MRC Mișcarea Română pentru Calitate

APPLICATION FOR APPROVAL OF QUALITY SYSTEM
For companies that produce, repair or install controlled measuring instruments

[ ] CERTIFICATION **[ ] CERTIFICATE UPDATE** **[ ] RECERTIFICATION**

Application number (to be completed by MRC)

This application form for the approval of the quality system is aimed for the companies that produce measuring instruments and non-automatic weighing instruments according to the 2014/31/EU European Parliment and Council Directive from february 26th regarding the non-automatic weighing instruments (codified version), transposed by the Government Decision no. 710/2015 for establishing the terms of putting on market and putting into function the non-automatic weighing instruments and the 2014/32/EU European Directive regarding Measuring intruments, transposed by the Government Decision no. 711/2015.

In order for us to prepare an assessment plan and send you a certification contract, please fill in all the sections of this form and to remit it to:

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

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

General information about the organisation

Name of applicant organization (manufacturer):
Office address:
Mailing address:
Registered in the Trade Register with No. ....., tax code .....
Bank account No.: ....., opened at the bank ..... Telephone/mobile:
.....
E-mail: ..... website : .....
Number of subsidiaries: _____
Address of subsidiaries: .....
NACE code: 281301
Contact person: .....; Position held: .....

Tel.: Fax: E-mail:

If the producer is not situated in European Economic Area:

Representative's name within the EEA: .....
Address:.....
.....
Contact 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/EU (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: The conformity assessment procedure to be followed depends on the category of measuring instruments. The compliance of a quality assurance system to the requirements of the Annexes above is determined according to the EN ISO 9001:2015 and the guidelines published by WELMEC (http://www.welmec.org) for D and H1 modules and procedures' application are used by MRC as an aid to audit.

2.2. Measuring instruments for which the CE marking is required

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

3. INFORMATION ABOUT THE COMPANY STRUCTURE

3.1 Company's workforce

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

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

3.2. Sites (branches) 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 involved 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 (e.g. projection, manufacturing, inspection and testing or marking) please give details:

Subcontractor's name	Address	The nature of subcontracting	Certification of quality management system	
			Yes[1]	Yes[1]

[1] Please attach a copy of the certificate/s.

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

5. INFORMATION ABOUT THE QUALITY 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 the 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 from ISO 9001:2015 requirements

The requirements of 8.3 clause of ISO 9001:2015 certification can be excluded from the area covered, in some cases allowed by 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 exclusions
.....

5.4. Providing consultancy

5.4.1. Has your 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 your 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 PRODUCT ASSESSMENT: METHOD OF CONFORMITY ASSESSMENT

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

Yes No

Specify them: _____

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

7. LANGUAGE to be used during the 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 of the quality management system: quality manual, process description (they are supposed to be provided for audit preparation, at least one month before the audit date):

☐ description of measuring instruments (provided within this application form)

☐ type examination file, approval file, file CE type examination, project examination (to be provided for audit preparation at least one month before the audit date.

During the audit, the descriptions of main procedures must be available in English, otherwise a translator must participate to the audit.

Deadline for certification audit: .....

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

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

7. DECLARATION

I confirm that the information provided in this application is correct. I also acknowledge that the application has not been lodged to 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 the folder with informative documents.

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

I pledge to maintain the approved quality system, to ensure the continuous suitability and efficiency.

Legal representative's signature:

(Name and surname, signature, date)