APPLICATION FOR APPROVAL OF QUALITY SYSTEM

For companies that produce, repair or install controlled measuring instruments

Application number(it will be completed by MRC): [ ]

[ ] CERTIFICATION [ ] UPDATE CERTIFICATE [ ] RECERTIFICATION

This form of application for the approval of quality system is aimed for the companies that produce measuring instruments and non-automatic weighing instruments according to the 20014/31/UE European Parliment şi a Council Directive from february 26, 2014 regarding the non-automatic weighing instruments (codified version) transposed by HG 710-. Government Decision nº 710/2015 for establishing the terms of putting on market and and putting into function the non-automatic weighing instruments and the 2014/32/UE European Directive regarding Measuring intruments.

In order for us to prepare an evaluation programme and send you a certification contract, please fill all the sections of this form and to retun it to:

ROMANIAN MOVEMENT FOR QUALITY
Parului street, nº. 8, Craiova, Romania

1. GENERAL INFORMATION ABOUT THE APPLICATION FOR APPROVAL OF QUALITY SYSTEM

General information about the organisation:

Name of applicant organizationl (manufacturer): ……

Office address:.....…….....

Mailing address:.....

registered with the Trade Register Nº.. .....; Tax code ....……..……

Bank account nº.:…….., opened at the bank ……..…....

Telephone/mobile:.....Fax .....

E-mail: .....…….....…….....…….. www : .....

Number of subsidiaries: _____

Address subsidiaries: _____

NACE code:.....

Contact name: .....

Position held: .....

Tel.: **Fax:** **E-mail:**

The president (the authorized person to sign the certification contract between MRC and organisation):

If the producer is not situated in European Economic Space :

Representative's name within the EEC: .....
Address:.....
.....
Contact's name: .....
Tel.: **Fax:** **E-mail:**

2. CERTIFICATION IN REGULATED FIELD (QUALITY SYSTEM APPROVAL)

2.1. Reference documents

☐ **2014/31/UE European Directive** regarding the non-automatic weighing instruments (codified version) transposed by HG 710/2015 -. Government decision no. 710/2015 for establishing of putting on market and and putting into function the non-automatic weighing instruments**, annex II - Module D, D1** for the CE marking of non-automatic weighing instruments (NAWI)

☐ **2014/32/UE (MID) European Directive:** for the CE marking of one or more categories of intruments that fall under the Directive (MID):

☐ **Annex II Module D** – declaration of conformity to type based on the quality assurance process of production*

☐ **Annex II Module D1** – declaration of conformity based on quality assurance process of production *

☐ **Annexa II Module E** – declaration of conformity to type based on quality assurance inspection of the finished product and trying*

☐ **Annex II Module E1** – declaration of conformity based on final product inspection and testing*

☐ **Annex II Module H** – declaration of conformity based on full quality assurance of *

☐ **Annex II Module H1** – declaration of conformity based on full quality assurance and consideration of the project *

* Note: Conformity assessemnt procedure to be followed depends on the category of measuring instruments. Compliance to a quality assurance system to the requirements of the Annexes above in determinate according to the SR EN ISO 9001:2008 or EN ISO 9001:2015. Guidelines published by WELMEC (http://www.welmec.org) for application modules and procedures D and H1 are used by RMQ-SCB as an aid to audit.

2.2. Measuring instruments for which the CE marking is needed

Type of measuring instrument Employed separate list if necessary	Brand name	Certification number: type examination, approvalCE examination or project examination	Initials test carried out	
			Regarding the company premises (Yes/No)	At the installation of the site (Yes/No)

3. COMPANIEI INFORMATION ABOUT THE COMPANY STRUCTURE

3.1. Comany's workforce

Total number of staff:	
The estimated numebr of company employees envolved in activities covered by the application of certification (including the support departments)	

Please attach a company brochure and an chart showing the departments in your company.

3.2. Sites where such activities (manufacturing and/or repairing and/or installation) are carried out

Name	Address or country	Main activity or activities	Number of employees	Number of employees envolved in activities that fall under the application

Are all these sites covered by a single quality system?

□ Yes; □ No

If Not, please indicate what quality systems are applied to each site
.....
.....
.....

Do you request that all sites are covered by a single certificate?
□ Yes; □ No

3.3. **Details regarding your activity (where appropriate)**

- The employees' working hours at the office: .....
- The working hours of employees in production: .....
- Do you have employees involved in the manufacturing process?
- Transit time between different buildings and/or sites:……..... .....

4. SUBCONTRACTED ACTIVITIES OR OUTSOURCED PROCESSES

In case that certain activities are subcontracted (for eg. projecting, manufacturing, inspection and testing or marking) please give details:

Subcontractor's name	Address	The nature of subcontracting	Certification of quality management system	
			Yes[1]	No[2]

[1] Please attach a copy of the certificate(certificates).

[2] If a subcontractor does not have a quality system certification, please specify the measures taken to control the quality of provided services (for eg. product specification, contracts, definition of process requirements, accepting inspection and testing, subcontracting audit, etc.)

5. INFORMATION ABOUT THE COMPANY MANAGEMENT SYSTEM

5.1. The company's certificate in force

5.1.1. Are any of your activities already covered by a quality system certification and/or the CE marking certification issued by an accredited body by a signatory of the Ea Agreement?

□ Yes □ No

5.1.2. Is you organization certified ISO 9001 ?

□ Yes □ No

If so, please attach a copy of the certificate (certifications).

Activities covered by the certification:

.....
.....

Name of certification body : …….....
The date of initial audit or the last renewal audit…….: .....

5.2. Quality documentation in force

- Quality manual: □ Yes □ No
- Manufacturing, repairing and installing procedures : □ Yes □ No
- Procedures for managing the identification number of the notified body: □ Yes No
- Initial verification precedures: □ Yes □ No

5.3. Exception form ISO 9001:2008/ISO 900 :2015 requirements

The requirements of clause 7.3 of ISO 9001:2008 or 8.3 of ISO 9001:2015 certification can be excluded from the area covered, in some cases allowed under the regulations.

For the certification according to SR EN ISO 9001, the organization must justify the exclusion of a clause.

Requirement(s) to be excluded:

.....
.....

justification for the excludions

.....

5.4. Providing consultancy

5.4.1. Has you company demanded advice or assistance in creating a quality management system in the last two years?

□ Yes □ No

If so, please specify what body has provided this service:

5.4.2. Has you company asked for advice or assistance regarding the conception of manufactured products, in the last 5 years?

□ Yes □ No

If so, please specify what body has provided this service

6. REQUIREMENTS FOR ASSESING PRODUCT: METHOD OF EVALUATION OF SELECTED COMPLIANCE

6.1. Have you applied the harmonized standards for the product concerned?

□ Yes □ No

what are they: _____

6.2. Specify which method you choose for the conformity assessment (mention the chosen module or modules):

7. LANGUAGE to be used at audit:

□ English □ Romanian

Distinct note for companies which do not use English or Romanian:

Regardless of the language on the sites that are to be auditated, the following documents available in English or Romanian:

- ✓ Documents quality management systems: quality manual, process description (they are to be provided for audit preparation, at least one month before the audit date):
- ✓ description of measuring instruments:
  they are to be provided with this application form
- ✓ File type examination, approval folder, file examination type CE, project file type examination (are to be provided for audit preparation at least one month before the audit date:
- ✓ During the audit, descriptions of main procedures must be available in English or French, otherwise a translator must participate to the audit.

Deadline for certification audit: .....

I confirm that the information provided in this form are correct and I request issuing a certification contract elaborated on the basis of these information.

I understand that the request for initiation of certification process by MRC is made only upon certification contract is signed by both parties.

8. DECLARATION

Confirm that the information in this application is correct. I acknowledge, too, that the application has not been lodged with any other notified body.

I agree to meet the requirements for certification and provide any necessary information. We take full responsibility on the provisions of Regulations presented in Map Information documents.

I undertake to fulfill all obligations arising from the quality system approval.

I pledge to maintain the approved quality system, to assure the continuing suitability and efficiency.

Date:

Company representative's signature: