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

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

Guidance

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# Contents

1. Introduction........................................................................................................................................3
2. Legislative Background ..................................................................................................................3
3. Scope ...............................................................................................................................................3
4. Requirements .....................................................................................................................................4
5. Obligations of manufacturers.........................................................................................................4
6. Obligations of authorised representatives.....................................................................................5
7. Obligations of importers..................................................................................................................6
8. Obligations of distributors...............................................................................................................7
9. Transitional arrangements.................................................................................................................8
10. UK Conformity Mark.......................................................................................................................8
11. Approved Bodies.............................................................................................................................9
12. Enforcement ......................................................................................................................................9
13. Where to find out more about Directive 2014/31/EU ....................................................................10
14. Glossary .........................................................................................................................................10
1. Introduction

The Non-Automatic Weighing Instruments Regulations 2016 (“the Regulations”) set out the essential requirements which must be met before regulated non-automatic weighing instruments can be placed on the UK market. The purpose of the legislation is to protect business and consumers from inaccurate non-automatic weighing instruments by requiring manufacturers to show how their instruments meet the ‘essential requirements’.

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

2. Legislative Background

The Regulations implemented Directive 2014/31/EU on non-automatic weighing 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.

3. Scope

The 2016 Regulations distinguish between non-automatic weighing instruments used for the purposes listed at (a) to (f) below (regulated non-automatic weighing instruments), and non-automatic weighing instruments used for any other purpose (non-regulated non-automatic weighing instruments).

a) “the determination of mass for commercial transactions”, which deals with trading transactions where the goods are bought or sold by mass. The cost therefore is directly proportional to the mass of the product. For example: weighing of fruit in a greengrocer’s or using a weighbridge to weigh a load of timber.

b) “the determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment”, this category of use not only includes situations where the payment is directly proportional to the mass, e.g. remuneration (money paid for work or service), tax, but also situations where the mass value determines the cost of the service, e.g. post office use, laundry or airport baggage tariff, charge for transporting goods, disposal of waste.

c) “the determination of mass for the application of laws or regulations or for an expert opinion given in court proceedings”, which covers the activities where an instrument is used by a person who is not an expert in metrology but is giving evidence based on weighing results. Instruments used for the same purposes by experts from metrological laboratories, government or public authority laboratories and forensic laboratories are therefore excluded on the condition that such laboratories keep their instruments properly maintained, calibrated and adjusted. This might however include, for instance: the weighing of aircraft in connection with statutory requirements, or the weighing of vehicles in connection with statutory weight restrictions.
d) “the determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment”, which covers those activities where medical staff are responsible for the weighing of patients. Examples are the use of weighing instruments in hospitals, health centres or taken into the community for medical purposes. Medical staff includes all persons that lawfully carry out the medical weighing tasks. Medical weighing tasks might include, for example, bed-weighers and baby-weighers.

e) “the determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories”, where medical laboratories are laboratories that carry out analyses at the request of medical practitioners and pharmaceutical laboratories are quality control laboratories of manufacturers of medicinal products for human use. Pharmaceutical laboratories do not include the research and development laboratories of manufacturers of these medicinal products.

f) “the determination of price on the basis of mass for the purposes of direct sales to the public and the making up of pre-packages”. The former case covers the use of instruments with price calculation, in particular price-calculating retail scales, and the latter refers to scales used to make up pre-weighed non-predetermined quantities.

4. Requirements

The essential requirements apply to all categories of regulated non-automatic weighing instruments as appropriate. All regulated non-automatic weighing instruments must undergo a conformity assessment procedure set out in Schedule 7 to demonstrate compliance with the essential requirements of Schedule 6 to the 2016 Regulations as amended.

Non-regulated non-automatic weighing instruments are not conformity assessed nor UK and M marked but are required to be marked with the manufacturer’s name, registered trade name or registered trademark and address and maximum capacity as set out in Part 4 of the 2016 Regulations as amended.

Non-regulated non-automatic weighing instruments are used for such purposes as domestic use (kitchen, bathroom etc), goods inwards inspection and medical practice except for the monitoring of patients for the purposes of diagnosis and medical treatment.

5. 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 trademark.

The obligations of manufacturers of regulated measuring instruments include:

1. Before placing a regulated non-automatic weighing instrument on the market, 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 6. They must also have carried out the appropriate conformity assessment procedures referred to in Schedule 7 and have technical documentation drawn up.
2. Once this has been done a manufacturer must draw up a declaration of conformity, the format of which is found in Schedule 9 and affix the UKCA marking and the M marking to the instrument. The declaration of conformity is not required to accompany each instrument.

3. Manufacturers must keep the declaration of conformity up to date and must keep it and the technical documentation for 10 years.

4. Manufacturers must ensure that procedures are in place for series production to remain in conformity with the essential requirements. They must also label regulated non-automatic weighing instruments with the type and serial or batch identification, the manufacturer’s name, registered trade name or registered trade mark and postal address and ensure that they are accompanied by instructions and information on the operation of the instrument in clear, legible and easily understandable English.

5. Manufacturers, when appropriate with regard to the performance of a regulated non-automatic weighing 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 instrument recalls, and keep distributors informed of any such monitoring.

6. Manufacturers must take action where they have reason to believe that the regulated non-automatic weighing 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.

6. Obligations of authorised representatives

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

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 non-automatic weighing instrument has been placed on the market;

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

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

An authorised representative must comply with all the duties, imposed on the manufacturer under the 2016 Regulations as amended, 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.
Mandated authorised representatives established in the EEA or Switzerland prior to the UK leaving the EU continue to be recognised as authorised representatives in 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.

7. 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’ 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 non-automatic weighing instrument or, where this would require the packaging to be opened, 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, some 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 non-automatic weighing instrument on the market an importer must ensure that the appropriate conformity assessment procedures referred to in Schedule 7 have been carried out by the manufacturer. This means that the instrument must comply with the essential requirements set out in Schedule 6. They must ensure that the manufacturer has drawn up technical documentation; the instrument bears the UKCA marking and the M marking and is accompanied by the required instructions and information in clear, legible and easily understandable English.

2. When deemed appropriate with regard to the performance of a regulated non-automatic weighing 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 instruments and recalls of instruments, and keep distributors informed of any such monitoring.
3. Importers must indicate their name, registered trade name or registered trademark and postal address in clear, legible and easily understandable English. Where this would require the packaging to be opened it may be provided on the packaging or accompanying documentation.

4. The importer must keep a copy of the declaration of conformity and technical documentation for a period of 10 years after the regulated non-automatic weighing instrument has been placed on the market.

5. The importer must ensure that regulated non-automatic weighing instruments under their responsibility are stored and transported in such a way that does not jeopardise conformity with the essential requirements.

6. The importer must take action where they consider or have reason to believe that regulated non-automatic weighing instruments they have placed on the market are not in conformity with the 2016 Regulations as amended.

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

8. **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 7 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 non-automatic weighing instruments available on the market.

   The obligations of distributors include:

   1. Before making a regulated non-automatic weighing instrument available on the market a distributor must take due care to ensure that it is in conformity with the 2016 Regulations as amended.

   2. Before making a regulated non-automatic weighing instrument available on the market a distributor must ensure that it bears the UKCA marking and the M marking, and that it is accompanied by instructions and information 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 non-automatic weighing instruments under their responsibility are 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 non-automatic weighing instruments, they have placed on the market or put into use are not in conformity with the 2016 Regulations as amended.

   5. The distributor must also cooperate with and provide information to a competent authority following any requests.
9. 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 prior to the UK leaving the EU do not need reassessment before being placed on the UK market. Furthermore, for a time-limited period, products assessed by an EU recognised notified body can be placed on the UK market. (For the status of UK notified bodies, please see section 11 below).

This 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.

10. 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, 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 UKCA 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.

Non-automatic weighing instruments exported to the EU Single Market must comply with EU Directive 2014/31/EU.

11. 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.

UK 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 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 [to be added].

12. Enforcement

In Great Britain local Trading Standards authorities (including in relation to Part 7 – Use for Trade of Regulated Non-Automatic Weighing Instruments in Great Britain), and in Northern Ireland the Department for the Economy, are responsible for enforcing the 2016 Regulations as amended (other Part 7).

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).
The Regulations provide the power to market surveillance authorities 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 enforcement 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 non-automatic weighing instruments which present a risk in relation to any regulated purpose.

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.


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.

13. Where to find out more about Directive 2014/31/EU

You can find further and more detailed guidance on Directive 2014/31/EU here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2014.096.01.0107.01.ENG

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/

14. Glossary

- **Approved Bodies** – A conformity assessment body which has been approved by the Secretary of State or was a ‘Notified Body’ prior to the UK leaving 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, among other things, the following:
  o The specific regulated non-automatic weighing instrument to which the declaration is referring;
  o 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 non-automatic weighing instrument was placed on the market. This declaration must be made available to the enforcing 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 trading standards is the competent authority responsible for enforcing the 2016 Regulations. In Northern Ireland the Department for the Economy are responsible for enforcing the 2016 Regulations (other than Part 7 as amended).

- **Importer** – A person established in the UK who places a regulated non-automatic weighing instrument from a country outside of the UK on the market. A person who before the UK left the EU distributed non-automatic weighing instruments within the EU (including the UK) or from Switzerland will now be an importer if they are bringing regulated non-automatic weighing instruments into the UK from another country (including EEA States or Switzerland).

- **Manufacturer** – A person who manufactures a regulated non-automatic weighing instrument or has a regulated non-automatic weighing 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.