

WELMEC Addendum to Guide 8.4
Issue 1

WELMEC

European cooperation in legal metrology

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WELMEC is a co-operation between the legal metrology authorities of the Member States of the European Union and EFTA. This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to Notified Bodies responsible for conformity assessment of their products. The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EC Directives. Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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Addendum to the Welmec guide 8.4

This addendum is intended to provide guidance when a manufacturer of a measuring instrument or sub-assembly is using parts that are critical regarding the conformity of the measuring instrument or sub-assembly to the essential requirement of the MID.

Definitions

Part

A part of a measuring instrument or a sub-assembly, which performs a specific function and can be evaluated separately. This also includes peripherals, for example but not limited to: printers, data storage devices and (personal) computers.

Producer

The Original Equipment Manufacturer that produces the part.

Manufacturer

A natural or legal person responsible for the conformity of the measuring instrument or sub-assembly with the MID with a view to either placing it on the market under his own name and/or putting it into use for his own purposes.

Responsibility

The manufacturer of the measuring instrument or sub-assembly may not transfer its responsibility regarding the conformity of the production of the part to the producer.

Audit of a producer

The provisions described in chapter 7.4 (Purchasing) of the Welmec guide 8.6 apply to the purchase of parts. Consequently, in some cases a notified body (NB) may consider that it is necessary to audit a producer.

Some producers provide parts to several different manufacturers and consequently it is possible that those producers will be audited several times in a year by more than one NB in charge of Module D for each of the different manufacturers. To reduce the costs associated with these audits, a producer may decide to be audited by one of these NB independently from the audits of manufacturers, following the provisions defined in guide 8.4. When this is the case, the NB in charge of the quality system (QS) approval of the manufacturer may take into consideration the audit reports issued by the NB that has evaluated the QS of the producer. To this aim, these audit reports are to be held available for the NB in charge of the QS approval of the manufacturer, by the producer.

It is not foreseen in all cases that the quality system of the producer has to be certified. However, in the case of voluntary audits, the report and the procedure used shall be in conformity with the guides 8.4 and 8.6 with the necessary adaptation.

Documentation

The manufacturer shall make available the technical documentation of the approved type and a copy of the EC type-examination certificate with the application for assessment of the quality system. This includes the technical documentation relating to the used parts.