QUALITY SYSTEM APPROVAL
MANUFACTURERS, REPAIRERS, INSTALLERS OF MEASURING INSTRUMENTS

Items to be provided

STRUCTURE OF THE FILE:

1. Application letter

The application letter for quality system approval shall include the following information:

- name and address of the various geographical sites concerned by the application (for example, when the place of final verification is different from the place of production),
- type designation of the instruments concerned by the application and references of the related type-examination certificates.

2. Filled-in Information Questionnaire

3. Documents to be joined to the application letter:

The documents shall be in French or in English.

- quality manual,
- existing quality plans concerning each type of measuring instrument under consideration, if any,
- description of the organization of your quality documentation and list of the items included in the documentation, if not described in the quality manual,
- procedure specifying control and verification conditions (including type conformity, if applicable) for each type of measuring instrument under consideration,

In the case of a quality system approval according to the module D of the 2014/31/UE and 2014/32/EU Directives or according to the French Decree n°2001-387, the documentation shall contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;
- the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

In the case of a quality system approval according to the annex H1 of the 2014/32/EU Directive (MID), the documentation shall contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to design and product quality;
- the technical design specifications, including standards, that will be applied and, where harmonized standards and normative documents will not be applied in full, the means that will be used to ensure that the essential requirements of the Directive will be met;
- the design control and design verification techniques, processes and systematic actions that will be used when designing the instruments pertaining to the instrument category covered;
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;
- the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.