

Introduction

If you import into, or manufacture equipment in the EU, it must comply with all of the requirements of all of the directives that apply to it. It is your job to ensure that this is the case. Simply relying on the CE mark being present is not a sufficient defence to prevent possible investigation or prosecution. You will have to undertake some of your own tests and back them up with all of the technical information relating to the equipment

What is market surveillance?

It is the responsibility of all governments to ensure that instruments that are placed on the market comply with all aspects of the Directives that apply to them.

If you take responsibility for manufacturing or importing weighing instruments it will be up to you to ensure that you comply with the requirements of all directives by carrying out checks on the instruments that you supply. A failure to carry out any checks may leave you open to action, and potential prosecution, by market surveillance authorities.

What is the difference between market surveillance and inspections?

Market Surveillance takes place when the instrument is first verified and put into use. This may be at the place that it is manufactured or imported, but if the accuracy is dependent upon where the instrument is used, such as weighbridges, the market surveillance will be carried out there.

Market surveillance will examine all of the technical aspects of the weighing instrument. In practice this will involve checking that the instrument complies with all aspects of the type approval certificates. It may involve a relatively cursory check, but could involve the market surveillance authorities examining all of the technical files relating to the instrument and may involve the testing of all aspects of the machine to ensure compliance. This can be very time consuming and the manufacturer or importer can be responsible for the any failure to comply with any of the requirements.

Inspection takes place after the instrument has been put into use, and will invariably be carried out by a local Weights and Measures Inspector. Inspection usually involves checking the accuracy of the instrument although some of the checks carried out when doing an inspection can be considered market surveillance.

Is the difference between market surveillance and inspection important?

The main difference between market surveillance and inspection is the powers available to the authorities if a manufacturer or importer does not comply with the requirements. If a non-compliance is revealed during an inspection, the instrument can be rejected, a notice can be left or advice can be given. The effect of the enforcement invariably will only relate to that instrument.

If the non-compliance relates to a matter of meeting the requirements of the directives, the market surveillance authority can ask for all instruments in the market place with that non-compliance to be withdrawn, can issue a warning to all other European states informing them of the problem. In certain circumstances can withdraw the right of the manufacturer to make EC Declarations of Conformity for up to a month.

If manufacturers or importers are to avoid the draconian powers that can be used they must take positive steps to ensure compliance

What should I do?

If you are a manufacturer, authorised representative or importer into the EU of equipment you must take positive steps to ensure that you are meeting the obligations of the directive. To do nothing will leave you open to actions in the event of a non-compliance being discovered by the authorities.

These checks do not have to be a repeat of the type approval test, but will be at a lower level to ensure that you have taken steps to ensure compliance. You would only need to keep the paper work records suggested in 1) below for each type of instrument that you manufacture or import, The number of instruments that you should carry out checks on will be dependant upon the type and number of instruments and whether you operate as a manufacturer or importer. If you are an importer it should include a small number of instruments in each batch that you import.

- 1) Checking and keeping a copy of all aspects of the technical assessments that have taken place ensure compliance of the instrument. This would include not only those certificates or reports that relate to the weighing aspects, but any documentation that relates to electrical safety or electromagnetic immunity.
- 2) To ensure that all of the appropriate markings are on the instrument and that the markings relate to the instrument to which they are applied: Is the maximum capacity of the instrument and the range of the tare the same as the one marked?
- 3) To ensure the correct edition of the software is on the instrument.
- 4) Correct sealing of the instrument to ensure that the security of the instrument is maintained. This should include the security of any software.
- 5) If you are not verifying the instrument you may carry out some basic metrological tests. This should include the application of known loads to the instrument and may include such things as a checking the instrument when the instrument is very hot or very cold or leaving a load on the instrument to check it does not creep.

This list is not exhaustive, but is intended to give examples of the type of checks that could be done.

It may not be necessary to carry out the suggested checks on each instrument. Depending upon the nature of your business they could be done on a sample of each consignment.

A checklist is attached to this document which may be of use in designing the type of checks that you carry out on the instruments. You should always keep records of the checks so that any inspection or market surveillance authority can see what you have done.