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REGULATION FOR THE CONFORMITY ASSESSMENT OF MEASURING INSTRUMENTS AND THE ISSUING OF CERTIFICATES OF CONFORMITY WITH HARMONISED REQUIREMENTS ACCORDING TO DIRECTIVE 2014/32/EU AND ITS TRANSPOSITION DECREE

N. Rev.	of	Description	Verified	Approved
5	16/11/2017	Modified for: Acknowledge ACCREDIA's findings of the PRD accreditation renewal audit *(Observation 5 of 10)*: - Description of NC definitions (p. 4.6.2); - Deletion of Chapter 13 'Transfer of certification from another Notified Body'.	Resp MID Ing G. Serafini RQ Ing M Carlini	CEO Dr. Arch. S. L. Giordano
6	22/07/2019	Modified for: - Update para. 1.8 Welmec guides - Introduction Chap. 13 Issue of EU Type Certificate for Measuring Instruments Dealers Certified by Istituto Giordano ; - Clarifications Chapter 17 - Confidentiality of Information; - certification application updated to comply with European Regulation 679/2016	Resp MID Ing. G. Arcaro RQ Ing M Carlini	CEO Dr. Arch. S. L. Giordano
7	20/04/2021	Modified for: - Clarifications Chap.13 Issue of EU Type Certificate for dealers of measuring instruments certified by Istituto Giordano.	Resp MID Ing. G. Arcaro sRQ Dr G.F. Ibba	CEO Dr. Arch. S. L. Giordano
8	14/10/2021	Modified for - acceptance of findings document review renewal of PRD accreditation	Resp MID Ing. G. Arcaro sRQ Dr G.F. Ibba	CEO Dr. Arch. S. L. Giordano
9	22/11/2021	Amended to update harmonised standards on measuring instruments in support of Directive 2014/32/EU	Resp MID Ing. G. Arcaro sRQ Dr G.F. Ibba	CEO Dr. Arch. S. L. Giordano
10	18/09/2024	Amendment to update Ch.18 in which they were detailed: - how to communicate negative results to other notified bodies; - manner of publication on the IG website.	Resp MID Ing. G. Arcaro sRQ Dr G.F. Ibba	CEO Dr. Arch. S. L. Giordano

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Chapter 1 - General Rules

1.1 - Applicability

This Regulation contains the rules and Technical Standards, relating to devices and systems with measurement functions (measuring instruments and sub-units), defined in the specific annexes of Directive 2014/32/EU, to be applied in order to obtain, at the request of interested parties, the relevant documents of conformity (see paragraph 2.1) to the Requirements laid down in the Directive itself transposed by Italy with Legislative Decree No. 84 of 19 May 2016 "Implementation of Directive 2014/32/EU on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments, as amended by Directive (EU) 2015/13" amending Legislative Decree No. 22 of 2 February 2007 'Implementation of Directive 2004/22/EC on measuring instruments.
Member States may prescribe the use of the measuring instruments referred to in Article 1 of the Directive with respect to functions for their placing on the market and/or putting into use for measuring tasks for reasons of public interest, public health, public safety, public order, protection of the environment, protection of consumers, levying of taxes and duties and fair trading, where they consider it justified.
The provisions of the Regulation shall be applied by Istituto Giordano S.p.A. (hereinafter the Institute) to the conformity assessment of systems with a measuring function (measuring instruments and sub-units), for which the Institute is authorised/notified, referred to in Article 1 of Directive 2014/32/EU, as defined in Annexes III to XII (replacing the previous Annexes MI-001 to MI-010) of that Directive.
At the time of issuing these regulations, the Institute is authorised/notified for:

a) Gas meters and volume conversion devices (Annex IV);
b) Active electricity meters (Annex V);

In the remainder of this Regulation, devices and systems with a measuring function (measuring instruments and sub-units) are for simplicity's sake referred to as 'Measuring Instruments' or 'Instruments'.
Access to certification is open to all Organisations and is not conditioned by whether or not they belong to any Association or Group. For the certification activity, Istituto Giordano S.p.A. shall apply its current rates, guaranteeing fairness and uniformity of application.
In the context of these Rules, conformity certification or simply certification means the positive verification by the Istituto Giordano of the conformity of the product/quality system/design/testing with the reference regulatory document that allows certification and therefore the CE marking of the product as defined in the EC Regulation No. 765/2008 issued by the European Parliament and the Council of 9 July 2008 and therefore the issue of the relevant "EU certificate"; by certificate, unless otherwise specified, is meant any of the conformity documents issued by the Institute upon successful completion of the verification activities.

The organisation applying for certification (sometimes referred to simply as 'the applicant') may be the manufacturer of the measuring instrument or, on behalf of the manufacturer and under its responsibility:

- its *Authorised Representative* (as defined in Art. 2 para. 9 of Directive 2014/32/EU),

or other *economic operator* other than the Manufacturer itself such as:

- *Importer* (as defined in Article 2 paragraph 10 of Directive 2014/32/EU),
  if on the basis of Article 12 of Directive 2014/32/EU it places a measuring instrument on the market under its own name or trademark or modifies a measuring instrument already placed on the market in such a way that its conformity with this Directive may be affected.
  NOTE: In such a case the importer shall also be considered in all respects as a Manufacturer and shall be subject to all relevant obligations of the Manufacturer specified in Article 8 of Directive 2014/32/EU.

- *Distributor* (as defined in Art. 2 para. 11 of Directive 2014/32/EU),
  if according to Article 12 of Directive 2014/32/EU it places a measuring instrument on the market under its own name or trademark or modifies a measuring instrument already placed on the market in such a way that compliance with this Directive may be affected. NOTE: In such a case the Distributor shall also be considered in all respects as a Manufacturer and shall be subject to all relevant obligations of the Manufacturer specified in Article 8 of Directive 2014/32/EU.

In the following text, Istituto Giordano S,p,A, is referred to as "Istituto" for the sake of brevity; by "Organisation" is meant the Manufacturer or its Authorised Representative as defined in the Directive or the Importer/Distributor if it places a measuring instrument on the market under its own name or trademark or modifies a measuring instrument already placed on the market in such a way as to be able to condition its conformity with the Directive.

1.2 - Legislative Provisions

These regulations presuppose knowledge of and reference to the following legal provisions:

a) Legislative Decree No. 84 of 19 May 2016 "Implementation of Directive 2014/32/EU on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments, as amended by Directive (EU) 2015/13" transposing Directive 2014/32/EU amending Legislative Decree No. 22 of 2 February 2007.
b) Directive 2014/32/EU on the harmonisation of the laws of the Member States relating to making available on the market of measuring instruments (recast) of the EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014,
c) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008,

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d) Regulation (EU) No 1025/2012,
e) Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008,

1.3 - Harmonised standards and normative documents

1.3.1 Measuring instruments shall be deemed to comply with the essential requirements set out in Annex I of Directive 2014/32/EU and Annexes III to XII thereto if they conform to the specifications corresponding to the relevant harmonised standard - as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012 - relating to them and the references of which have been published in the C series of the Official Journal of the European Union, as referred to in Article 15 "Publication of the references of normative documents" - paragraph b) of Directive 2014/32/EU.
In the Official Journal of the Italian Republic the reference to the above mentioned standards or to any technical standards as defined in Art. 2 paragraph 13 of Directive 2014/32/EU is published.
1.3.2 Measuring instruments complying with the essential requirements set out in Annex I of Directive 2014/32/EU and Annexes III to XII thereto shall also be deemed to comply with the normative documents understood as those documents containing technical specifications adopted by the International Organisation of Legal Metrology (OIML), i.e. specifications of Directive 2014/32/EU.
1.3.3 Where a measuring instrument complies with parts of the documents in Article 14 - paragraph 2 of Directive 2014/32/EU.
1.3.4 The manufacturer may use any technical solution that complies with the essential requirements set out in Annex I and Specific Annexes III to XII. Furthermore, in order to benefit from the presumption of conformity, the manufacturer shall correctly apply the solutions mentioned in the relevant harmonised standards or normative documents, consistent with the statements of paragraphs 1.3.1, 1.3.2, 1.3.3 above. the list of which has been published in the Official Journal of the European Union, that instrument shall be presumed to comply with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes as indicated in
1.3.5 The relevant tests referred to in Article 18(3)(i) of Directive 2014/32/EU, constituting the technical documentation referred to in paragraph 4.3 of this Regulation, are fulfilled if the corresponding test programme has been carried out in accordance with the relevant documents referred to in paragraphs 1, 2 and 3 of Article 14 of Directive 2014/32/EU and paragraph 1.3 of this Regulation and if the results of the tests ensure compliance with the essential requirements.

The Institute keeps the collection of these standards/regulations constantly updated and makes them available to the personnel involved in certification activities.

1.4 - Essential Requirements

The measuring instrument must provide a high level of metrological protection so that the parties can trust the measurement result; the design and manufacture of the measuring instrument must be of high quality with regard to measurement technology and security of measurement data.
Annex I 'Essential Requirements' of Directive 2014/32/EU sets out the requirements that measuring instruments must comply with in order to achieve these objectives, supplemented by instrument-specific requirements in specific annexes III to XII, where some aspects of the general requirements are explained in more detail.
The solutions adopted to meet the requirements take into account the intended use of the instrument as well as foreseeable misuse of the instrument.

1.5 - Internal Operating Procedures

For the applicability of these regulations, it is assumed that the following Manuals/Regulations published by the Institute are known and provided:
a) P-MID000 - DIRECTIVE 2014/32/EU (MID) - Conformity Assessment Process;
b) General Terms and Conditions for Certification;
c) Procedures for the qualification of external laboratories;
d) Collection, on a database, of test standards and regulations (harmonised European technical standards, equivalent national technical standards, normative documents) of measuring instruments.

1.6 - Definitions

For the purposes of this Regulation, the definitions set out in Article 4 of Directive 2014/32/EU apply.

1.7 - Applicability Tables Name/Normative

A list of the harmonised standards/standards and combinations of conformity assessment modules applicable, depending on the intended use, to the various categories of devices and measuring systems is given in Annex 2 of this Regulation.

1.8 - WELMEC European cooperation in legal metrology guides

The WELMEC guides are application guides for both the activities of the Notified Body and the activities of the Manufacturer, these guides do not impose any restrictions or additional technical requirements beyond those contained in the MID Directive 2014/32/EU.
Alternative approaches may be considered acceptable, but the guidance in the guides is, in WELMEC's opinion, the best practice to follow.
These guides are used in the current revision found at https://www.welmec.org/.

Chapter 2 - Documents of Compliance

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2.1 - Types of documents issued, their meaning and validity

The issuance and maintenance of conformity documents is subject to the successful completion of conformity assessment procedures (Modules) chosen by the Applicant (these assessment procedures may be generically referred to hereafter as Certification); for each applicable Module, the relevant conformity documents and the modalities for issuing and maintaining them are established.
The identification of the documents of compliance issued, their validity and the surveillance procedures for their maintenance are outlined below and summarised in Annex 1 to this Regulation.

Chapter 3 - Conformity Assessment Procedures

3.1 - Generalities

The assessment procedures and related responsibilities of the Manufacturer and the Notified Body are described in Annex 3 of this Regulation.
A detailed description of the activities and related responsibilities in the implementation of the various Conformity Assessment Modules is given below and in the applicable internal procedures.
The procedures and these regulations are in accordance with the applicable standards for the operation of certification bodies and testing and calibration laboratories of the ISO/IEC 17000 series - specifically UNI CEI EN ISO/IEC 17065 "Conformity assessment - Requirements for bodies certifying products, processes and services" - and consider the relevant EA/IAF guides/documents.

3.2 - Applicable conformity assessment modules, their combinations and choice

The choice of the Assessment Modules or their combinations is up to the Applicant according to the possible options identified in Directive 2014/32/EU and its transposition decree and listed below.

Specifically, the Assessment Modules applicable to the various products falling within the scope of Directive 2014/32/EU and with reference to this Regulation, those applicable by Istituto Giordano in relation to its current notification are as follows:

- Module B - Type Examination;
- Module D - Declaration of conformity to type based on quality assurance of the production process;
- Forms F - Declaration of conformity to type based on product verification;
- Module H1 - Declaration of Conformity based on full quality assurance and design review.

Module B is always associated, at the choice of the manufacturer or its authorised representative or other economic operator *(see p. 1.1)* and according to applicability, with one of the modules D or F.
Conformity assessment according to module H1 must be carried out by a single Notified Body, whereas conformity assessment according to combinations B+D and B+F may be carried out by two different Bodies.
At the time of issue of these regulations, the Giordano Institute operates under authorisation/notification and may certify according to the evaluation forms and for the measuring instruments highlighted below with "✓" ; *while the evaluation forms for each category of instruments for which the Institute does not have authorisation/notification are highlighted with " o ".*

Annex Directive 2014/32/EU	Measuring instruments	A	A1	B	B1	C	C1	D	D1	E	E1	F	F1	G	H	H1
III (ex MI-001)	Water meters			*o*				*o*				*o*				*o*
IV (ex MI-002)	Gas meters and volume conversion devices			✓				✓				✓				✓
V (ex MI-003)	Active electricity meters			✓				✓				✓				✓
VI (ex MI-004)	Thermal energy meters			*o*				*o*				*o*				*o*
VII (ex MI-005)	Measuring systems for continuous and dynamic measurement of quantities of liquids other than water			*o*				*o*				*o*		*o*		*o*
VIII (ex MI-006)	Automatic Weighing Instruments: - mechanical systems; - electromechanical instruments; - Electronic systems or systems con-			 *o* *o*				 *o* *o*	 *o*	 *o* *o*		 *o* *o*	 *o*	 *o* *o*		 *o* *o*

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Annex Directive 2014/32/EU	Measuring instruments	A	A1	B	B1	C	C1	D	D1	E	E1	F	F1	G	H	H1
	taining software			o				o				o		o		o
IX (ex MI-007)	Taximeters			o				o				o				o
X (ex MI-008)	Materialised measurements - length measurements - capacity measurements		o	o o				o o	o o	o	o		o o	o	o o	
XI (ex MI-009)	Dimension measuring instruments: - mechanical or electromechanical instruments - electronic instruments or instruments containing software			o o				o o	o	o	o	o o	o	o o	o	o o
XII (ex MI-010)	Exhaust gas analysers			o				o				o				o

Chapter 4 Conformity Assessment Process

4.0 - Contractual Clause

The rules described in this regulation and in the applicable parts of the technical specifications/harmonised standards/regulations and the General Terms and Conditions for Certification (GTC) referred to in Chapter 19 have a contractual character in the relationship between the Institute and the applicant for documents of attestation of conformity (Certificates of Conformity) within the scope of this regulation.
Istituto Giordano collects and keeps constantly updated and under control the repertoire of the internal assessment and certification operating procedures for the application of the conformity assessment modules foreseen; the assessment personnel, with reference to the activities carried out, receive in controlled distribution a copy of the internal operating procedures; each operating procedure also contains or refers to the records to be produced in its implementation.

4.1 - Application for Certification

Before proceeding with the production of a measuring instrument, the Manufacturer or his Authorised Representative or other eco- nomic operator (see p. 1.1), as applicable, must submit an application for EU conformity assessment specifying the name and address of the Manufacturer, the place of production, the designation of the product type, and possibly, in order to facilitate communication with market surveillance authorities and consumers, the address of the Manufacturer's website in addition to the postal address.

If the application is submitted by the Manufacturer's Authorised Representative or by another economic operator (see p. 1.1), it must contain the latter's information together with the Manufacturer's information (including web addresses and Internet sites in addition to the postal address).

Additional information/documents must be attached to the applications:

- technical documentation described in section 4.3.3
- documentation on the Quality System described in 4.3.4, when applicable;
- representative samples of the production considered in sufficient number for the performance of the tests envisaged, in the event that the Applicant intends to perform the type tests, referred to in paragraph 4.4, at the Istituto Giordano.

In the application, the manufacturer or its authorised representative or any other economic operator (see p. 1.1), must specify which evaluation procedure it intends to adopt.

An application for EU conformity assessment of a certain measuring instrument may not be submitted to two (or more) different Notified Bodies at the same time.

Therefore, the Applicant must explicitly state in the application that it has not also been sent to other notified bodies. The template of the application for EU conformity assessment for measuring instruments can be found in Annex 4.

4.2 - Appointment of the evaluation team

For each application for the certification of measuring instruments covered by these Rules, the Institute appoints a specific "Evaluation Group" (Audit Group, abbreviated to GVI); the composition of the group guarantees the necessary competences relating to the management of the certification process and to the activities of documentation examination, test/analysis and verification at the Applicant's production site, including one or more experts in the instrument production technology and in the field of metrology subject to evaluation.

The appointed team must also be familiar with the applicable requirements of the Directive. The members of the team are qualified in advance by the Institute, based on its internal procedures.

The Institute informs the Applicant of the name(s) of the "Evaluation Group" (GVI) personnel it intends to employ by means of an order confirmation, identifying, according to applicability:

- the composition of the GVI
- any external contracted laboratory (module B and F)

The Applicant may communicate, in writing, any objections concerning the GVI/External Laboratory that the IG intends to use, giving reasons therefor; the External Laboratory/GVI will be appropriately changed if the reasons are found to be legitimate by mutual agreement.

If no justified and written reasons are received from the Applicant within no later than 5 working days from the communication of the name, the GVI/laboratory is deemed to be accepted by the Applicant.

4.3 - Technical Documentation provided by the Manufacturer

4.3.1 - Generalities

The technical documentation must describe the design, manufacture and operation of the measuring instrument in an intelligible manner and must enable its conformity to be assessed on the basis of the requirements of Directive 2014/32/EU and set out in this Regulation.

4.3.2 - Examination of Documentation

Upon receipt of the application for conformity assessment, the Institute, after review, assesses the conformity of the attached documents with the provisions of these Regulations.

In the event that the documentation is incomplete or non-compliant in any of its parts or attachments, the Applicant is informed and the certification file is suspended until the deficiencies found have been rectified.

In particular, the conformity of the documents described in the following paragraphs is assessed:

- 4.3.3 - Content of the technical documentation.
- 4.3.4 - Documentation provided for Quality System audits (where applicable).
- 4.3.5 - Documentation provided for project examination

The Institute may also, at its own discretion, request additional documents for the purposes of a further and more specific evaluation, in support of the information received previously if this additional information is deemed necessary for the purposes of the certifica- tion in question.

During the period of validity of the certification, the Applicant must keep the approved documentation under control in accordance with its own documentation control procedures.

Following the positive outcome of the evaluation, the Institute (Evaluation Group) plans the subsequent evaluation activities.

4.3.3 - Content of Technical Documentation

The technical documentation must be sufficiently detailed to allow assessment and ensure:

1. the definition of metrological characteristics;
2. the reproducibility of the measurement results of the instruments produced when they are correctly calibrated using the ap-

propriate means;
3. the integrity of the instrument

For the purposes of assessment and identification of the type or instrument, the technical documentation must include the following

a) a general description of the instrument;
b) a risk analysis and assessment of the instrument's compliance with the relevant requirements of Directive 2014/32/EU;
c) design and manufacturing drawings, as well as plans for components, sub-assemblies, circuits and similar parts;
d) manufacturing procedures in order to ensure homogeneous production;
e) a description of electronic devices with schematics, diagrams, logical and general software information flow diagrams illustrating their characteristics and operation;
f) descriptions and explanations necessary for understanding (b), (c) and (d), including the operation of the instrument;
g) a list of the harmonised standards or normative documents (ref.: point 1.3 of this Regulation), applied in whole or in part, the references of which have been published in the Official Journal of the European Union;
h) descriptions of the solutions adopted to meet the essential requirements where the harmonised standards or normative documents have not been applied (ref: point 1.3 of these Regulations);
i) the results of design calculations, examinations;
j) relevant test results, where necessary, to demonstrate that the type or instrument complies with:
    1. the requirements of the directive according to declared rated operating conditions and specific environmental disturbances;
    2. durability specifications for gas meters/converters and active electricity meters;
k) EU Type Examination Certificates or EU Design Examination Certificates for instruments containing parts identical to those of the design.
l) any other document that enables the Institute to improve evaluation.

In addition:

m) The manufacturer (or its representative, see p. 1.1) must specify the position of the seals (metric-legal seal plan) and markings.
n) The manufacturer (or whoever, see p. 1.1) must indicate compatibility requirements with interfaces and sub-assemblies, if applicable.
o) The Manufacturer (or whoever, see p. 1.1) may, if in possession, attach the parts certificate (or evaluation certificate) issued in accordance with Welmec Guide 8.8:2017.

4.3.4 - Documentation Provided for Quality System Audits

For the approval and surveillance activities of the Quality System foreseen for Modules D and H1, the documentation provided by the manufacturer includes

a) All relevant information on the intended category of instruments;
b) Quality System documentation (policies, objectives, manual, procedures, instructions, etc.);
c) the technical documentation relating to the approved type and a copy of the EU type certificate (only for module D).

4.3.5 - Documentation provided for project examination

For design verification activities, the documentation provided by the manufacturer additionally includes:

a) the technical documentation as described in paragraph 4.3.3. of this Regulation. This documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of Directive 2014/32/EU; it shall include the design and operation of the instrument and an adequate analysis and assessment of the risks as far as relevant for the assessment;
b) documentation proving the adequacy of the technical design. These supplementary documents must mention all the documents that have been applied, in particular where the harmonised standards and normative documents have not been applied in full (ref.: point 1.3 of these Regulations) and include, if necessary, the results of tests carried out by the Manufacturer's laboratory or, on his behalf and under his responsibility, by another test laboratory.

4.4 - Testing/analysis and evaluation of results

4.4.1 - Directory of Evaluation and Testing Standards and Reports

The repertoire of test/analysis/examination standards for the measuring instruments covered by these Regulations is available in the Institute's internal database in electronic format.

The records relating to the evaluation and testing/analysis/examination activities carried out on the measuring instruments subject to the application for certification are made on the relevant forms/templates prepared by the Institute; these forms/templates are available in the Institute's internal database in electronic format.

4.4.2 - Type and identification of applicable test/analysis/examination standards

In carrying out the activities foreseen by the Evaluation Modules on the measuring instruments subject to the certification application, the Institute carries out or has carried out standardised laboratory tests and analyses/examinations, i.e. test/analysis/examina- tion standards applicable to the products covered by these Rules.

These test/analysis/examination standards defining the operating methods and requirements for the evaluation of results are identified in 1.7. and 1.3.

4.4.3 - Quality plans in laboratory tests/analyses/examinations

The Institute records the planned and performed test/analysis/examination activities relating to each measuring instrument covered by these Rules. The Institute communicates the test/analysis/examination plan/programme and, where applicable, the sampling plan to the Applicant.

4.4.4 - Sampling

If the Institute carries out the applicable tests/analyses/laboratory examinations directly, the Applicant shall send the product samples according to the sampling plan received. In the event that the Applicant intends to carry out the type tests at the Istituto Giordano, the samples shall be representative of the production considered in sufficient number for the tests/analyses/examinations envisaged to be carried out.

For sampling carried out at the Manufacturer's premises, by the Institute, for the relevant evaluation forms (Forms F or D) or on the occasion of unannounced visits or visits for additional analyses/tests/examinations, a sampling report must be drawn up.

4.4.5 - Tests/analyses/examinations

In application and according to the applicable conformity assessment modules, the tests/analyses/laboratory examinations foreseen in the specific plan/programme prepared for the specific measuring instrument subject to certification are carried out.

The Institute carries out the tests/analyses/examinations on its own responsibility, as notified body, at its own laboratories; these tests/analyses/examinations may also be carried out, in the opinion and under the responsibility of the Institute, at the Manufacturer's laboratory or another laboratory qualified by the Institute.

In the implementation of Module B, the Institute carries out or has carried out the Type tests/analyses/examinations for the purpose of issuing the EU Type Examination Certificate.

4.4.6 - Evaluation of test results/analysis

The test/analysis/examination results are verified by the competent function of the Giordano Institute; upon completion of this activi- ty, confirmation of the test/analysis/examination results is sent to the Applicant by means of a written communication:

- for positive results, by sending test reports/analyses/examination or inspection/witness test reports to the test (e.g. if performed at the Manufacturer's or another laboratory qualified by the Institute);
- for negative results, by sending any non-conformities found on the product regarding the results of the test/analysis/examination activities (see 4.6).

4.4.7 - Additional tests

The Institute reserves the right to carry out additional tests/analyses/examinations and/or checks on the product for the purpose of issuing the certificate in the cases provided for in 4.6.3.

4.4.8 - Qualification of laboratories outside the Institute

In the event that the Applicant for certification intends to use its own in-house laboratories or other laboratories other than the Institute for the performance of the tests/analyses/laboratory examinations programme, these laboratories will be qualified in advance by the Institute in accordance with the internal procedures in force; the purpose of this qualification is to guarantee the suita- bility of the laboratory for the performance of the tests in question. The Institute may also request that its own technicians be present to carry out the tests at the applicant's laboratory or at another laboratory other than the Institute.

4.5 - Evaluation Visits

4.5.1 - Type of visits

a) Quality System Verification Visits

The initial audits of a system module (Mod. D and H1) include a two-stage initial audit.

Verifications of the documentation (see Section 4.3.2 of this Regulation) and of the QS setup constitute Phase 1 of the initial verification activity.

Phase 1 audits are normally started at Istituto Giordano and completed at the organisation according to the criterion of achieving all the Phase 1 objectives set out below.

In Phase 1 evaluations at the Applicant's premises, the Lead Assessor may supplement the previously requested documents, if necessary, with other documents.

Phase 1 and Phase 2 activities may, in the opinion of the Giordano Institute, be conducted consecutively at the Organisation subject to availability and agreement with the Organisation.

In special and justified cases, for which the relevant records must be kept, and following specific agreements with the Applicant, Phase 1 may only be carried out at the Istituto Giordano provided that the following conditions are simultaneously fulfilled:

- all the objectives of Phase 1 verification set out below are met;
- the organisation is small;
- the Applicant's management system and organisation are not complex.

Or:

- if the applicant already applies a certified QS complying with 9001 whose scope of certification includes the production of the measuring instruments subject to MID certification.

Phase 1 audits are carried out with the aim of:

1. verify the organisation's management system documentation;
2. assess the location and particular conditions of the Applicant's site and undertake an exchange of information with theApplicant's personnel in order to establish the degree of preparedness for the Phase 2 audit;
3. reviewing the status and understanding of the Applicant regarding the essential requirements of the MID and the regula- tions it intends to apply in whole or in part and the requirements of the quality system;
4. assess compliance with applicable legal and regulatory requirements for the MID;
5. assess the adequate identification of key performance or significant aspects, processes, objectives and functioning of the management system;
6. collect the necessary information concerning the scope of the management system, the processes and the location(s) of the Applicant, including relevant legal and regulatory aspects and compliance therewith;
7. focus on the planning of the Phase 2 audit, acquiring sufficient knowledge of the management system and activities of theApplicant's site, with reference to possible significant aspects;
8. assess that the level of implementation of the management system provides evidence that the organisation is ready for theStage 2 audit.

The findings of the Stage 1 Audit are communicated to the Organisation, without any classification, to be managed by it, in particular, problems that could be classified as Non-Compliance in Stage 2 will be identified.

Should the findings of the Phase 1 verifications reveal significant problems, the Lead Assessor informs the Applicant that Phase 2 of the evaluation may not take place until such problems have been taken care of and resolved by the Applicant.

The outcome of the verification is communicated to the Applicant in good time before the Phase 2 verification.

Upon successful completion of the Phase 1 audits, with reference to the relevant objectives, i.e. that the quality system has been adequately set up, Phase 2 audits are carried out.

After analysing and evaluating the Applicant's documents and completing the Phase 1 activities, the appointed Assessor prepares the Phase 2 audit plan.

b) Product verification visits

In application of Conformity Assessment Modules B and F, the Institute, according to applicability, may carry out product verification visits to the organisation.

The evaluation team records the results of product verifications on special checklists/Test Reports/Verification Reports of the Giordano Insti- tute.

During these visits, the Institute may also carry out, depending on applicability, product sampling/sampling for tests/analyses/examinations (see section 4.4.4) or inspection/witnessing activities for any tests carried out by the Manufacturer or by laboratories qualified by the Institute.

4.5.2 - Appointment of the evaluation team

The Evaluation Team in charge of the on-site visits of the Certification Applicant is appointed pursuant to Section 4.2 of this Regula- tion.

4.5.3 – Scheduling audits

The Institute shall plan in advance the verification activities to be carried out and notify the Organisation of them, excluding any unannounced surveillance visits.

The contents of this planning are prepared in relation to the evaluation modules applied and the type of visit (first evaluation, surveillance, unannounced surveillance visit) as shown below.

The Institute carries out field audits at the organisation (the Manufacturer's production site), as specified below, for the assessment modules, identified in section 4.5.1, for which it is notified (ref. section 1.1 and 3.2).

For Modules D, F, field inspections are only carried out after verifying that the Manufacturer or whoever on his behalf (see p. 1.1) is in possession, for Modules D and F, of the relevant valid EU Type Examination certificate (such certificate may have been issued by a notified body other than the Istituto Giordano) as evidence of having successfully undergone the conformity assessment procedure foreseen for the products subject to certification.

In particular, for module H1 Istituto carries out both the field inspection for the quality system assessment and the EU design ex- ami- nation, as all audits for module H1 must be carried out by the same notified body.

a) Quality System Verification Audits

The elements of the quality system to be verified in relation to the application of the relevant Assessment Modules and the type of visit are identified below:

Module	**Elements of the Quality System to be evaluated**	**Type Visit**	**Purpose and planning of the audit**
D Production Quality System, inspection and tests carried out on the final product	*Annex II - MODULE D para-graph 3 of Directive 2014/32/EU (point 3, Mo- dule D, of Annex II set out in Annex A to Legislative Decree No. 84 of 19 May 2016 transposing Directive 2014/32/EU)*	First Evaluation Audit	Provide evidence that the quality system to be approved ensures conformity of the management system re- lating to production and final testing/inspection (First inFactory Verification) and guarantees conformity of the products with the type described in the EU Type Exami-nation Certificate. Also provide evidence that the quality system includesthe implementation of appropriate ways to ensure the homogeneity of products during production.
D Production Quality System, inspection and tests carried out on the final product	*Annex II - FORM D para-graph 4 of Directive 2014/32/EU (Point 4, Form D, of AnnexII set out in Annex A to Le-gislative Decree No. 84 of 19 May 2016 transposing Directive 2014/32/EU)*	Planned annual surveillance Audit	Provide evidence that the supervised quality system en- sures that the manufacturer fulfils over time all the obli-gations arising from the approved quality system. Also provide evidence that the quality system includes the implementation of appropriate ways to ensure the homogeneity of products during production.
D Production Quality System, inspection and tests carried out on the final product	*Annex II - FORM D para-graph 4.4 of Directive 2014/32/EU (Section 4.4, Module D, of Annex II set out in Annex Ato Legislative Decree No. 84 of 19 May 2016 transposing Directive 2014/32/EU)*	Unannounced surveillance Audit	Provide evidence that the supervised quality system en-sures that the manufacturer fulfils over time all the obli-gations arising from the approved quality system. In particular: - verify the elements chosen on the basis of the resultsof the verifications previously carried out; performs or has performed product tests to verify the proper functioning of the quality system.
H1 Declaration of Con-formity based on Total Quality Assurance and Examination of the Project	*Annex II - FORM H1 para-graph 3 of Directive 2014/32/EU) (Point 3, Form H1, of Annex II set out in Annex A toLegislative Decree No. 84 of 19 May 2016 transposing Directive 2014/32/EU)*	First Evaluation Audit	Provide evidence that the quality system to be appro- ved ensures conformity of the management system re-lating to design, production and final testing/inspection(First in Factory Verification) and ensures conformity ofproducts with the EU Design Examination Certificate. Also provide evidence that the quality system includes the implementation of appropriate ways to ensure the homogeneity of products during production.
H1 Declaration of Con-formity based on Total Quality Assurance and Examination of the Project	*Annex II - FORM H1 para-graph 5 of Directive 2014/32/EU (Point 5, Form H1, of Annex II set out in Annex A toLegislative Decree No. 84 of 19 May 2016 transposing Directive 2014/32/EU)*	Planned annual surveillance Audits	Provide evidence that the supervised quality system en-sures that the manufacturer fulfils over time all the obli-gations arising from the approved quality system. Also provide evidence that the quality system includes the implementation of appropriate ways to ensure the homogeneity of products during production.
H1 Declaration of Con-formity based on Total Quality Assurance and Examination of the Project	*Annex II - FORM H1 para-graph 5.4 of Directive 2014/32/EU (Section 5.4, Module D, of Annex II set out in Annex Ato Legislative Decree No. 84 of 19 May 2016 transposing Directive 2014/32/EU)*	Unannounced surveillance audit	Provide evidence that the supervised quality system en-sures that the manufacturer fulfils over time all the obli-gations arising from the approved quality system. In particular: - verify the elements chosen on the basis of the resultsof the verifications previously carried out; performs or has performed product tests to verify the proper functioning of the quality system

If the standards/regulations (paragraphs 1.3 and 1.7), applicable to the measuring instruments subject to certification, require ISO9001 quality system certification, the institute shall also verify the validity of the ISO 9001 certificate and that its scope of appli- cation covers the elements of the quality system required by the Directive for the instrument subject to CE marking.

b) Product **verification audits**

The product verification activities are determined by the Institute according to the conformity assessment module to be applied (Mod. B, F) and the results of the documentary examination.

In accordance with evaluation form F, sampling/sampling of the product may be carried out in order to perform the required tests (see sections 4.4.3, 4.4.4, 4.4.5 and 4.4.6).

4.5.4 - First Evaluation Audit

The visit consists of:

a) an initial meeting to agree on the modalities of the visit itself and to illustrate/present:
   - the evaluation team;
   - the way in which verifications are carried out;
   - confidentiality aspects;
   - logistical aspects;
   - Non-conformity management. Observations and Corrective Actions;
   - the documentation constituting the visit report.

b) an inspection of the offices, of the production site(s), and, where necessary, of the site(s) where the raw materials, semi-finished products, products, etc. are collected/deposited, as well as of the laboratory(s), to verify that the Manufacturer's ManagementSystem allows the production of products that comply with the essential requirements of the Directive and of any applicable standards; in particular, as regards the Manufacturer's company laboratories where the First-in-Factory Verification is carried out, the compliance of the laboratory with standard UNI CEI EN ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories" is assessed;

c) a final meeting for:
   - illustrate/present the outcome of the verification;
   - provide clarification of the results;
   - formalise deviations (Major Non-conformities, Minor Non-conformities and Observations);
   - explain the continuation of the certification process;
   - formalise any reservations concerning the work of the evaluation team on the part of the organisation;
   - deliver a copy of the visit report.

The evaluation team shall verify the suitability, depending on the evaluation module to be applied, of the Manufacturer's or product's Quality System for compliance with all applicable requirements of Directive 2014/32/EU and its transposition decree, see paragraph

4.5.3 for Quality System requirements and paragraph 1.4 for essential requirements and specific requirements relating to the type of measuring instrument (Annexes III to XII of Directive 2014/32/EU).

In the event of deficiencies or deviations from what is declared on the system or product documentation, the evaluation team may notify the organisation of one or more non-conformities.

During the visit, the organisation must demonstrate, in addition to compliance with the reference standards applicable to it, that the system is fully operational and that it effectively implements this system and its documented procedures.

To this end, even during surveillance audits (specified below), the Institute's technicians/ GVI must be guaranteed free access to the production sites, personnel and documentation and the necessary assistance from the Organisation's personnel in charge of the audit.

At the end of the evaluation visit, a report of the evaluation visit (Audit Report) is delivered to the organisation, on which any non-conformities/observations found are noted.

For the management of findings (non-conformities and observations) and their treatment and corrective/preventive actions, see section 4.6.

4.5.5 - Surveillance Audit for Quality Systems

The evaluation modules D and H1 provide for periodic surveillance of the organisation's Quality System. To this end, the Institute carries out annual surveillance visits on the Quality System, providing for a complete reassessment over a three-year period with a view to reissuing the certificate at the end of the three-year period (see Annex 1).

For surveillance audits, the modalities described for initial first evaluation visits (sections 4.5.1 to 4.5.4) are followed, as applicable.

The Institute provides the organisation with an evaluation visit report (Audit Report) and any test report or inspection/witness test report.

4.5.6 - Unannounced surveillance audits

The Institute may also carry out unannounced visits to the organisation (manufacturer's production site).

On this occasion, the Institute may carry out or have carried out, if deemed necessary, tests/analyses/examinations to verify the correct functioning of the approved Quality System.

The Institute provides the organisation with an evaluation visit report (Audit Report), complete with any test report performed or the inspection/witness test report.

4.5.7 - Additional Audit

The Institute reserves the right, justified in writing to the Organisation, to carry out additional tests and/or analyses and/or visits and/or checks and/or controls; this may take place, for example:

- to verify the implementation and effectiveness of the treatments (corrections) of non-conformities and corrective/preventive ac- tions implemented by the organisation;
- when complaints or reports, considered particularly significant, are received concerning the compliance of the product or the certi- fied quality system with the requirements of the reference standards and these Rules;
- for the purpose of reinstating the validity of the certificate following a suspension (where applicable);
- following changes made by the Manufacturer Organisation to the product and/or quality system and considered relevant by theInstitute (applicable for Evaluation Modules D and H1).

In the event of refusal by the Organisation of additional verifications without valid reasons Istituto Giordano may:

- initiate the process of suspension and/or revocation of the issued certification (see Chapter 12);
- block the certification process;

All costs relating to any additional verifications shall be borne by the Organisation, except for additional verifications following reports or complaints, which shall be borne by the Organisation if they are deemed justified by the Institute.

4.5.8 - Audit Report and Checklists

During the assessment, a checklist is drawn up by the appointed assessment team to collect/identify the objective evidence assessed.

At the end of the above-mentioned inspections, an evaluation visit report is delivered to the organisation, on which any non-confor- mities and observations found are noted (see section 4.6).

the organisation may note its reservations or observations, if any, regarding the conduct/performance of the evaluation team and the remarks made, on an appropriate space in the evaluation visit report.

4.5.9 - Confirmation of findings and outcomes of the inspection visit

The contents of the assessment visit report, including the relative annexes constituting the inspection dossier, (e.g.: check/check lists, docu- mentary evidence on paper or in electronic format, non-conformity forms, etc.) and any findings that emerge are verified by the competent function of the Institute and, if no variations are made, it confirms them by means of a specific written communication to the Organisation; otherwise, any changes in content are duly reported and justified in writing to the Organisation.

4.6 - Non-conformity management. observations, corrective actions

4.6.1 - Generalities

The Organisation, after analysing the causes of any non-conformities reported on the Quality System verification report and any non-confor- mities found on the product in relation to the results of the above test/analysis/verification activities, must propose to the Institute/Responsi- ble for the GVI (RGVI), by the date indicated on the report itself and on the Non-conformity forms, the necessary corrections and correc- tive/preventive actions and the timeframe envisaged for their implementation in compliance with the following.

Acceptance of these proposals and their implementation timeframes shall be communicated in writing by the Institute/RGVI to the Organisa- tion.

In particular, non-conformities found during audits, tests/analyses are classified, evaluated and produce the effects illustrated below.

4.6.2 - Definition and Classification of Surveys

Major Non-Conformity

Major Non-Conformity are considered, by way of example and not exhaustively:

- the total disregard of one or more requirements of the applicable reference standards/regulations;
- the non-conformity of the results of the tests/inspections/inspections with the criteria laid down in the applicable reference standards/regulations;
- any non-compliance or situation that could result in the placing on the market/delivery of a product that does not comply or does not meet the standards/regulations/laws applicable to it or that could result in the product not being used or being used less for its intended purpose
- non-compliance with one or more of the requirements of these Rules.
- a non-compliance or situation which, in the judgement and experience of the audit team (GVI), could lead to a deficiency in the product or quality system and/or materially reduce the ability of the quality system to ensure compliant products or controlled processes,

or cause a non-compliant product to be placed on the market/delivered;
- changes to the product or quality system, production lines, design, construction procedures, materials, components, sub-units of certified products not authorised by the Institute.
- a number of minor non-conformities associated with the same requirement or aspect could give evidence of a systemic criticality and thus constitute a major non-conformity.

Minor Non-Conformity

Minor non-conformity are considered, by way of example and not exhaustively:

- non-conformity/situation which, in the judgement and experience of the GVI, does not cause deficiencies in the "product" such as to ensure its non-conformity or, does not cause the placing on the market/delivery of a non-conforming product.
- non-conformity/situation which, in the judgement and experience of the GVI, does not cause significant deficiencies in the quality system or in the quality control system of the production line such as to reduce its ability to ensure conforming products or controlled processes or to cause the placing on the market/delivery of a non-conforming product.
- The partial absence of an element of the Quality System with regard to the applicable reference standards/regulations (lack of application and/or documentation) which, on the basis of available objective evidence, does not affect the conformity of the product/production.
- Failure to document an element of the Quality System, against the reference standard/regulation, which is nevertheless implemented.
- In the presence of occasional errors.

Comments (only applicable for evaluation modules subject to surveillance)

That which is not covered by the definitions of non-conformity and which constitutes a possible improvement in the effectiveness of the quality system or product and which is not directly related to the requirements of the reference standards/regulations applicable to the product/quality system. By way of example and not exhaustive:

- Where there is no need for rapid management of the deviation detected.
- findings that, if left unmanaged, could develop into non-compliance;.
- Slight deviations of the quality system from normal practice, with no negative evidence found.
- If one of the three fundamental points on which non-conformities are based is missing:
  - Specified requirement
  - Deviation or lack of application of the requirement
  - Objective evidence.

4.6.3 - Findings Management

Certification may not be granted or maintained until any **major non-conformities** have been adequately removed and the Institute has ascer- tained, with a favourable outcome, by means of a supplementary audit (paragraph 4.5.7) and/or supplementary tests (paragraph 4.4.7) and/or examination of documentary evidence, the correction/closure of the same and the effectiveness of the relative corrective/preventive actions; a similar procedure is followed in the case of other findings, the number and extent of which, in the Institute's opinion, are such as to prejudice the correct operation of the quality/production system and/or may result in the delivery of a non-compliant product or one that does not comply with the standards/regulations in force.

For findings classified as **minor non-conformities**, certification may be granted or maintained:

- for evaluation modules involving surveillance activities (Modules D, H1):

  only after approval by the GVI/Jordan Institute of the treatment proposal and AC/AP formulated by the Organisation.

- for evaluation modules that do NOT involve surveillance activities (Modules B, F):

  what is defined for the major CNs applies.

For observations classified as "**Observations/Recommendation**s", the organisation is not obliged to define and implement any treatments (corrections) and/or corrective/preventive actions. Istituto Giordano is limited to verifying in the subsequent surveillance audit whether, and how, the organisation has taken these observations into account.

The Organisation is responsible for defining and notifying to Istituto Giordano the treatments (corrections) of nonconformities and the correc- tive/preventive actions it intends to undertake for approval, and to implement them within the agreed deadlines depending on the class of the specific nonconformity, and reported in the visit reports/verification reports/non-conformity forms, in compliance with the criteria set out in the following table.

	VISIT TYPE (AUDIT) / TE-STS / EXAMINA-TIONS	DEFINITION ANDNOTIFI-CATION PRO-POSAL ENTRO ( )[1]	IMPLEMEN-TA- TION AND CLO-SURE ENTRO ( )[1]	VERIFICATION OF IMPLEMENTATION AND EFFECTIVENESS THROUGH
NC MAJOR or MINORS	Each Type	2 Weeks	3 Months	Additional audits/tests/analyses within 3 months **(1)** and/or Examination of Documentary Evidence within 3 months **(1)** and Checks in the subsequent surveillance audit **(2)**, where applicable

OBSERVA-TIONS	Each Type	No	NO	Subsequent Surveillance Audit **(²)**

Notes:

(¹) The RGVI/MID Technical Directorate, in compliance with the indications of the table, defines and formalises the time schedules, depending on the specific situation detected and on the influence that the non-conformity may have on the product and/or on the effectiveness of the Quality System and on its capacity to ensure products conforming to the applicable prescriptions/requi-rements.

(²) The frequency and extension of the surveillance audits is established/confirmed with the decision of the Technical Committee for the issue of the certificate and communicated/confirmed to the organisation at the same time as the transmission of the certifi-cate. The frequency and extension of the surveillance audits may be modified by Istituto Giordano on the basis of the results of the assessments performed; these modifications, approved/decided by the Technical Committee, are communicated to the or- ganisation.
The Technical Committee also decides on additional audits and may request the examination of documentary evidence.

The following cases are distinguished for management:

1. ***For initial audits/rehearsals/exams***
   After a period of twelve months without positive conclusion of the evaluation, the Institute may consider the certifi-cation file closed, charging the time and expenses incurred up to that moment. In such cases, the Organisation wishingto continue with the Giordano Institute certification must present a new application and repeat the certification pro- cess.
   The aforementioned time limits may in particular cases be varied at the reasoned request of the Organisation, at theInstitute's discretion.
   Unsuccessfully filed certification files are in any case reported by Istituto Giordano to the competent administration (ref. chap. 18).

2. ***For periodic or unannounced audits/tests/examinations***
   In the presence of major non-conformities or other findings, the number of which in the opinion of the assessment team is such as to jeopardise the correct operation of the quality/product/production system and/or may result in the delivery of a non-compliant product or one that does not comply with the laws in force, the organisation will be subjected to **additional checks** (visit and/or tests/analysis and/or examination of documentary evidence at the di- scretion of the institute) within the time limits established by the institute, in relation to the importance of the non- conformities themselves and, in any case, no later than (3) three months from the end of the inspection/test/exami-nation.
   If these non-conformities are not resolved within the established time limits, the Institute may suspend certification until the non-conformities have been corrected. If the non-conformities do not concern all the certified products/si- tes, the Institute may proceed, at its own discretion, to partially suspend certification (paragraph 12.1).

4.7 - Issuing and Maintenance of Certificates

On successful completion of all the examinations/tests/visits and audits required by these Rules, chapter 4 and annex 3), applicable on the basis of the chosen evaluation module, and specified in the contract with the Organisation, the competent function of the Institute prepares the file complete with all the documentation and presents it to the relevant Technical Committee for verification of the certification file for the purposes of the certification decision. On successful completion of this verification and approval of the relative certification proposal, the Institute issues the certificate of conformity envisaged by the chosen evaluation module and sends it to the manufacturer with the appropriate communication.

In the event of a negative outcome, the Institute shall notify the Organisation of this outcome and agree with it on the modalities for the possible repetition of tests/examinations/evaluations.

The issuance of the conformity documents foreseen by the chosen evaluation module and the relevant confirmations of maintenance are carried out by Istituto Giordano on the standard forms used by the Institute.

Annex 1 shows, for each conformity assessment module, the validity of the conformity documents and the surveillance activities foreseen for their maintenance.
In particular:
- the validity of the EU Type Examination Certificate and the EU Design Examination Certificate for modules B, H1, respectively, is 10years and may be renewed for a further 10 years, provided that the certification procedure laid down in these Regulations is repeated.
- the validity of the Certificate of Conformity of the Quality System Module D and of the Certificate of Conformity of the Total Quality System relating to Module H1 is 3 years and may be renewed upon complete reassessment of the quality system within 3 years.
It should be noted, for module H1, that the validity of the EU project certificate and its use are subject to the continued validity of the certificate of conformity of the total quality system.

Chapter 5 - Declaration of Conformity

Prior to the placing on the market of a measuring instrument covered by Directive 2014/32/EU and its transposition decree, the Manufacturer (or whoever on his behalf, see p. 1.1), in order to certify that it complies with the applicable legislation, must always draw up Clarification D of Conformity in accordance with Article 19 "EU Declaration of Conformity" and Annex XIII of Directive 2014/32/EU (Article 8a and Annex XIII set out in Annex B of Legislative Decree No. 84 of 19 May 2016).

Chap.6 - Marking CE

Products which are in conformity with the essential requirements and specific requirements for measuring instruments (see paragraphs 1.3 and 1.4) referred to in Annex I and the specific instrument annexes (III to XII) of Directive 2014/32/EU and which have been subject to the assessment procedures, in accordance with the rules of this Regulation, shall bear the indelible marking of the "CE marking" and the "Supplementary metrology marking" in the form provided for in Article 20 "Conformity marking" and Article 21 "General principles governing CE marking and supplementary metrology marking" of Directive 2014/32/EU (paragraph 1 art. 5 ofLegislative Decree No. 22 of 2 February 2007 and Article 13 of Legislative Decree No. 84 of 19 May 2016).
These markings must be affixed by the manufacturer (or its authorised representative see p. 1.1).

Chapter 7 - Use of the certificate and the Institute's identification number as notified body forthe directive

Once the organisation has obtained the certificate and throughout its period of validity, it may use it for the purposes of the CE marking of the product (measuring instruments) covered by the certification.
The organisation may publicise the fact that it has been certified by the Institute in the most appropriate manner, e.g. the organisation may make such references using full copies of the original certificate by enlarging or reducing it as long as it remains legibleand is not altered in any way.
When using the certificate or the Institute's identification number as an authorised/notified body for Directive 2014/32/EU, the Organisation must avoid that the certification and the related CE marking can be understood as being extended to other production sites or other products or other than those covered by the certification.
In all cases in which the use of or reference to the certificate or identification number of the Institute as an authorised/notified body for Directive 2014/32/EU may lead to misinterpretation, and whenever the Organisation is not certain that it will use it in accordance with these Regulations, authorisation must be requested from the Institute.
The organisation must immediately cease referring to the certificate or to the Institute's identification number as an authorised/notified body for Directive 2014/32/EU or to the reference to them:

- after suspension or revocation or surrender of certification;
- in the presence of any other circumstance that may adversely affect the value of the certification and the related CE marking.

Chapter 8 - Extension/Reduction of Documents of Compliance Issued

8.1 - General Extent

An organisation wishing to extend certification in the scope or to other products manufactured in the same plant or for products al- ready certified but to be manufactured in another plant, must submit the relevant application.

8.2 - Evaluation Extension

The Institute carries out the inspections deemed necessary and if their results are satisfactory issues the requested certification ex- tension and/or a new certification.

8.3 - General Reductions

The organisation may request variations by reducing the scope of certification (e.g. to reduce the type of products produced under the certified quality system, to eliminate one or more locations or establishments, etc.).

8.4 - Evaluation Reductions

The reduction of the certification is evaluated and if necessary ordered by Istituto Giordano, upon specific request of the Organisa- tion or on its own initiative if, for example, the Organisation does not comply with the conditions set by Istituto Giordano for the reactivation of the certification after partial suspension.

Reduction of certification (module B, D, H1) is also ordered if the organisation does not produce a product for a considerable period of time (in the order of 12 months).

Following the reduction, the conformity document is reissued.

Chapter 9 - Amendments to Reference Documents, these Rules and Technological Progress

9.1 - Generalities

The Institute monitors generally recognised technological progress and assesses whether the certificates issued no longer comply with the applicable requirements of the Directive. In addition, the Institute assesses whether such progress requires further investi- gation and if so informs the Organisation.

In particular, the Institute notifies in writing (by fax or other legally valid means) the organisation in possession of the certificates or the applicant undergoing certification of any changes made to regulatory documents (e.g. amendments to the MID directive, harmonised standards and relative technological progress, etc.) or to its own regulations that are applicable to the products (inclu- ding, where applicable, their design/type and/or the quality systems subject to certification) and that have an implication on the validity of the certificates.

It also notifies, in the same manner, the effective date of the changes, the terms of the transition and any adjustments required, in- cluding the necessary evaluation/verification activities.

A copy of these notifications will be filed in the certification file.

It is emphasised that the organisation (manufacturer or its authorised representative, see p. 1.1) in possession of certificates attesting the conformity of measuring instruments, including, where applicable, the design/type and/or quality systems, has a permanent responsibility to ensure that these measuring instruments, subject to certification, maintain conformity with the corresponding technological progress.

9.2 - Assessments/Assessments

Additional evaluations are to be carried out by the appointed date at the Organisation's expense. The evaluations deemed necessary by the Institute include one or more of the following activities:

- inspections/tests/examinations to verify the conformity of the product and/or design with the new regulations on samples taken from production and/or on a new product prototype;
- documentary checks and/or audits to verify the compliance of the quality system with the new regulations.

For such evaluations, the procedures laid down in this regulation for the relevant evaluation module are followed, as applicable. The organisation must accept the Institute's decisions, motivated in writing, regarding the possible need to carry out additional assessments as indicated above or a complete repetition of the assessment process; in the event of non-acceptance, the provisions of section 9.4 shall apply.

9.3 - Reissue of Documents of Attestation of Conformity (Certificates)

Upon successful completion of the assessments/investigations (Section 9.2), the Institute issues a revised certificate attesting to the conformity of the type, or design, or product, or system, modified as appropriate to cite the new standard.

9.4 - Renunciation, Suspension and Revocation

An organisation that does not accept the decisions of the Institute may renounce the documents of attestation of conformity (certi- ficates) in the manner set out in Chapter 11 or incur the sanctions set out in Chapter 12.

If the organisation fails to adapt the products/projects/quality system to the new reference standard within the established deadli- ne, or if the results of the tests/analyses/examinations or audits/verifications are not satisfactory, the certificate of conformity sub- ject to the regulatory revision will be suspended/withdrawn (see chapter 12).

Chap. 10 - Modifications to products/quality systems/production facilities made by the organisation

10.1 - Generalities

The Organisation must inform the Institute in advance of any changes it intends to make:

- to a measuring instrument for which it has obtained certification;
- to the Quality System adopted in the production plant for which it has obtained certification;
- to the project for which it obtained certification;
- production facilities or the installation of new production facilities.

The documentation concerning the changes must be submitted to the Institute, which will carry out all the necessary verifications/assessments. The Institute undertakes to communicate its decisions to the Organisation in writing, within 20 working days of notification of the proposed changes, specifying the necessary checks, evaluations and assessments to be carried out.

It is emphasised that the organisation (manufacturer or its authorised representative, see p. 1.1) in possession of certificates attesting the conformity of measuring instruments, including, where applicable, the design/type and/or quality systems, has a permanent responsibility to ensure that these measuring instruments, subject to certification, maintain conformity with the corresponding technological progress.

In this regard, the manufacturer must follow the methods defined in this chapter of the regulation for communicating the changes he intends to make to measuring instruments / designs / types / quality systems / production facilities in order to adapt the instru- ments to technological progress.

10.2 - Audits, assessments and evaluations

The Institute, following the evaluation of the influence that the proposed changes have on the conformity of the product / project / quality system, carries out the evaluations deemed necessary, which include one or more of the following activities:

- inspections/tests/examinations to verify the conformity of the product and/or design with the new regulations on samples taken from production and/or on a new product prototype;
- documentary checks and/or audits to verify the compliance of the quality system with the new regulations.
- the complete repetition of the evaluation process.

For such evaluations, the procedures laid down in this regulation for the relevant evaluation module are followed, as applicable.

All costs related to additional evaluations or to the complete repetition of the evaluation process are to be borne by the organisation.

The organisation must accept the Institute's decisions, motivated in writing, regarding the possible need to carry out additional assessments as indicated above or a complete repetition of the assessment process; in the event of non-acceptance, the provisions of section 10.4 shall apply.

10.3 - Reissue of Documents of Attestation of Conformity (Certificates)

Following the positive outcome of the aforementioned inspections, the Institute, where necessary, issues a revision of the certifica- tes attesting conformity with reference to the changes made to the measuring instruments and/or the quality system and/or the project and/or the production facilities and/or the installation of new production facilities.

10.4 - Renunciation, Suspension and Revocation

Organisations that do not accept the decisions of the Institute may renounce their certifications in the manner set out in Chapter 11 or incur the sanctions set out in Chapter 12.

In the event that the results of the tests/analyses/examinations or audits/inspections are not satisfactory or the organisation fails to close the findings in accordance with chapter 4.6 of these Rules, the certificate of conformity subject to the audit/inspection shall be suspended/revoked as prescribed in chapter 12.

10.5 - Limitations on the Use of Certification and Related CE Marking

The organisation may not use the EU Mark, nor the references to the conformity documents issued, nor the references to the iden- tification number of the Institute as Notified Body for measuring instruments that have been modified or for which the quality sy- stem/design/production site has been modified until it has obtained written approval from the Institute.

Chapter 11 - Renunciation of Certification

The organisation may submit a request to the Institute to renounce certification for some or all of the products for which it had ob-tained certification due to the cessation of their production or for other reasons.
In the case of partial renunciation, the Institute re-examines the reasons given by the organisation for the reduction in the scope of the certificate and reissues the certificate excluding the products subject to renunciation, prescribing, if necessary, also any actions to be taken by the organisation for products already manufactured (e.g. actions on products in stock or made available to the mar- ket).

Chapter 12 - Suspension or Revocation

12.1 - Suspension

The Institute, for reasons considered serious and formalised in writing to the Organisation by registered letter with return receipt (signed by the Managing Director or other delegated person), PEC, or other equivalent means, has the right to suspend, for a maxi- mum period of 6 months, the certification (certificate of conformity) issued. The same communication shall indicate the conditions for reinstating the certification and the deadline within which they must be implemented.

For example, suspension may be applied when:

(a) in the case provided for in paragraph 4.6.3;
(b) in the presence of modifications made to the measuring instrument/quality system and/or modifications to the manufactu- ring and control methods and/or modifications to the design and/or other changes that significantly affect the factors deter- mining whether or not measuring instruments conform to applicable requirements without due, prior, notification to the In- stitute or in the absence of approval by the latter;
(c) the organisation fails to adapt its product/project/quality system to new provisions/regulations applicable to the product/project/quality system itself and/or does not or cannot comply with the new provisions issued by the Institute (chapter 9);
(d) Istituto Giordano changes the rules of its certification system and the organisation refuses to comply with the new require- ments;
(e) for refusal or obstruction of surveillance audits/visits/examinations to maintain conformity documents within the prescribed deadlines;
(f) the organisation does not handle complaints correctly;
(g) the visits/tests/maintenance examinations reveal serious deficiencies in the manufactured measuring instruments/quality sy- stem, but which, in the Institute's opinion, are not such as to lead to the immediate withdrawal of certification;
(h) the organisation does not respect the deadlines set for communicating the treatment of non-conformities and corrective/preventive actions;
(i) the organisation does not comply with what is foreseen and approved by the Institute for the implementation of the resolu- tion of nonconformities and the implementation of corrective/preventive actions;
(j) the organisation contravenes the requirements of these Rules or the regulations applicable to the product/quality system or makes a formal request to that effect to the Institute;
(k) response to justified and serious complaints received by the Institute;
(l) for delinquency in the payment of the Institute's services within the terms of the contract;
(m) the organisation misuses or improperly publicises the certification obtained, in particular has made improper use of the Insti- tute's identification details to be affixed to the CE marking of the product or the manufacturer's declaration of conformity and has not taken the measures required by the Institute;
(n) the organisation refuses or obstructs participation in any inspections by observers from the competent Administration or Ac- creditation Body;
(o) any other circumstance that the Institute, in its opinion, considers to have a negative influence on the conformity of the certi- fied measuring instruments/quality systems;
(p) the organisation misuses or improperly publicises the certification obtained;
(q) the organisation discontinues the production and supply of products or interrupts the implementation of the quality system for a considerable period of time (generally not exceeding 12 months);

The organisation may also apply to the Institute, giving reasons, to suspend certification for a period generally not exceeding six (6) months.

Istituto Giordano reserves the right to communicate the suspension measure to the competent Administrations (Chapter 18) and/or other third parties who request it, as well as to make the suspension public, for example, by posting the information on its website.

If the organisation satisfies, within the time limits indicated, the conditions set by the Institute, the suspension is lifted (reactivation of certification) and the organisation is notified.

Otherwise, the Institute will proceed to revoke the certification (certificate of conformity) or reduce it in the case of partial suspen- sion.

Reactivation of certification is subject to verification of the elimination of the shortcomings, which had caused the suspension itself, by means of in-depth inspections/tests/examinations that verify the compliance of the Product/Quality System with all the requi- rements of the reference standard.

The Institute reserves the right to communicate the revocation of the suspension to the competent administrations (Chapter 18) and/or other third parties who request it, as well as to make the revocation of the suspension public, e.g. on its website, if the news of the suspension had been made public.

12.2 - Revocation

Failure by the organisation to fulfil, within the prescribed time limit, the conditions set by the Institute for revocation of the su- spension (reactivation) of certification, as per point 12.1, will lead to revocation of certification (document attesting conformity) or reduction of certification in the case of partial suspension.

The Institute, for particularly serious reasons formalised in writing to the Organisation by registered letter with advice of receipt (signed by the Managing Director or other delegated person), PEC, or other equivalent means, may cancel the certification (certifi- cate of conformity) issued and revoke it without necessarily suspending it. This may occur, for example, when:

(a) circumstances occur, such as those mentioned in 12.1 for suspension, which are deemed by the Institute to be particularly se- rious;
(b) there are significant non-conformities of the manufactured/manufactured measuring instrument and/or quality system with respect to the technical documentation submitted to the Institute or with respect to the applicable regulatory requirements;
(c) surveillance audits/visits/examinations for the maintenance of certification reveal serious and repetitive deficiencies of a sy- stematic nature;
(d) in the case of findings concerning product safety aspects or non-compliance with applicable mandatory rules;
(e) changes have occurred to the standards and/or requirements applicable to the measuring instrument/project/quality system and the organisation does not or cannot comply with them and/or does not or cannot comply with the new provisions issued by the Institute (ref. chapter 9);
(f) Istituto Giordano changes the rules of its certification system and the organisation refuses to comply with the new require- ments;
(g) the organisation repeatedly fails to handle complaints properly;
(h) the organisation discontinues the production and supply of the measuring instruments or interrupts the implementation ofthe quality system mentioned in the conformity document for a considerable period of time (generally in the order of 12 mon-ths);
(i) the Organisation is in breach of its agreements with the Institute;
(j) if the Organisation does not accept the new economic conditions established by the Institute in the event of a change in the contract;
(k) at the formal request of the organisation (waiver of certification - chapter 11) for some or all of the measuring instruments for which it had obtained certification. In the case of partial renunciation, the Institute will reissue the conformity document is- sued excluding the measuring instruments subject to renunciation;
(l) for persistent arrears in the payment of the Institute's services within the terms of the contract;
(m) the organisation repeatedly misuses or improperly publicises the certification obtained, in particular has made improper use ofthe Institute's identification details to be affixed to the CE marking of the product or the manufacturer's declaration of con- formity, and has failed to take the measures required by the Institute;
(n) for any other valid reason, in the opinion of the Institute.

Revocation of the certification (Certificate of Conformity) and of the possibility of affixing the CE Marking is notified in writing by registered letter (signed by the Managing Director or other delegated person), or other equivalent means, to the organisation, ex- cept in the case of a request made by the organisation.

The Institute communicates the revocation measure to the competent administrations (Chapter 18) and/or other third parties who request it, and also makes the revocation public, e.g. by placing the information on its website.

An organisation that wishes to be re-certified after revocation must submit a new application following the entire procedure.

12.3 - Limitations on the Use of CE Marking and Certification

During the period of suspension or in case of revocation, the organisation must no longer affix the CE mark to the measuring in- struments concerned.

During the period of suspension or in the event of revocation, the Organisation may not use the certification (conformity document number, identification number of Istituto Giordano as notified body, etc.) either for the CE marking of the products concerned or for the manufacturer's declaration of conformity, or for any other technical or advertising document.

The suspension and revocation notification also contains the safeguard actions, determined on a case-by-case basis, to be taken by the organisation, e.g. actions for products already in stock or placed on the market.

In addition to the points mentioned in this Chapter 12, in the event of revocation, the Organisation undertakes to

- no longer use the issued document of conformity;
- note on the original document of conformity the words "Revoked" with the date;
- do not use any copies and reproductions of the conformity document issued;
- remove all references to certification (conformity document issued) from technical and advertising documentation.

If the organisation continues to refer to it in any way after revocation of certification (compliance documents), the Institute may ta- ke legal action.

13 - Issuing of Certificate for dealers of measuring instruments certified by Istituto Giordano

13.1 - Generalities

In the event that the holder of a Certificate, issued by Istituto Giordano, authorises the marketing of measuring instruments subject to certification and the use of the relative certificate, in favour of an organisation, which is configured as a Manufacturer authorised to market under its own name or trade mark (hereinafter referred to for convenience as "Reseller"), the following modalities shall be followed. These modalities set out below supplement the criteria of these Rules for the issue of Certificates to resellers of mea- suring instruments certified by Istituto Giordano.

13.2 - Activation of Certification Procedures

The application for certification must be signed by the 'Reseller'. Documentation to be provided

The "Reseller" must provide Istituto Giordano with the following documentation:

- Chamber of Commerce certificate issued by the relevant Chamber of Commerce of recent date;
- draft declaration of conformity;
- draft of nameplates;
- declaration of identity duly completed, stamped and signed by the "Retailer" containing the following commitments:
  - not to make any modifications to the measuring instrument;
  - handle complaints received on measuring instruments and promptly notify the manufacturer holder of the Certificate of Origin;
  - to provide correspondence between the trade names defined by the manufacturer and those defined by the retailer;
  - and the following statement: "It is hereby declared that between the firms/companies there exists and in force on the date of this declaration a contract of commercial collaboration with reciprocal obligations and with a duration until the end of _____Any modification of said contract, as well as its termination, revocation or cancellation shall be communicated to Istituto Giordano."
- copies of the manuals of the models marketed in the name of the reseller;
- possible coding of the production site to be included in the Certificate;
- Duly completed, stamped and signed Certificate of Origin declaration containing at least the following information:
  - Authorisation given to the reseller to market under his own name or trademark the measuring instruments covered by Cer- tificate of "Origin" No. xxxx of xx/xx/xxxx;
  - correspondence between the trade names defined by the manufacturer and those defined by the retailer;
  - commitment of the manufacturer to notify the "Retailer":

  a) any changes to the Certificate of Origin or to its validity;

  b) any modifications made to machinery and/orinternal provisions applied to maintain conformity of series production measu-ring instruments with the provisions of this Directive;

  c) to the management of anynon-compliant measuring instruments marketed by the dealer;
  - and the following statement: "It is hereby declared that between the firms/companies there exists and in force on the date of this declaration a contract of commercial collaboration with reciprocal obligations and with a duration until the end of____Any modification of said contract, as well as its termination, revocation or cancellation shall be communicated to Istituto Giordano."

13.3 - Issuing the "Reseller" Certificate

It is permissible, in the Institute's judgement, not to perform the inspection visit at the retailer's premises unless certain activities may affect the certified characteristics (e.g. warehouse, traceability, NC management, regulatory registration plate, etc.) or there is insufficient information/evidence to support it.

Following the successful verification of the documentation listed above (p. 13.2), of the documentation of any inspection visit and of the management and successful closure of any findings, the competent function of the Institute prepares the file complete with all the documentation and presents it to the relevant Technical Committee for verification for the purposes of the certification de- cision.

Upon successful completion of the checks and approval of the relevant certification proposal (positive decision of the TC), the Institute issues the certificate of conformity and makes it available in the download area of the documents / sends it to the reseller with a special communication.

13.4 - Maintaining the validity of the "Reseller" certificate

The validity of the "Reseller's" Certificate is subject to the validity of the "Certificate of Origin" in the name of the manufacturer making the product.

13.5 - Certificate

The Certificate will be issued for models marketed by the dealer:

- will show, in the case of the EU Type Certificate, in the 1st line of the section "Technical documents of reference" the referen- ce of the "original" EU Certificate of the manufacturer;
- in the case of the EU Type Certificate the expiry date of the retailer's certificate congruent with the expiry date of the com- mercial contract (between the holder of the "Certificate of Origin" and the retailer) and in any case no later than the expiry da-te of the "Certificate of Origin".

14 - Transfer of the certificate

In the event that the Organisation intends to change the corporate name, or in the event that it intends to transfer, assign, transform or confer the Company or the Business, the Organisation must formally and in advance notify Istituto Giordano of these in- tentions.

14.1 - Assessments/Assessments

The institute shall communicate, in writing, the procedure to be followed and the relevant documentation to be submitted, as well as any additional assessments deemed necessary in order to proceed with the transfer.

These additional activities are at the expense of the applicant.

For such evaluations, the procedures laid down in this regulation for the relevant evaluation module are followed, as applicable.

14.2 - Reissue of Documents of Attestation of Conformity (Certificates)

Following the positive outcome of the aforementioned checks and assessments, the Institute reissues a new document of attesta- tion of conformity (certificate), revoking the previous one.

14.3 - Limitations on the Use of Marking

The new organisation may not use the conformity documents issued nor the references to the Institute's identification number as a Notified Body and may not apply the relevant CE Marking until it has obtained written approval from the Institute.

Chapter 15 - Registration of Customer Complaints

The organisation must keep, as part of its Quality System documentation, a record of any complaints concerning the certified pro- ducts and/or project and/or quality system it has received and of the relative actions taken to remedy them *(treatments and cor- rective/preventive actions)* and must keep them available for the Institute's inspectors/technicians.

Chapter 16 - Complaints, Appeals and Litigation

The provisions of the GTC "General Terms and Conditions for Certification" in their current edition apply.

Chapter 17 - Confidentiality of Information

Istituto Giordano assures that all information acquired in the course of the certification activity is treated in a strictly confidential manner, with the exception of, and already authorised for, any information provided to Accreditation/Notification/Authorisation Bodies in the course of their regular verification activities for Accreditation/Notification/Authorisation.
For anything not specified above, the provisions contained in the GTC "General Terms and Conditions for Certification" in their cur- rent edition shall apply.

Chap.18 - Communications with the administration and online publications

In this regard, the procedures for transmitting and/or making available the lists and data prescribed by the competent administra- tion are followed.
In particular, Istituto Giordano has set up a dedicated telematic access to the database of certificates issued by the competent Mi- nistry, by means of appropriate customised credentials, for the purposes of the administrative surveillance activities conducted by the aforementioned Ministerial Division.
Specifically, the institute informs the relevant administration:

(a) any rejection, limitation, suspension or withdrawal of a certificate;
(b) any circumstances that may influence the scope and conditions of the notification;
(c) any requests for information received from market surveillance authorities in connection with conformity assessment activities;
(d) upon request, of conformity assessment activities performed in the context of notification and any other activities, including cross-border and subcontracting activities.

Istituto Giordano provides other bodies notified under Directive 2014/32/EU, whose conformity assessment activities are similar or cover the same apparatus, with relevant information on issues related to negative and, on request, positive conformity assessmentresults. This information is uploaded to a special directory in the NoBoMet (European Coordination Group of the Conformity As- sessment Bodies notified by the European Commission for the Directives 2014/31/EU and 2014/32/EU) working area of the CIR- CABC website, as foreseen by the NoBoMet Information Letter of 07 February 2022 on the information obligation of Notified Bo- dies on certificates. This information is accessible to all NoBoMet members and, upon request, to market surveillance authorities. Istituto Giordano also publishes data on certificates on its website; this data is updated at least weekly.

Chapter 19 - Contractual Conditions

For anything not expressly stated herein, the contractual conditions contained in the current edition of the Institute's document"General Terms and Conditions for Certification" shall apply.

Annex 1

Annex 1.1 - Conformity assessment forms, conformity attestation documents (certificates) issued, their validity and surveillance

For conformity assessment procedures, modules D and F are always used, at the choice of the manufacturer or its representative (see p. 1.1), in conjunction with module B, while the remaining modules may be used individually.

Modules	Name	Documents of attestation of conformity (certificates) issued by the Notified Body (Istituto Giordano)	Validity	Surveillance (*)
B	Type examination	EU Type Examination Certificate	10 years (***), with the possibility of renewal	N/A
D	Declaration of Conformity to Type based on *Quality Assurance of the Production Process*	Certificate of conformity of the quality system module D.	3 years	Annual visit and full reassessment over 3 years plus any unannounced visits
F	Declaration of conformity to type based on: • *Product verification*	Certificate of Conformity Form F	unlimited	N/A
H1	Declaration of Conformity to Type based on: • *Total Quality Assurance*	- EU Project Examination Certificate**	- 10 years (***)(**)	N/A
		- Certificate of Conformity of theQuality System Form H1	- 3 years	Annual visit and full reassessment over 3 years plus any unannounced visits

Note: (*) For surveillance activities, the Institute issues, according to applicability, the relevant surveillance assessment reports/certificates/test reports and confirmations of maintenance of certification.
(**) The validity of the EU project certificate and its use are subject to the continued validity of the certificate of conformity of the total quality system.
(***) validity is subject to compliance with the development of technological progress (for more details see Chapter 9 of this Regulation).

Annex 1.2 - Surveillance/Maintenance of documents of attestation of conformity (certificates) issued

1.2.1 - Certificates of conformity of the quality system with modules D, H1

In order to maintain the validity of the certificates of conformity of the quality system to modules D and H1, they are subject to

- annual surveillance audits by means of visits to verify the quality system and full reassessment within three years;
- any unannounced visits at the discretion of the Jordan Institute; during such visits, the notified body may also have product tests performed to verify the proper functioning of the quality system.

1.2.2 - Certificates of Conformity concerning Examinations and Tests, Modul F

The product is subjected to verification by the Giordano Institute in order to affix/have the body's identification number affixed un- der its responsibility to each approved instrument.

Verifications for Module F:

Examinations and tests to verify the conformity of the instruments with the type described in the EU Type Examination Certificate and the relevant applicable requirements:

- on each individual measuring instrument;
- on a statistical basis (instruments presented for verification by homogeneous batches).

Certificates of Conformity relating to examinations and tests for F-Modules are issued by the Jordan Institute on the occasion of the manufacture of measuring instruments produced in homogeneous batches by the Manufacturer (or whoever, see p. 1.1).

1.2.3 - The EU-Type Examination Certificate, Mod. B

The EU Type Examination Certificate is not subject to surveillance during its 10 years of validity; it is renewed, in agreement with the customer, on its expiry date, if the product is still in production and there have been no changes in the reference standards, de- sign, materials and/or construction procedures.

In any case, for renewal, the Institute reserves the right to repeat the type tests in part or in full.

1.2.4 - The EU Design Examination Certificate

The EU Design Examination Certificate is not subject to surveillance during its 10 years of validity; it is renewed, in agreement with the customer, on its expiry date, if the product is still in production and there have been no changes in the reference standards, de- sign, materials and/or construction procedures. In any case, for renewal, the Institute reserves the right to repeat the design examination in part or in full.

Annex 2 - List of harmonised standards/standards and combinations of conformity assessment modules applicable to the various categories of devices and measuring systems according to their intended use

(only for Annex IV and V categories)

This list contains the standards and their editions in force at the time of the issuance of these regulations; it should be noted that the standards and their updated editions published in the Official Journal of the European Union with reference to the MID Directive apply.

Categories of Measuring Devices and Systems	Measuring Devices/Systemsand intended use	Harmonised reference standards (+EU Revision)	Tasks Giordano Institute [1]						
			Essential requirements	Examinations of the type	Declaration of conformity to type based on quality assurance of the production process	Declaration of conformity to type based on quality assurance of final product inspection and testing	Declaration of conformity to type based on product verification	Declaration of conformity based on single-product verification	Declaration of conformity based on full quality assurance and design examination
Gas meters and volume conversion devices (All. IV)	Gas meters - Membrane gas meters *Use: for residential, commercial and light industrial use; in the public interest*	EN 1359:2017	I	B			F		
				B	D				
	Gas meters - Turbine gas meters	EN 12261:2018							H1
	Gas Meters - Rotoid Gas Meters	UNI EN 12480:2006 (EN 12480:2002/A1:2006)							
	Gas meters - Ultrasonic home gas meters	EN 14236:2018							
	Gas meters - Conversion devices - Part 1: Volume conversion	EN 12405-1:2018							
Active electricity meters (All. V)	Electricity metering equipment (a.c.) - Acceptance testing - Part 11: General methods of acceptance testing	EN 62058-11:2010	I	B			F		
				B	D				
									H1
	Electricity metering equipment (a.c.) - Acceptance test - Part 21: Particular requirements for electromechanical active energy meters (classes A and B)	EN 62058-21:2010	I	B			F		
				B	D				
									H1

Categories of Measuring Devices and Systems	Measuring Devices/Systemsand intended use	Harmonised reference standards (+EU Revision)	Tasks Giordano Institute [1]						
			Essential requirements	Examinations of the type	Declaration of conformity to type based on quality assurance of the production process	Declaration of conformity to type based on quality assurance of final product inspection and testing	Declaration of conformity to type based on product verification	Declaration of conformity based on single-product verification	Declaration of conformity based on full quality assurance and design examination
	Electricity metering equipment (a.c.) - Acceptance test - Part 31: Particular requirements for static active energy meters (classes A, B and C)	EN 62058-31:2010		B			F		
			I	B	D				
									H1
	Electricity metering equipment (a.c.) - Acceptance test - Part 11: General acceptance test methods	CEI EN 62058-11:2011 EN 62058-11:2010 IEC 62058-11:2008 (Modified)		B			F		
			I	B	D				
									H1
	Electricity metering equipment (a.c.) - Acceptance test - Part 21: Particular requirements for electromechanical active energy meters (classes A and B)	CEI EN 62058-31:2012 EN 62058-21:2010 IEC 62058-21:2008 (Modified) A, B and C)		B			F		
			I	B	D				
									H1
	EN 62058-31:2010 Electrical energy measurement equipment (a.c.) - Testing of acceptance - Part 31: Particular requirements for static meters of active energy (classes A, B and C)	EN 62058-31:2010 IEC 62058-31:2008 (Modified		B			F		
			I	B	D				
									H1
	EN 62059-31-1:2012 Electricity metering equipmentment -Dependability - Part 32-1: Durability -Testing of the stability of metrological characteristics by applying elevated temperature	EN 62059-31-1:2012 IEC 62059-31-1:2011		B			F		
			I	B	D				
									H1

Note (1): Possible combinations of applicable conformity assessment modules are indicated at the choice of the manufacturer (or his representative, see p. 1.1).

Annex 3 - Conformity Assessment Modules, assessment procedures for each individual module and related responsibilities in charge of the Organisation (Manufacturer or whoever, see p. 1.1) and in charge of the Notified Body Istituto Giordano S.p.A.

N.B.: THE REFERENCES OF THE ARTICLES AND ANNEXES CITED WITHIN THE VARIOUS FORMS ARE THOSE OF DIRECTIVE 2014/32/EU.

Module B - TYPE EXAMINATION

1. Type examination is the part of the conformity assessment procedure by which the Institute examines the technical design of a measuring instrument and ascertains that this technical design complies with the relevant provisions of this decree.
2. The type examination can be carried out in one of the following methods. The Institute decides on the most appropriate method and the specimens required.
   a) Examination of a specimen of the complete measuring instrument that is representative of the production in question.
   b) Examination of specimens of one or more essential parts of the measuring instrument that are representative of the production envisaged, plus assessment of the adequacy of the technical design of the other parts of the measuring instrument, by examination of the technical documentation and supplementary documentation referred to in paragraph 3.
   c) Verification of the adequacy of the technical design of the measuring instrument by examination of the technical documentation and the supplementary documentation referred to in section 3, without examination of a specimen.
3. The manufacturer must submit an application for type examination. The application shall include:
   - the name and address of the Manufacturer
   - a written declaration stating that the same application has not been submitted to any other notified body;
   - the specimens, representative of the production in question, for which Type Examination is required;
   - The technical documentation must be sufficiently detailed to allow assessment and ensure:
     1. the definition of metrological characteristics;
     2. the reproducibility of the measurement results of the instruments produced when they are correctly adjusted using the appropriate means;
     3. the integrity of the instrument.

     For the purposes of type or instrument evaluation and identification, the technical documentation must include the fol- lowing:
     a) a general description of the instrument;
     b) design and manufacturing drawings, as well as plans for components, sub-assemblies, circuits and similar parts;
     c) manufacturing procedures to ensure homogeneous production;
     d) if applicable, a description of the electronic devices with diagrams, flowcharts of the logic and general software information illustrating their characteristics and operation;
     e) descriptions and explanations necessary for understanding (b), (c) and (d), including the operation of the instrument;
     f) a list of the harmonised standards or normative documents (ref. point 1.3 of this Regulation), applied in full or in part, whose references are published in the Official Journal of the European Union;
     g) descriptions of the solutions adopted to meet the essential requirements where the harmonised standards or normative documents (ref. 1.3 of this Regulation) have not been applied, including a list of the other relevant technical specifications applied;
     h) the results of design calculations, examinations;
     i) the results of relevant tests, where necessary, to demonstrate that the type or instrument complies with
        - the requirements of the directive according to declared rated operating conditions and specific environmental disturbances;
        - durability specifications for gas meters/converters, active electricity meters;
     j) EU Type Examination Certificates or EU Design Examination Certificates for instruments containing parts identical to those in the design.
     k) any other document that enables the Institute to improve the assessment.

     In addition:
     The manufacturer must specify the position of the seals and markings.
     The manufacturer must indicate, where appropriate, the compatibility requirements with interfaces and sub-assemblies
   - This technical documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of the Directive and shall include an adequate analysis and assessment of the risk. It shall specify the applicable requirements and cover, as far as relevant for such assessment, the design, manufacture and operation of the instrument.
   - Documentation confirming the adequacy of the technical design of those parts of the measuring instrument for which no specimens are required. These supplementary documents shall mention any relevant documents applied, in particular where the relevant documents referred to in 1.3 of this Regulation have not been applied in full, and shall include, where

necessary, the results of tests carried out by the appropriate laboratory of the manufacturer or, on his behalf and under his responsibility, by another testing laboratory.

4. The Institute must

As for the specimens:

4.1 examine the technical documentation, verify that the specimens have been manufactured in accordance with it and identify those elements that have been designed in accordance with the applicable provisions of the harmonised stan- dards and normative documents referred to in 1.3 of this Regulation, as well as those elements that have been desi- gned without applying the relevant provisions of those documents;

4.2 carry out, or have carried out, the appropriate examinations and tests to check whether, where the Manufacturer has chosen to apply the solutions set out in the harmonised standards and normative documents referred to in 1.3 of these Regulations, those solutions have been correctly applied;

4.3 carry out, or have carried out, the appropriate examinations and tests to check whether, in cases where the Manufac- turer has chosen not to apply the solutions set out in the harmonised standards and normative documents referred to in 1.3 of these Regulations, the solutions adopted by the Manufacturer meet the corresponding essential requirements of these Regulations;

4.4 agree with the applicant on the place where the examinations and tests will be carried out.

For other parts of the measuring instrument:

4.5 examine the technical documentation and supplementary documentation to assess the adequacy of the technical de- sign of the other parts of the measuring instrument.

Regarding the manufacturing process:

4.6 examine the technical documentation to ensure that the manufacturer has adequate means to guarantee homoge- neous production.

5. The Institute shall draw up an evaluation report on the actions taken in accordance with Section 4 and their results. Without prejudice to its obligations vis-à-vis the notifying authorities, the Institute shall make the contents of this report pu- blic, in whole or in part, only with the consent of the Manufacturer.
6. If the technical design satisfies the provisions of this Decree applicable to the measuring instrument, the Institute issues the Manufacturer with an EU Type Examination Certificate. This certificate contains the name and address of the Manufacturer, the conclusions of the examination, any terms of validity and the data necessary for the identification of the instrument. The certificate may have one or more annexes.
   The EU type-examination certificate and annexes contain all relevant information for the purpose of conformity assessment and control of the device in operation, in particular for the purpose of assessing the conformity of manufactured instruments with the examined type with regard to the reproducibility of measurement results, when they are correctly calibrated using the appropriate means provided; the certificate includes

   - the metrological characteristics of the instrument type;
   - the measures required to guarantee the integrity of the instrument (seal, software identification);
   - information on other elements necessary for the identification of the instrument and to verify its visual confor- mity to type;
   - where appropriate, any specific information necessary to verify the characteristics of the instruments manufac- tured;

   in the case of a sub-unit, all information necessary to ensure compatibility with other sub-units or measuring in- struments.
   The certificate shall be valid for ten years from the date of issue and may subsequently be renewed for periods of ten years each. The Institute shall draw up an evaluation report in this regard, which it shall keep at the disposal of the notifying Mem- ber State.
   If the type does not satisfy the requirements of this Directive that apply to it, the notified body shall refuse to issue an EU ty- pe examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.
7. The Institute (Notified Body) monitors the development of generally recognised technological progress and assesses whether the approved type no longer complies with the applicable requirements of this Directive. It shall decide whether such progress requires further investigation and, if so, shall inform the Manufacturer.
8. The manufacturer shall inform the Institute that keeps the technical documentation relating to the EU-type examination certificate of all modifications made to the instrument that may affect its conformity with the essential requirements or the conditions for validity of the certificate. Such modifications require additional approval in the form of a supplement to the original EU Type Examination Certificate.
9. The institute informs its notifying authority about the EU type examination certificates and/or any supplements it has issued:

   - the EU type-examination certificates, including the annexes issued;
   - supplements and amendments to certificates already issued;

- the list of those certificates and/or any supplements rejected, suspended or otherwise restricted;
- The possible withdrawal of EU type examination certificates.

The Institute keeps the technical file, including the documentation submitted by the Manufacturer, until the end of the certi- ficate's period of validity.

The Commission, the Member States and the other Notified Bodies may obtain, on request, copies of the EU type examina- tion certificates and/or their additions. The Commission and the Member States may obtain, on request, copies of the tech- nical documentation and results of examinations carried out by the Notified Body.

10. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and supplements together with the technical documentation at the disposal of the national authorities for ten years after the measuring instrument has been placed on the market.

Authorised **Representative**

11. The Authorised Representative of the Manufacturer may submit the request under item 3 and fulfil the obligations under items 8 and 10 of this Regulation, provided that they are specified in the mandate.

Module D - TYPE CONFORMITY BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down hereafter and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and sa- tisfy the requirements of Directive 2014/32/EU.The manufacturer ascertains and declares that the measuring equipment is in conformity with the type described in the EU Type Examination Certificate and satisfies the relevant requirements of the relevant Decree transposing Directive 2014/32/EU.
2. **Manufacturing**
   The manufacturer shall operate a recognised quality system for production, final product inspection and testing of the measuring instruments concerned, as specified in paragraph 3, and shall be subject to surveillance as specified in paragraph 4.
3. **Quality system**

3.1 The Manufacturer shall submit to the Istituto Giordano an application for assessment of its quality system for the products concerned in accordance with the procedure described in Module D - Directive 2014/32/EU, enclosing the following docu- mentation:

- the name and address of the manufacturer and, if the application is submitted by the authorised representative, the name and address of the latter;
- a written declaration that the same application has not been submitted to any other notified body;
- all relevant information on the intended category of instruments;
- the quality system documentation;
- the technical documentation relating to the approved type and a copy of the EU type examination certificate.

3.2

3.2 The quality system ensures that measuring instruments conform to the type described in the EU type examination certificate and to the requirements of Directive 2014/32/EU that apply to them.

All criteria, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly man- ner in the form of written measures, procedures and instructions. This quality system documentation shall permit a uniform interpretation of quality programmes, plans, manuals and records.

The manufacturer ensures and declares that the measuring instruments are in conformity with the type described in the EU Type Examination Certificate and satisfy the relevant requirements of Directive 2014/32/EU.

This documentation must in particular include an adequate description:

- the quality objectives, organisational structure, responsibilities and powers of the management personnel with re- gard to product quality;
- of the corresponding manufacturing processes, ;
- the examinations and tests that will be carried out before, during and after manufacture with an indication of the frequency with which they will be carried out;
- quality records, such as inspection reports and data on tests, calibrations, reports on the qualifications of the per- sonnel concerned;
- the means of monitoring the achievement of the required level of product quality and the effective operation of thequality system.

3.3 The Jordan Institute appoints an evaluation team, the evaluation team shall, in addition to having experience in quality manage- ment systems, include at least one member with experience in evaluating the sector and technology of the product being evaluated and who is familiar with the requirements of Directive 2014/32/EU (for more details see Chapter 4.2).

The auditing team shall examine all documentation received, as well as the technical documentation referred to in Section 3.1(e), verify the manufacturer's ability to identify the applicable requirements of this decree, and submit any findings (see Chapter 4.3); it shall carry out the necessary examinations to ensure the conformity of the instrument with those requirements.

When the Manufacturer considers that he has aligned the documentation of his Company Quality System to the MID purpo- ses, he asks Istituto Giordano to carry out the audit which includes an assessment visit to the Manufacturer's premises. The conformity assessment procedure is described in detail in sections 4.3, 4.5 of these Rules and in the relevant internal IG pro- cedures.
On successful completion of the assessment activities, i.e. in the event of non-serious findings or simple recommendations, the Institute issues a Certificate of Conformity of the Quality System to the requirements of Module D (Production Quality As-surance) and its Implementing Decree (see chapter 4.7 of these Rules).
In the event of serious findings or a number of findings, even non-serious ones, that are such as to jeopardise compliance with the essential requirements, Istituto will carry out a (supplementary) audit within the time limit stated on the Audit Report (such as to allow the Manufacturer to act on its quality system by incorporating the required changes) (see chapters 4.6 and 7 of these regulations).
In the event that subsequent supplementary audits also prove negative, demonstrating that the previous find-

ings have not been taken into account, Istituto will inform the other Notified Bodies of the denial of Conformity Certification (see chapter 18).

3.4 The manufacturer undertakes to fulfil the obligations arising from the approved quality system and to ensure that it remains ade- quate and effective.

3.5 The Manufacturer keeps the Institute informed of any planned changes to the Approved Quality System. Institute evaluates the proposed changes and decides whether the modified quality system continues to meet the requirements described in paragraph 3.2 or, if necessary, a field audit.

The Institute shall notify the Manufacturer of its decision. The notification shall contain the conclusions of the examination and the detailed grounds for the decision.

For details concerning the management of changes to its Quality System implemented by the Manufacturer, please refer to Chapter 10 'Changes to Products/Quality Systems/Production Plants Made by the Organisation'.

4. Surveillance under the responsibility of Istituto Giordano

4.1 The objective of surveillance is to ensure that the manufacturer fulfils all the obligations arising from the approved quality system.

4.2 On the occasion of scheduled and/or unannounced visits, the Manufacturer must allow the Institute access for inspection, te- sting and storage purposes to the manufacturing premises and must provide all necessary information, in particular

- the quality system documentation;
- internal inspection reports;
- evidence data;
- calibration data;
- information on the qualifications of the personnel employed.

4.3 The Institute carries out surveillance audits on an annual basis to ensure that the Manufacturer maintains and applies the quali- ty system and will issue an audit report at the end of the audit.

4.4 In addition , Istituto may make unannounced visits to the Manufacturer. On this occasion, Istituto may carry out, or have carried out, tests on the product to verify the proper functioning of the quality system. The Institute sends a report on the visit and, if tests have been carried out, a report on these tests.

5. EU Marking and Written Declaration of Conformity

5.1 The Manufacturer affixes the CE marking, the supplementary metrology marking and, under the responsibility of the Institute, the latter's identification number to each measuring instrument that conforms to the type described in the EU Type Examina- tion Certificate and meets the relevant requirements of this Decree.

An EU Declaration of Conformity shall be drawn up by the manufacturer for each instrument produced and kept at the disposal of the national authorities for a period of 10 years after the instrument has been placed on the market . A copy of the EU Declaration of Conformity shall be made available to the competent authorities upon request. TheEU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of this declaration shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be understood to refer to a batch or consignment rather than to individual instruments in cases where a large number of instruments is supplied to a single user.

6. For a period of ten years from the date of placing the last instrument on the market, the manufacturer must keep at the dispo- sal of the national authorities:
   - the Quality system documentation (ref. section 3.1 and 3.2);
   - changes in the Quality System, and its approval (ref. paragraph 3.5);
   - the decisions and reports forwarded by the Institute concerning the approval of Quality System modifications (ref. paragraph 3.5), reports of the periodic and unannounced audits carried out (ref. paragraph 4.3) and any test reports carried out during the latter (ref. paragraph 4.4).

7 The Institute periodically communicates to its notifying authority the list of quality system approvals issued or withdrawn and periodically or upon request, makes available to that authority the list of quality system approvals refused, suspended or otherwise restricted by Istituto Giordano.

8 Authorised representative

The obligations incumbent on the Manufacturer set out in points:

- 3.1and 3.5 "Quality System
- 5 and 6 'EU Marking and Declaration of Conformity'.

may be performed, on behalf of the manufacturer and under its responsibility, by its authorised representative provided that they are specified in the mandate.

MODULE F - CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

1. Conformity to type based on product verification is that part of the conformity assessment procedure whereby the Manufacturer fulfils the obligations set out in paragraphs 2, 5.1 and 6 below, and ensures and declares, on his sole responsibility, that the measuring instruments subjected to the provisions of point 3 are in conformity with the type described in the EU Type Examination Certificate (Module B) and satisfy the requirements applicable thereto relevant to Directive 2014/32/EU and Legislative Decree No. 84 of 19 May 2016.

2. Manufacturing

The Manufacturer shall take all necessary measures to ensure that the manufacturing process and its control ensure conformity of the manufactured instruments with the approved type described in the EU Type Examination Certificate and with the relevant requirements of Directive 2014/32/EU and its transposition decree (Legislative Decree No. 84 of 19 May 2016).

The Manufacturer shall send to the certifying body Istituto Giordano S.p.A. a request for authorisation to CE mark according to the procedure described in Module F of Directive 2014/32/EU and relative transposition Decree, enclosing the following documentation for each type of instrumentation he intends to CE mark

a) a general description of the equipment;
b) design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for understanding these drawings and diagrams and the operation of the equipment;
c) copy of the EU Type Examination Certificate issued by Notified Body with all relevant technical documentation attached;
d) a copy of the company Quality System certification according to the reference standard ISO9001, if any, or alternatively a copy of the company Quality Manual and of the system procedures in order to demonstrate to the notified body that the manufacturer takes all necessary measures so that its manufacturing process can guarantee the homogeneity of each lot produced, and can therefore present its instruments for verification in the form of homogeneous lots.
e) A binding declaration by which the Manufacturer declares that he has exclusively submitted the application for certification according to Form F (PRODUCT CONFORMITY DECLARATION BASED ON VERIFICATION OF THE PRODUCT) to Istituto Giordano.

3. Verification

The Institute examines the documentation produced and sends any findings to the manufacturer (see Chapter 4.3) .

The Institute verifies the conformity of each instrument with the requirements of the MID Directive by examining and testing each individual product, as described in the following paragraph.

Product verification

The Institute then carries out, or arranges for the appropriate examinations and tests to be carried out, to verify the conformity of the instruments with the type described in the EU Type Examination Certificate and with the relevant requirements of the MID Directive and its transposition decree.

The examinations and tests aimed at verifying compliance with the metrological requirements shall be carried out, at the request of the Manufacturer and following approval by Istituto Giordano, either by examination and testing of each individual instrument as set out in paragraph 4, or by examination and testing of the instruments on a statistical basis as set out in paragraph 5.

4. Verification of compliance with metrological requirements through examination and testing of each individual instrument

4.1 All instruments are examined individually and appropriate tests are carried out on them in accordance with the relevant documents (harmonised standards and/or normative documents and/or equivalent tests foreseen by other relevant technical specifications), and/or equivalent tests to verify their conformity as foreseen by other relevant technical specifications in order to assess their conformity with the approved type described in the EU type examination certificate and with the relevant requirements of the MID Directive and its transposition decree.

In the absence of normative documents or harmonised standards, the notified body decides which tests are preferable

4.2 The Institute issues a certificate of conformity relating to the examinations and tests carried out, and affixes, or has affixed under its own responsibility, its identification number to each approved instrument.

4.3 The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for a period ending ten years after the instrument has been placed on the market.

5. Statistical verification of compliance

5.1 The manufacturer shall take all necessary measures to ensure that the manufacturing process and its control guarantee the homogeneity of each batch produced and shall submit its instruments for verification in the form of homogeneous batches

5.2 Samples are taken from each lot by Istituto Giordano at a significant number depending on the sampling standard adopted in accordance with the requirements of paragraph 5.3. All the products included in the sample shall be examined individually and appropriate tests shall be carried out on them, in accordance with what is indicated in the harmonised standards and/or normative documents (see paragraph 1.3 "Harmonised standards and normative documents" and paragraph 4.3.3 "Content of the technical documentation" of this Regulation) and/or equivalent tests established in other relevant technical specifications to verify their conformity with the type described in the EU type examination certificate and with the applicable requirements of the MID Directive and its transposition Decree in order to determine whether the lot is to be accepted or rejected.

In the absence of relevant documents, the Institute decides which tests are appropriate.

5.3 The statistical procedure chosen by the Institute is based on the sampling standard UNI ISO 2859/1 *"Sampling procedures in attribute testing. Indexed sampling plans according to the level of acceptable quality (LQA) for lot-by-lot testing'* and this procedure meets the following requirements:

Statistical control is based on attributes. The sampling system ensures that:

- a quality level corresponding to a 95 per cent probability of acceptance, with a non-conformity rate of less than 1 per cent;
- a borderline quality corresponding to a probability of acceptance of 5 %, with a non-conformity rate of less than 7 %.

5.4 If a batch is accepted, all instruments in the batch are approved, except for those instruments in the sample that were found to be nonconforming.

The Institute issues a certificate of conformity with regard to the examinations and tests carried out, and affixes or causes to be affixed - under its own responsibility - its identification number to each approved instrument.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for a period ending ten years after the instrument has been placed on the market.

5.5 If a batch is rejected, the Institute takes appropriate measures to prevent it from being placed on the market.
If rejection of batches is frequent, the Institute may decide at its sole discretion to suspend the statistical verification and take appropriate measures.

6. EU Marking and Declaration of Conformity

6.1 The Manufacturer affixes to each measuring instrument that conforms to the approved type described in the EU Type Certificate and that meets the applicable requirements of the MID Directive and its transposition Decree, the CE marking and the supplementary metrology marking and, under the responsibility of Istituto Giordano, its identification number (No. 0407).

6.2 For each instrument model the manufacturer shall draw up a written EU declaration of conformity which shall be kept at the disposal of the national authorities for a period of ten years after the instrument has been placed on the market. The EU declaration of conformity in question shall identify the instrument model for which it has been drawn up.
A copy of the EU declaration of conformity is made available to the competent authorities upon request.
A copy of this EU declaration shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be understood to refer to a batch or consignment rather than to individual instruments in cases where a large number of instruments are supplied to a single user.
If the Institute has given its consent, the Manufacturer shall also affix the identification number of the body in question to the measuring instruments, under the responsibility of the latter.

7. If the Institute has given its consent and under its responsibility, the Manufacturer may affix the identification number of the body in question during the manufacturing process.

8. Authorised representative

The obligations incumbent on the Manufacturer may be fulfilled, on behalf of the Manufacturer and under its responsibility, by its Authorised Representative provided that they are specified in the mandate.
An authorised representative may not fulfil the Manufacturer's obligations set out in points 2 "Manufacturing" and 5.1 "Statistical verification of conformity with metrological requirements" of this paragraph MODULE F - CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION.

MODULE H1 - CONFORMITY BASED ON FULL QUALITY ASSURANCE AND DESIGN REVIEW

1. Conformity based on full quality assurance and design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down hereafter (ref. paragraphs 2 and 6), and ensures and declares on his own responsibility that the measuring instruments concerned satisfy the relevant requirements of Directive 2014/32/EC and its transposition decree.

2. Production

Under this procedure, the manufacturer shall operate an approved quality system for design, production, final product in- spection and testing of the measuring instrument concerned as specified in paragraph 3 below, and shall be subject to sur- veillance as specified in paragraph 5.

The adequacy of the technical design of the measuring instrument was examined in accordance with the provisions of para- graph 4.

3. Quality System

3.1. As part of this procedure, the Manufacturer submits an application to Istituto Giordano for the evaluation of its quality system for the measuringinstrumentsin question
The application shall contain:

a) The name and address of the manufacturer and, if the request is made by the authorised representative, the name and address of the latter;
b) All relevant information on the intended category of instruments;
c) Quality system documentation;
d) A written declaration that the same application has not been submitted to any other notified body

3.2. The quality system guarantees the conformity of the measuring instruments with the requirements of the Decree transposing the MID Directive applicable to it.
All criteria, requirements and provisions adopted by the manufacturer must be documented in a systematic and order- ly manner in the form of written measures, procedures and instructions. This quality system documentation shall per- mita uniform interpretation of quality programmes, plans, manuals and records.
It must in particular include an adequate description:

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

(b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards and/or normative documents are not applied in full, the means of ensuring that the essential requirements of this decree applicable to measuring instruments will be met by applying other relevant technical specifications

(c) the techniques, processes and systematic design control and verification measures that are intended to be applied in the design of measuring instruments belonging to that category

(d) the corresponding processes and manufacturing, quality control and quality assurance techniques, processes and systematic interventions that will be applied

(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) quality records, such as inspection reports and test and calibration data, reports on the qualifications of the personnel concerned

(g) the means of monitoring whether the required design and product quality is achieved and whether the system is functioning effectively

3.3. Istituto Giordano shall assess the quality system to determine whether it satisfies the requirements set out in paragraph 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that conform to the relevant specifications of the corresponding harmonised standards.
In addition to experience in quality management systems, the auditing team shall have at least one member with experien- ce as an assessor in the specific field of the instrument and related technology, and shall be familiar with the applicable re- quirements of the Decree implementing the MID.
The audit includes anassessment visit to the Manufacturer's premises.
The decision is notified to the Manufacturer and his Authorised Representative, if any. In particular, the no- tification must contain the conclusions of the inspection and a detailed justification of the decision.

3.4. The manufacturer undertakes to fulfil the obligations arising from the approved quality system and to ensure that it remainsadequate and effective

3.5. The Manufacturer shall keep Istituto Giordano, which approved the quality system, informed of any envisaged changes to the quality system. system.

IstitutoGiordano shall evaluate the proposed changes and decide whether the modified quality system continues to meet

the requirements of paragraph 3.2, or whether a second assessment is necessary.

It notifies the decision to the Manufacturer or its Authorised Representative

The notification shall contain the conclusions of the audit and a detailed justification of the decision.

3.6. Istituto Giordano shall inform its notifying authority of quality system approvals issued or withdrawn and shall periodically or upon request make available to that authority the list of quality system approvals it has refused, suspended or otherwise restricted.

4. Project Examination

4.1. The Manufacturer submits an application for examination of its project to Istituto Giordano referred to in 3.1 above.

4.2. The application must provide an understanding of the design, manufacturing process and operation of the instrument, as well as an assessment of compliance with the relevant requirements of the MID and its transposition decree.

The application shall contain at least the following information:
(a) the name and address of the Manufacturer;
(b) a written declaration that the same application has not been submitted to any other notified body;
(c) the technical documentation (described in Article 18 'Technical Documentation' of Directive 2014/32/EU). This documentation shall be sufficiently detailed to permit assessment and to ascertain the conformity of the instrument with the relevant requirements of the MID and shall include an adequate risk analysis and assessment; it shall specify the applicable requirements and cover the design and operation of the instrument to the extent relevant for the assessment. It shall also include:

1. definition of the design and operating characteristics of the instrument (including metrological characteristics);
2. the reproducibility of the measurement results of the instruments produced when they are correctly calibrated using the appropriate means;
3. the integrity of the instrument.

d) the documentation proving the adequacy of the technical design. This documentation shall mention any documents that have been applied, in particular where the relevant harmonised standards and/or normative documents have not been applied in full (see paragraph 1.3 "Harmonised standards and normative documents" and paragraph 4.3 "Technical documentation provided by the manufacturer" of this Regulation), and shall include, where necessary, the results of tests carried out in accordance with the other relevant technical specifications by the manufacturer's laboratory or, on his behalf and under his responsibility, by another testing laboratory.

For the purposes of evaluation and identification of the instrument, the technical documentation must include the following:

a) a general description of the instrument;
b) design and manufacturing diagrams, as well as plans for components, sub-assemblies, circuits;
c) manufacturing procedures to ensure homogeneous production;
d) if applicable, a description of the electronic devices with diagrams, flowcharts of the logic and general software information illustrating their characteristics and operation;
e) descriptions and explanations necessary for understanding (b), (c) and (d), including the operation of the instrument;
f) a list of harmonised standards and normative documents (ref. point 1.3 of these Regulations), applied in whole or in part;
g) descriptions of the solutions adopted to meet the essential requirements where harmonised standards and normative documents have not been applied (ref. 1.3 of this Regulation);
h) the results of design calculations, examinations;
i) relevant test results, where necessary, to demonstrate that the instrument complies with:
   - the requirements of the directive according to the declared rated operating conditions and specific environmental disturbances;
j) EU Type Examination Certificates or EU Design Examination Certificates for instruments containing parts identical to those of the design.
k) any other document that enables the Institute to improve the assessment.

In addition:
The manufacturer must specify the position of the seals and markings.
The manufacturer must indicate, where possible, compatibility requirements with interfaces and sub-assemblies.

4.3. The Istituto Giordano examines the application and if the design complies with the provisions of the MID Directive and its transposition decree applicable to the measuring instrument, issues an EU Design Examination Certificate to the Manufacturer.This certificate contains the name and address of the manufacturer, the conclusions of the examination, the conditions of validity, if any, and the data necessary to identify the approved instrument.

This certificate may include one or more annexes.

All relevant parts of the technical documentation are attached to the certificate.

The certificate and its annexes contain all relevant information for the purpose of assessing the conformity of the manufactured measuring instruments with the examined design and the control of the device in service, in particular to ensure the conformity of the manufactured instruments with the design with regard to the reproducibility of the results and measurements, when they are correctly calibrated by the appropriate means.

The certificate includes:

- (a) the metrological characteristics of the instrument type;
- (b) the measures required to guarantee the integrity of the instrument (seal, software identification, etc.);
- (c) information on other elements necessary for the identification of the instrument and to verify its visual conformity to the design;
- (d) where appropriate, any specific information necessary to verify the characteristics of the instruments manufactured;
- (e) in the case of a sub-assembly, all information necessary to ensure compatibility with other sub-assemblies or measuring instruments.

The Institute shall draw up an assessment report in this regard, which it shall keep at the disposal of the Member State that designated it. Without prejudice to the provisions of Article 27(10) of Directive 2014/32/EU, that body shall make the contents of that report public, in whole or in part, only with the consent of the Manufacturer.

The certificate is valid for ten years from the date of issue and may be renewed for successive ten-year periods.

If the design does not comply with the applicable requirements of the MID Directive and its transposition decree, the Institute decides to refuse to issue an EU Design Examination Certificate, and informs the Manufacturer accordingly, giving detailed reasons for this decision.

4.4. The Istituto Giordano monitors the evolution of generally recognised technological progress and assesses whether the approved type no longer complies with the applicable requirements of the Decree implementing the MID Directive.

In this case Istituto Giordano decides whether such progress requires further investigation and if so, the notified body informs the Manufacturer.

The Manufacturer shall keep the Jordan Institute informed of any significant changes to the approved design.

Where changes to the approved design may affect conformity with the essential requirements of this Directive, the conditions of validity of the certificate, or the intended conditions of use of the instrument, such changes must be subject to further approval by the Istituto Giordano that issued the EU Design Examination Certificate.

This new approval is issued in the form of a supplement to the original 'EU Design Examination Certificate'.

4.5. The Institute informs its notifying authority about:
- the EU design examination certificates issued and their annexes;
- supplements and amendments to certificates already issued.

The Institute informs its notifying authority of the withdrawal of an EU Type Examination Certificate and/or any supplements as well as those refused, suspended or otherwise restricted.

The Commission, the Member States and the other notified bodies may obtain, on request, copies of the EU design examination certificates and/or their additions. The Commission and the Member States may obtain, on request, copies of the technical documentation and results of examinations carried out by Istituto Giordano.

Istituto Giordano keeps a copy of the EU Design Examination Certificate and its annexes and supplements together with the technical documentation (technical file) with the documentation submitted by the Manufacturer, until the expiry of the validity of the certificate.

The manufacturer shall keep a copy of the EU design examination certificate and its annexes and supplements together with the technical documentation (technical file) at the disposal of the national authorities for a period of ten years after the instrument has been placed on the market.

5. Supervision under the responsibility of Istituto Giordano.

5.1. Surveillance is intended to ensure that the manufacturer correctly fulfils all the obligations arising from the approved quality system.

5.2. The Institute carries out periodic audits by implementing a time schedule to ensure that the manufacturer maintains and applies the quality system.
During scheduled and/or unannounced visits, the Manufacturer allows the Institute access for inspection purposes to the design, manufacturing, inspection, testing and storage premises and provides it with all necessary information, in particular
- (a) the quality system documentation;
- (b) the quality documents required by the design part of the quality system, such as results of analyses, calculations, tests, etc;
- (c) the quality records required by the manufacturing part of the quality system, such as inspection reports and data on tests, calibrations, qualification of personnel employed, etc.

5.3. The Institute carries out annual audits to ensure that the Manufacturer maintains and applies the quality system and provi- des the Manufacturer with a report on the audits carried out.

5.4. In addition, the Jordan Institute may make unannounced visits to the Manufacturer.
On this occasion, the Institute may carry out, or have carried out, product tests to verify the proper functioning of the quali- ty system.
The Institute sends the Manufacturer a report on the visit and, if tests have been carried out, a report on them.

6. Marking and written declaration of EU conformity.

6.1. The Manufacturer shall affix the CE marking, the supplementary metrology marking and, under the responsibility of Istituto Giordano, referred to in point 3.1 (Institute), the latter's identification number to each measuring instrument that meets the relevant requirements of the MID Directive and its transposition decree.

6.2. The manufacturer shall draw up an EU declaration of conformity for each instrument model, which shall be kept at the disposal of the national authorities for a period of ten years after the instrument has been placed on the market.
The declaration in question identifies the instrument model for which it was drawn up and mentions the number of the

EU Design Examination Certificate.
A copy of this EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be understood to refer to a batch or consignment rather than to individual instruments in cases where a large number of instruments are supplied to a single user.

7. For a period of ten years from the manufacture of the last instrument, the Manufacturer must keep at the disposal of the national authorities:
   - a) the documentation on the quality system referred to in paragraph 3.1 c;
   - (b) the information concerning, and approval of, the change referred to in paragraph 3.5;
   - (c) the decisions and reports forwarded by Istituto Giordano referred to in paragraphs 3.5, 5.3 and 5.4.

8. Authorised representative

The Authorised Representative of the Manufacturer may submit the application referred to in 4.1 and 4.2 and fulfil the obligations referred to in 3.1, 3.5, 4.4, 4.6, 6 and 7 of this Regulation on behalf of the Manufacturer and under its responsibility, provided that they are specified in the mandate.

Annex 4 - Facsimile model application for certification. - APPLICATION FOR EU CONFORMITY ASSESSMENT OF MEASURING INSTRUMENTS - DIRECTIVE 2014/32/EU

ANNEX 1 - APPLICATION FOR ASSESSMENT OF CONFORMITY RELATED TO MEASURING INSTRUMENTS - DIRECTIVE 2014/32/UE

SEND TO ISTITUTO GIORDANO BY THE MANUFACTURER OR BY HIS AGENT ESTABLISHED IN THE COMMUNITY			
APPLICANT:			
Company Name:			
Legal address:			
Authorised representative pursuant to art. 9 Directive 2014/32/EU (Name and Surname or Company Name):			
Reference person:		Any consultant	
Phone:		Fax:	
Tax Code:			
Bank support:		Code BIC (or SWIFT):	
Any administrative headquarters different from the registered office:			
MANUFACTURER (if different from the above):			
Company Name:			
Legal address:			
Reference person:			
Phone:		Fax:	
TOTAL NUMBER OF PERSONS INVOLVED IN THE ACTIVITY TO BE CERTIFIED			
Tax Code:			
Bank support:		Code BIC (or SWIFT):	
Any administrative headquarters different from the registered office:			
MANUFACTURING (If different from above)			
Denomination:			
Address:			
Phone:		Fax:	
Reference person:			
PRODUCT INFORMATION:			
Overview	Trade Name		
	Type Tool Measurement		

Modules of conformity assessment *(tick where applicable)*	B	D	F	H1

In accordance with the Directive MID is required to start the certification process provided for the conformity assessment in the form required certification in its annexes (MI001÷MI010) of the Directive MID.

The company states that it has submitted a similar request to another Notified Body

The Company is committed to:

a) comply with the requirements contained in Directive 2014/32/EU,and in the Regulations and MID Institute (REG-MID);
b) observe, recognize contractual nature and approve the "Regulations for the release of documents of compliance with the technical specifications for the MID" (REG_MID) and the "General Conditions of Contract for certification" (CGC) latest revisions in force (available on www.giordano.it, or sent at the request of the Company;
c) cooperate and give the necessary assistance to Istituto Giordano SpA to the assessment/verification object of the present application;
d) comply with the conditions of **QUOTATION NO. / dated** what constitutes an integral part of this application, and correspond to the same rights relating to the activity of certification, with the reimbursement of expenses incurred, even if the activity of conformity assessment does not end with the issue of acts of certification;
e) therefore correspond to Istituto Giordano rights relating to the activity of testing, with the reimbursement of expenses incurred, even if the activity does not end with the issue of test reports;
f) do not misuse or misleading certification achieved or likely to bring discredit to Istituto Giordano SpA;

Name and position: .....

Date:.....

***Stamp and Signature* of Authorized Representative for confirmation**

.....

The parties after rereading, declare specifically approves, pursuant to and for the purposes of Articles 1341 and 1342 of the Italian Civil Code, the provisions referred to in points a), c), d), e), f) of this contract, clauses 3, 4, 5, 6, 8, 9, 10, 11, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 28, 30, 31, 32 , 33, 35 of the "General Conditions of Contract for certification" (CGC) and chapters 4.0, 4.1, 4.4, 4.5, 4.6, 4.7, 6, 7, 8, 9, 10, 12, 14, 15, 16. 18 , the "Regulations for the conformity assessment of measuring instruments and for issuing documents of conformity to harmonized requirements under Directive 2014/32/EU (REG-MID).

Name and position: .....

Date: .....

Stamp and signature of Authorized Representative for confirmation

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