI-005 Measuring systems, other liquids than water ☐ MI-006 Automatic weighing instruments ☐ MI-007 Taximeters

☐ MI-008 Material Measures of length

Product (group/family):

Model/type/ identification

Description, intended use etc.

Continue with:

- **Information about the applicant, page 3**
- **Confirmation/signature, page 2**

The application shall be accompanied by:

- **For module H and H1: the documentation concerning the quality system, see page 4 for details**
- **Specific for module H: See page 5**
- **Specific for module H1: See page 6**

The documentation shall be listed in a cover sheet or separate document.
We prefer to have the documentation in pdf or similar.

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The applicant confirms:

- That no application for conformity assessment of products covered by this application has been sent to any other Notified Body.
- That the applicant as the certificate holder allows RISE to publish issued certificates, in listings over certified products.
- That the applicant/manufacturer will keep him-/herself informed about any restrictions of the validity of referred standards and if necessary adjust the product(s) in order to adapt to the changed requirements.
- That the applicant/manufacturer has taken all relevant requirements stated in Directive 2014/32/EU in consideration.
- That the requirements for certification, as given in Certification Rules SPCR 302 will be followed.
- That the notified body (RISE) will, during the validity period of the certificate, be informed about changes of products before carried out (it may be necessary to perform new tests, make a review of accompanying documents or/and revision of the EC certificate/decision) the applicant/manufacturer during the validity period of the certificate will not make any changes of the product, without first contacting RISE.

Specific for quality system assessment:

- That the applicant/manufacturer will fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient
- That the applicant/manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

_____
Place, date

_____
Signature of the person representing the company

_____
Clarification/name of the person representing the company

This application together with relevant documentation refererred to in the application is sent to your contact person at RISE according to the model: first_name.last_name@ri.se and to certifiering@ri.se

Regarding which information to appended see the following pages.

RISE – Research Institutes of Sweden AB
RISE Certification
Box 857, 501 15 Borås
Tfn: +46 (0)10-516 50 00
E-post: certifiering@ri.se Internet: www.ri.se

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Information about the applicant

☐ Manufacturer (in accordance with the definition in MID article 4 (8) ☐ Authorised representative (in accordance with the definition in MID article 4 (9)

Company name:	
Full postal address:	
Invoice address (if other than above)	
Visiting address:	
Org./VAT No.:	
Phone company:	
E-mail company:	
Internet (www):	
Contact person:	
Phone contact person:	
E-mail contact person:	
Manufacturing places:	

Information about the manufacturer (if other than applicant):

Company name:	
Full postal address:	
Visiting address:	
Org./VAT No.:	
Phone company:	
E-mail company:	
Internet (www):	
Contact person:	
Phone contact person:	
E-mail contact person:	
Other information	

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For assessment of the quality system, the application shall be accompanied by :

the documentation concerning the quality system:

The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.
All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.
It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards, and/or normative documents will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the measuring instruments will be met applying other relevant technical specifications;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

(This text is an modified extract from Directive 2014/32/EU)

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Specific for module H:
the technical documentation, for one model of each category of measuring instruments intended to be manufactured. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument

Contents of technical documentation as stated in Article 18 of Directive 2014/32/EU.
The technical documentation shall, wherever applicable, contain at least the following elements:

	Reference	*RISE note*
(a) a general description of the measuring instrument;		
(b) conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits, etc.		
(c) manufacturing procedures to ensure consistent production;		
(d) if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;		
(e) descriptions and explanations necessary for the understanding of the information referred to in points (b), (c) and (d), including the operation of the measuring instrument;		
(f) a list of the harmonised standards and/or normative documents referred to in Article 14, applied in full or in part, the references of which have been published in the Official Journal of the European Union;		
(g) descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and/or normative documents referred to in Article 14 have not been applied, including a list of other relevant technical specifications applied;		
(h) results of design calculations, examinations, etc.;		
(g) descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and/or normative documents referred to in Article 14 have not been applied, including a list of other relevant technical specifications applied;		
(i) the appropriate test results, where necessary, to demonstrate that the type and/or the measuring instruments comply with the following: — the requirements of this Directive under declared rated operating conditions and under specified environmental disturbances, — the durability specifications for gas-, water-, thermal energy-meters as well as for liquids other than water;		
(j) the EU-type examination certificates or EU design examination certificates in respect of measuring instruments containing parts identical to those in the design.		

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Specific for module H1:

- all relevant information for the instrument category envisaged
- the technical documentation, for one model of each category of measuring instruments intended to be manufactured.
- the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or normative documents have not been applied in full, and shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications, by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

Contents of technical documentation as stated in Article 18 of Directive 2014/32/EU.
The technical documentation shall, wherever applicable, contain at least the following elements:

	Reference	*RISE note*
(a) a general description of the measuring instrument;		
(b) conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits, etc.		
(c) manufacturing procedures to ensure consistent production;		
(d) if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;		
(e) descriptions and explanations necessary for the understanding of the information referred to in points (b), (c) and (d), including the operation of the measuring instrument;		
(f) a list of the harmonised standards and/or normative documents referred to in Article 14, applied in full or in part, the references of which have been published in the Official Journal of the European Union;		
(g) descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and/or normative documents referred to in Article 14 have not been applied, including a list of other relevant technical specifications applied;		
(h) results of design calculations, examinations, etc.;		
(g) descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and/or normative documents referred to in Article 14 have not been applied, including a list of other relevant technical specifications applied;		
(i) the appropriate test results, where necessary, to demonstrate that the type and/or the measuring instruments comply with the following: — the requirements of this Directive under declared rated operating conditions and under specified environmental disturbances, — the durability specifications for gas-, water-, thermal energy-meters as well as for liquids other than water;		
(j) the EU-type examination certificates or EU design examination certificates in respect of measuring instruments containing parts identical to those in the design.		

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