For use only if the UK has left the EU without a deal

MEASURING INSTRUMENTS REGULATIONS 2016 as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Guidance

September 2019
1. Introduction

The Measuring Instrument Regulations 2016 (“the Regulations”) set out the essential requirements which must be met before measuring instruments can be placed on the UK market. The purpose of the legislation is to protect business and consumers from inaccurate measuring instruments by requiring manufacturers to show how their instruments meet the ‘essential requirements’.

This guidance is designed to help you understand the Regulations now the UK has left the EU, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (“2016 Regulations as amended”).

2. Legislative Background

The Regulations implemented Directive 2014/32/EU on measuring instruments. The EU Withdrawal Act 2018 preserves the Regulations and enables them to be amended so as to continue to function effectively now the UK has left the EU. Accordingly, the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 fix any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the UK market.

The 2016 Regulations replaced fifteen individual regulations (including non-prescribed instruments) with one single omnibus regulation.

3. Scope

The Regulations regulate the following kinds of measuring instruments:

- water meters used for trade for the supply of potable water in the temperature range from 0.1°C to and including 30°C;
- gas meters for use for trade except a gas meter which is used under an agreement providing for the supply of a quantity of gas at a rate of flow which, if measured at a temperature of 15°C and a pressure of 1013.25 millibars, would exceed 1600 cubic metres an hour (or the equivalent quantity in kilograms);
- active electrical energy meters for use for trade other than an instrument which is used under an agreement providing for the supply of active electrical energy where:
  - the maximum quantity supplied exceeds 100 kilowatts per hour; and
  - the instrument provides measurement on a half-hourly basis;
- non-water liquid measuring systems for use for trade of the following descriptions:
  - a measuring system which is used for the continuous and dynamic measurement in a quantity not exceeding 100 litres or 100 kilograms of a liquid fuel, lubricant or a mixture of fuel and lubricant other than:
    - liquefied petroleum gas; or
    - liquefied natural gas;
  - a measuring system (other than one used in connection with the refuelling of aircraft, ships or hovercraft) which is used for the continuous and dynamic measurement in a quantity exceeding 100 litres or 100 kilograms of liquid fuel delivered from a road tanker other than:
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(aa) liquefied gases;
(bb) lubricating oils;
(cc) liquid fuels of a temperature below -153°C; or
(dd) liquid fuels of a dynamic viscosity exceeding 100 millipascal seconds at 15°C;

- automatic weighing instruments of the following kinds which are for use for trade—
  - automatic catchweighers;
  - automatic gravimetric filling instruments;
  - discontinuous totalisers;
  - beltweighers; and
  - automatic rail weighbridges;

- taximeters intended for use for the protection of consumers;

- material measures which are for use for trade of the following kinds:
  - material measures of length (excluding dipping and strapping tapes);
  - capacity serving measures for the measurement of draft beer or cider of the following capacities: 1/3 pint, ½ pint, 2/3 pint, 1 pint, 2 pints, 4 pints, 8 pints and 16 pints;
  - capacity serving measures for the measurement of liquids other than draught beer or cider of the following capacities in millilitres (ml) and litres (l): 5 ml, 10 ml, 20 ml, 25 ml, 35 ml, 50 ml, 70 ml, 100 ml, 125 ml, 150 ml, 175 ml, 200 ml, 250 ml, 500 ml, 1 l, 2 l, 2.5 l, 5 l, 10 l and 20 l;

- exhaust gas analysers intended for use for the protection of the environment and public health except where the exhaust gas analyser includes or is connected to a device which is not used for the protection of the environment and public health.

4. Obligations of manufacturers

A manufacturer is a person who manufactures regulated measuring instruments, or has regulated measuring instruments designed or manufactured, and markets those regulated measuring instruments under their name or trade mark.

The obligations of manufacturers of regulated measuring instruments include:

1. Before placing a regulated measuring instrument on the market or putting into use, a manufacturer must ensure that it has been designed and manufactured in accordance with the essential requirements. The 2016 Regulations as amended set these out in Schedule 1A and the instrument specific requirements in Schedule 1C to 1J. They must have carried out the appropriate conformity assessment procedures referred to in Schedule 1B and have drawn up technical documentation.

2. Once this has been done a manufacturer must draw up a declaration of conformity, the format of which is found in Schedule 1K. The manufacturer must ensure the declaration accompanies the regulated measuring instrument and affix the UKCA marking and the M marking to the instrument.

3. Manufacturers must keep the declaration of conformity up to date and keep it and the technical documentation for 10 years after the measuring instrument has been placed on the market.
4. Manufacturers must ensure that procedures are in place for series production to remain in conformity with the essential requirements and the regulated measuring instruments are labelled with the type, serial or batch identification. They shall indicate their name, registered trade name or registered trade mark and postal address on every regulated measuring instrument. Where this is not possible it may be provided on the packaging or accompanying documentation. They must ensure regulated measuring instruments are accompanied by instructions and information on their operation in clear, legible and easily understandable English.

5. Manufacturers, when appropriate with regard to the performance of a regulated measuring instrument, carry out sample testing of instruments and investigate any complaints that the instruments are not in conformity and keep records of these complaints, any non-conforming instruments and measuring instrument recalls, and keep distributors informed of any such monitoring.

6. Manufacturers must take action where they have reason to believe that the regulated measuring instruments are not in conformity with the 2016 Regulations as amended.

7. Manufacturers must also cooperate with and provide information to competent authorities following any requests.

5. Obligations of authorised representatives

Manufacturers are able to appoint authorised representatives to perform certain tasks on their behalf under a written mandate.

Mandated authorised representatives established in the EEA or Switzerland prior to the UK leaving the EU continue to be recognised as authorised representatives by the UK to act in the UK for the purposes of the legislation. However, any authorised representatives appointed and mandated after the UK left the EU to act in the UK must be established in the UK to be recognised under UK law.

Businesses with an existing authorised representative based in an EEA State or Switzerland can continue to use the same authorised representative.

No UK-based authorised representatives are recognised under EU law. This means they cannot carry out tasks on the manufacturer’s behalf for products being placed on the EU market. Therefore, a manufacturer exporting products to the EU, who wishes to appoint an authorised representative to carry out tasks for them in respect of those products, must appoint an authorised representative recognised in EU law.

An authorised representative must comply with all the duties, imposed on the manufacturer under the Regulations, that they are appointed for and mandated by the manufacturer to perform. A manufacturer remains responsible for the proper performance of any obligations the authorised representative performs on their behalf.

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1 WELMEC Guide 8.9 allows for glass, ceramic and plastic moulded capacity serving measures, due to the physical characteristics of such products, to provide this information in a document accompanying the batch or consignment and on the packaging.
The mandate shall at least allow the authorised representative to perform the following tasks:

1. keeping the declaration of conformity and the technical documentation at the disposal of the national market surveillance authorities for 10 years after the regulated measuring instrument has been placed on the market;

2. further to a reasoned request from a competent authority, providing that authority with all the information and documentation necessary to demonstrate the conformity of the regulated measuring instrument; and

3. cooperating with the competent authorities, at their request, on any action taken to eliminate the risks posed by the regulated measuring instrument covered by the mandate.

6. Obligations of importers

An importer is a person or business based in the UK who places a product on the UK market from a country outside the UK. This means that UK businesses who used to act as a ‘distributor’ will legally become an ‘importer’ if they place products from an EEA country on the UK market.

Importers have additional legal obligations which go beyond those of distributors, such as checking that manufacturers have carried out the right conformity assessment procedures and included their name, registered trade name or mark and a postal address on the regulated measuring instrument or, where this is not possible, on its packaging or in accompanying documentation.

To assist with the transition, the UK is applying a transitional period of 18 months to allow UK distributors of goods from the EEA or Switzerland (who post exit are importers) to provide their details on the accompanying documentation as an alternative to placing them on the product itself.

The EU does not have any such transitional provision. In the absence of this, products being exported from the UK to the EU must be labelled with the EU-based importer’s address.

The obligations of importers include:

1. Before placing a regulated measuring instrument on the market or putting into use, an importer must ensure that the appropriate conformity assessment procedures referred to in Schedule 1B have been carried out by the manufacturer. This means that the instrument must comply with the essential requirements set out in Schedule 1A and the instrument specific requirements in Schedule 1C to 1J.

2. The importer must ensure that the manufacturer has drawn up the technical documentation; the instrument bears the UKCA marking and the M marking and is accompanied by the declaration of conformity and where relevant the required documents and information on its operation in clear, legible and easily understandable English.

3. When deemed appropriate with regard to the performance of a regulated measuring instrument, the importer must carry out sample testing of instruments made available on the market by the importer, keep a register of complaints, non-conforming regulated measuring instruments and recalls of regulated measuring instruments, and keep distributors informed of any such monitoring.
4. Importers must indicate their name, registered trade name or registered trade mark and postal address. Where this is not possible it may be provided on the packaging or accompanying documentation. This must be in clear, legible and easily understandable English.

5. The importer must keep a copy of the declaration of conformity and technical documentation for a period of 10 years after the regulated measuring instrument has been placed on the market or put into use.

6. The importer must ensure that regulated measuring instruments under their responsibility are safely stored and transported in such a way that does not jeopardise conformity with the essential requirements.

7. The importer must take action where they consider or have reason to believe that regulated measuring instruments they have placed on the market or put into use are not in conformity with the 2016 Regulations as amended.

8. The importer must also cooperate with and provide information to a competent authority following any requests.

7. Obligations of distributors

UK businesses which were distributors of goods within the EU single market should now consider whether they are importers from the EU single market and therefore what additional requirements they might face – see section 6 above. The same applies to distributors of goods from the EEA and Switzerland.

A distributor is any person, other than the manufacturer or importer, who makes a regulated weighing instrument available on the market.

The obligations of distributors include:

1. Before making a regulated measuring instrument available on the market or putting into use, a distributor must take due care to ensure that it is in conformity with the 2016 Regulations as amended.

2. Before making a regulated measuring instrument available on the market or putting into use, a distributor must ensure that it bears the UKCA marking and the M marking, and where relevant that it is accompanied by instructions and information on the operation of the instrument, and that the manufacturer and importer have complied with the marking requirements to allow for identification of the instrument.

3. The distributor must ensure that the regulated measuring instruments under their responsibility are safely stored and transported in such a way that does not jeopardise their conformity with the essential requirements.

4. The distributor must take action where they have reason to believe that the regulated measuring instruments they have placed on the market or put into use are not in conformity with the 2016 Regulations as amended.

5. They must also cooperate with and provide information to a competent authority following any requests.

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2 WELMEC Guide 8.9 allows for glass, ceramic and plastic moulded capacity serving measures, due to the physical characteristics of such products, to provide this information in a document accompanying the batch or consignment and on the packaging.
8. Transitional arrangements

‘Deeming’ provision

Products which have undergone full conformity assessment under the equivalent EU requirements and bear the CE conformity mark are deemed compliant with the UK legislation and can be placed on the UK market as if they had been UKCA conformity marked.

The UK continues to recognise the competency of EU recognised conformity assessment bodies (notified bodies) to assess products for the UK market. Products assessed by an EU recognised notified body before the UK left the EU do not need reassessment before being placed on the UK market. This means that for a time-limited period, products assessed by an EU recognised notified body after the UK left the EU can be placed on the UK market. (For the status of UK notified bodies, please see section 10 below).

This ‘deeming provision’ will be available for a time-limited period. This will be the subject of amending legislation in the future at a time yet to be decided. The Government will consult with industry and provide notice before ending this time-limited period.

9. UK Conformity Mark

Assessment through third-party organisations:

The UKCA conformity mark will replace the CE marking for products placed on the UK market which have been assessed by a UK approved body. In all other cases, manufacturers will be able to continue using the CE marking for products being placed on the UK market instead of the new UKCA marking for a time-limited period. The Government will engage with industry before making any decision on when this period will end.

Rules around physically affixing the new UKCA conformity marking mirror those which currently apply for the application of the CE marking.

Self-assessment:

CE marking based on self-declaration of conformity by the manufacturer is still possible, where it was pre-exit, including when exporting to the EU.

Manufacturers selling goods on the UK market can alternatively affix the new UKCA conformity marking before placing a product on the UK market. It will also be possible to affix both the UKCA marking and the CE marking to the same product on the basis of self-declaration. When exporting to the EU, the CE marking remains mandatory.

Placing CE marked goods on the UK market:

Goods that meet EU regulatory requirements, including those with a CE marking, which have been assessed by an EU recognised conformity assessment body or which have been self-declared can still be placed on the UK market for a time-limited period. ‘EU-recognised’ does not include UK approved bodies. Manufacturers which have had their products assessed by EU recognised bodies are obliged to use the CE marking and cannot use the UKCA marking.
Testing Certificates:
Where conformity assessment is a 2-stage process, it is possible for products to have an EU-type-examination certification (1st stage) followed by a UK declaration by the manufacturer or third party of the production process under the responsibility of a UK Approved Body (2nd stage). Such equipment and protective systems should have the UK conformity mark followed by the UK Approved Body Number.

Further guidance on UK marking can be found here: https://www.gov.uk/government/publications/prepare-to-use-the-ukca-mark-after-brexit/using-the-ukca-marking-if-the-uk-leaves-the-eu-without-a-deal

The M Marking is still required when either the UK conforming marking or the CE marking is used.

Measuring instruments exported to the EU Single Market must comply with EU Directive 2014/32/EU.

10. Approved Bodies

The UK has established a new framework for UK based bodies to assess products against UK rules. Existing UK notified bodies have been granted new UK ‘approved body’ status and are listed on a new UK database. There is no need for existing UK notified bodies to seek re-accreditation in order to benefit from UK approved body status. These approved bodies have been given a 4-digit approved body number.

Approved bodies can assess products for the UK market against UK essential requirements (which are the same as EU essential requirements).

Approved bodies are conformity assessment bodies which were UK notified bodies before the UK left the EU or have been approved by the Secretary of State to carry out the procedures for conformity assessment and certification as set out in the 2016 Regulations as amended.

Approved bodies must be established in the UK and be independent of the manufacturer. Approved bodies must examine the technical documentation and supporting evidence in respect of a regulated non-automatic weighing instrument to assess the adequacy of the technical design.

Where an approved body finds that essential requirements have not been met by a manufacturer, they must not issue a certificate of conformity and they must require the manufacturer to take corrective measures.

A list of UK Approved Bodies can be found [link to be added].

11. Enforcement

In Great Britain, local Trading Standards authorities (including in relation to Part 6 – Use for Trade of Certain Regulated Measuring Instruments), and in Northern Ireland the Department for the Economy, are responsible for enforcing the 2016 Regulations as amended (other than Part 6) in relation to all regulated measuring instruments apart from gas meters, active electrical energy meters, taximeters and exhaust gas analysers.

In Great Britain, the Office for Product Safety & Standards on behalf of the Secretary of State is responsible for enforcing the 2016 Regulations in relation to gas meters and active electrical energy meters. The Secretary of State for Transport is responsible for enforcing the 2016 Regulations in relation to taximeters and exhaust gas analysers.
In Northern Ireland, the Department for Infrastructure are responsible for enforcing the 2016 Regulations in relation to taximeters and exhaust gas analysers. The Utility Regulator is responsible for enforcing the 2016 Regulations in relation to gas meters and active electrical energy meters.

The Regulations also provide powers to the Secretary of State or a person appointed to act on their behalf to enforce the Regulations and RAMS (Regulation (EC 765/2008, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, which sets out requirements for market surveillance of products) in relation to regulated measuring instruments.

The UK market surveillance authority for regulated measuring instruments is the Secretary of State. The Regulations provide the power to the market surveillance authority to take action against economic operators for products that are not in conformity with the Regulations. There are requirements on economic operators to co-operate with the competent authority as appropriate on request.

The UK market surveillance authority will take all appropriate measures to withdraw from the market or to prohibit and restrict the supply of regulated measuring instruments which present a metrological risk on grounds of public interest, protection of the environment, protection of consumers, the levying of taxes and duties or fair trading.

**Regulators’ Code**

Market surveillance authorities must continue to have regard to the Regulators’ Code when developing the policies and operational procedures that guide their regulatory activities in this area. They should carry out their activities in a way that supports those they regulate to comply and grow, including choosing proportionate approaches that reflect risk.

In responding to non-compliance that they identify, regulators should clearly explain what the non-compliant item or activity is, the advice being given, actions required, or decisions taken, and the reasons for these. Unless immediate action is needed to prevent a serious breach, regulators should provide an opportunity for dialogue in relation to the advice, requirements or decisions, with a view to ensuring that they are acting in a way that is proportionate and consistent. The Secretary of State takes account of the provisions of both the Regulators’ Code and the Growth Duty in exercising his regulatory functions.

A link to the Regulators’ Code can be found here:


**Criminal penalties and Civil penalties**

An economic operator or persons committing an offence in relation to an ‘event of default’ under the 2016 Regulations as amended are liable to a criminal penalty. Criminal penalties are enforced by trading standards. An economic operator or approved body committing an offence in relation to activities associated with the market surveillance authority are liable to civil penalties enforced by the Secretary of State.
12. Where to find out more about Directive 2014/32/EU

You can find further and more detailed guidance on Directive 2014/32/EU here:
https://www.welmec.org/documents/guides/

The European Commission’s ‘Blue Guide’ aims to give a better understanding of EU product rules and to their application across different sectors and throughout the EU single market. You can view that here: http://ec.europa.eu/DocsRoom/documents/18027/

13. Glossary

- **Approved Bodies** – A conformity assessment body which has been approved by the Secretary of State or was a UK based ‘Notified Body’ before the UK left the EU.

- **Authorised Representative** – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly. This includes persons who are based in the EEA or Switzerland, if they were appointed before the UK left the EU.

- **Declaration of conformity** – A document prepared by the manufacturer which must detail the following:
  - The specific regulated measuring instrument to which the declaration is referring;
  - The name and address of the manufacturer and, where applicable, their authorised representative;

  This must be kept by the manufacturer for a period of ten years from the date on which the regulated measuring instrument was placed on the market. This declaration must be made available to the competent authority upon request.

- **Distributor** – Any person in the UK supply chain, other than the manufacturer or the importer, who makes a regulated measuring instrument available on the UK market.

- **Competent Authority** – In Great Britain, for regulated measuring instruments other than gas meters; active electrical energy meters; taximeters; and exhaust gas analysers, this is trading standards. The Office for Product Safety & Standards, on behalf of the Secretary of State for Business, Energy and Industrial Strategy, is responsible for enforcing the 2016 Regulations in relation to gas meters and active electrical energy meters. The Secretary of State for Transport are responsible for enforcing the 2016 Regulations in relation to taximeters; and exhaust gas analysers. In Northern Ireland this is the Department for Infrastructure for taximeters and exhaust gas analysers; the Utility Regulator for gas meters and active electrical energy meters; the Department for the Economy for cold water meters, automatic weighing instruments, material measures and non-water liquid measuring systems (other than Part 6 of the 2016 Regulations as amended).

- **Importer** – A person established in the UK who places a regulated measuring instrument from a country outside of the UK on the market. A person who before the UK left the EU distributed measuring instruments within the EU (including the UK) or from Switzerland will now be an importer if they are bringing regulated measuring instruments into the UK from another country (including EEA states or Switzerland).
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- **Manufacturer** – A person who manufactures a regulated measuring instrument or has a regulated measuring instrument designed or manufactured and markets that instrument under their name or trademark.

- **UK Conformity Marking** – The UKCA (UK Conformity Assessed) marking is the new UK conformity marking used for certain goods being placed on the UK market, in place of the CE marking which is the conformity marking used in the European Union.

This only applies if the UK leaves the EU without a deal.