

Guideline

4/15

CLAP

FORM N°290

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Directive 97/23/EC

Keywords :

Quality assurance

Declaration of conformity

Certificate

Conformity assessment

Directive references:

Article 15 § 1 - 97/23 EC

Annex III - Module D - 97/23 EC

Annex III - Module E - 97/23 EC

Annex III - Module H - 97/23 EC

Adopted by WPG: 06/03/2012

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Subject: Conformity assessment – Expiry date of QA certification

Question:

A manufacturer has equipment in stock manufactured under a QA module (D/D1, E/E1 or H/H1). After expiry of the QA system certification the manufacturer switches from Notified Body "X" to Notified Body "Y" for the new certification. Can the manufacturer deliver equipment with Notified Body number "X" to his customers after the expiry date of the certificate?

Answer:

Yes, provided that the final assessment has been performed under the QA system certified (and surveyed) by Notified Body "X" before the expiry date of the system certificate.

The manufacturer must keep records of which notified body approval his equipment was manufactured under. One solution is to include a date on the declaration of conformity.