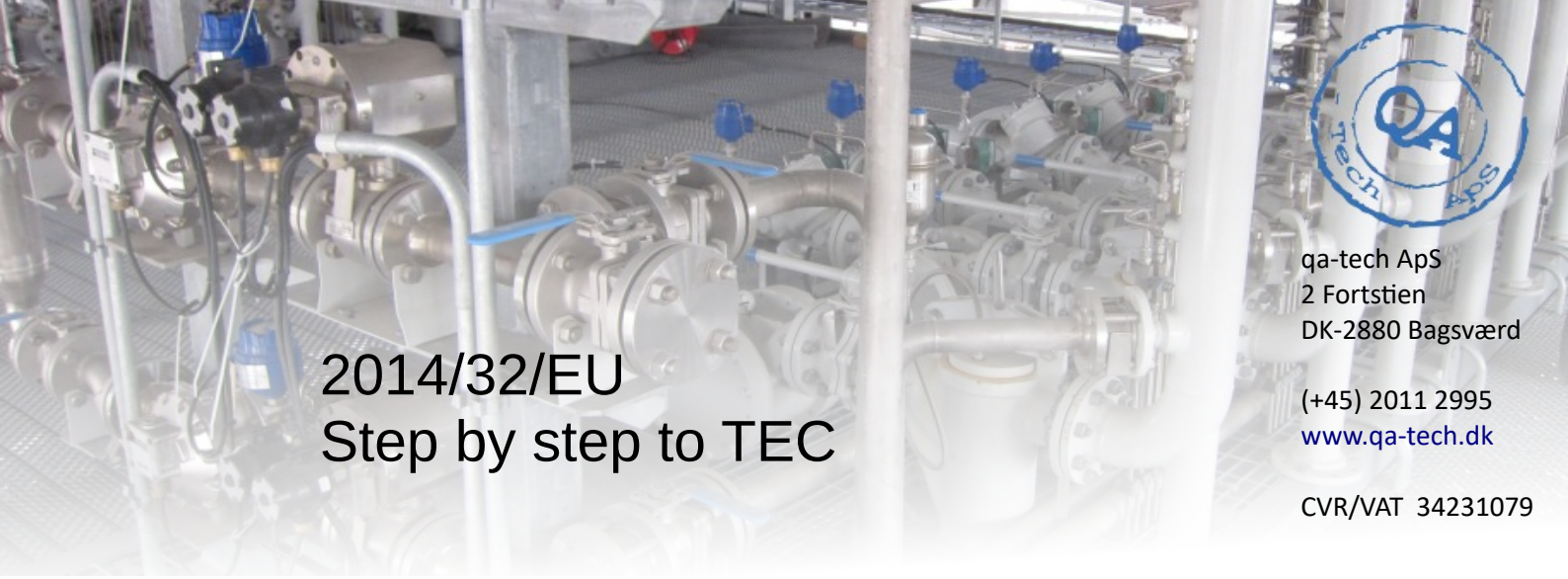

2014/32/EU
Step by step to TEC

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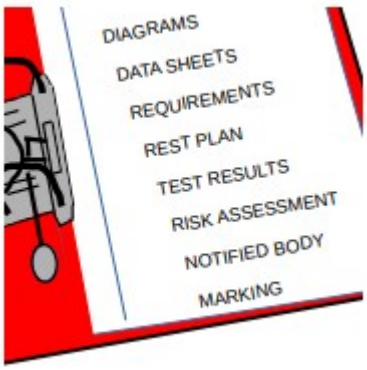
Contents

Summary

This paper describes how to prepare for an EU TEC. It is focussed on the measuring Instruments directive, but most parts apply to other product directives as well.



Step 1 Define your product

As for all products documentation is critical. You need to define your product and the definition needs to be sharp and factual. This is not a sales talk, but precise descriptions of materials, functionality, risks and methods.

Key components in this are

Product name	The name will be used later on in you application
Overviews of the product	Overviews of the product like split drawings, system overviews may be useful. If the product consists of more parts or if product functionality is distributed over more parts an overview is needed.
Description	A clear description of the product and its application is also a clear limitation of your liabilities and therefore also a less economic risk for you as a manufacturer.

Step 2 Find the requirements for the product

Requirements can be hard to find, but you need to make sure that you have a good understanding of all the requirements relevant for your product. Some products may have requirements found in other sectors, like the fiscal sector or national regulations on accessibility may apply.

Key components in this are

Define the market	Requirements are different for different markets
Check for every sub-assembly	Some parts may be subject to e.g. fiscal regulations

Step 3 Document your product

Based on the defined product full documentation is needed. This is of cause especially needed if the product is developed and constructed by you, as it is a basic requirement for all products.
It is also needed if your product is based on some finished parts or sub-assemblies from other manufacturers alone or combined with parts of your make.

Key components in this are

Documentation of components	Description and specifications on all components that are relevant to the product
Diagrams, drawings, BOM’s	
Software	Software is a component too. OIML R117-1:2019 and WELMEC WG7.2 needs to be fulfilled.
Acceptance to use	For some components it may be required to obtain acceptance from a certification owner (another manufacturer or even a competitor) to make use of the component in your product.

Your final product	The final product needs to meet the requirements. It is not enough that the individual components on paper may seem to do the job. You need to make sure that the combination works according to requirements
User documentation	Users are authorities, installers, operators, repairers, decommissioners.
Define markings/labels	Specific marking may appy to your product. In case of 2014/32/EU, there are requirements for various environmental parameters as well as somemetological date. General information on marking is found in the Blue Guide and specific information in each directive and in some cases also in WELMEC guides.

Step 3 may include a testing plan for the final product.
In case tests are to be carried out, make sure that the tests are made in a way that they are accepted by Notified Bodies.
Tests that are performed according to harmonized standards etc. and are reported as accredited tests are accepted by most (should be all) Notified Bodies.

When you have sufficient information on your product, carry out a risk analysis and a risk assessment. The scope should be “does the product meet the essential requirements”. Risk assessment may prove that you need to redefine something. The earlier you find a need to make changes, the better.

Step 4 Decide on which the conformity module(s) to use

For some product directives, like 2014/32/EU, it is mandatory, that the manufacturer contracts a Notified Body to assist the manufacturer in the conformity process. Most products does not have this requirement.

All products make use of a model, where the manufacturer may chose between more modules.

Module	Covers	Description
An Internal production control	Design & production	The manufacturer ensures the conformity of the product to the legislative requirement
A1 Internal production control plus supervised product testing		A + tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer
A2 Internal production control plus supervised product checks at random intervals		A + product checks at random intervals carried out by a notified body or in house accredited body.
B EU-type examination	Design, only	Module B is always followed by one other module by which the conformity of the product to the approved EU-type is demonstrated.

		A Notified Body examines the technical design and or the specimen of a type and verifies and attests that it meets the requirements of the legislative instrument that apply to it by using an EU-type examination certificate.
C Conformity to EU-type based on internal production control	Production and follows module B	Manufacturer must internally control the production in order to ensure product conformity to the EU-type certified under module B
C1 Conformity to EU-type based on internal production control plus supervised product testing	Production and follows module B	C + tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer
C2 Conformity to EU-type based on internal production control plus supervised product checks at random intervals	Production and follows module B	C + product checks at random intervals carried out by a notified body or in house accredited body.
D Conformity to EU-type based on quality assurance of the production process	Production and follows module B	The manufacturer operate a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to EU-type. The Notified Body assesses the quality system.
D1 Quality assurance of the production process	Design & production	The manufacturer operate a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to legislative requirements (no EU-type, used like D without module B). The Notified Body assesses the production (manufacturing part and inspection of final product) quality system
E Conformity to EU-type based on product quality assurance	Production and follows module B	The manufacturer operates a product quality (=' production' quality without the manufacturing part) assurance system for final product inspection and testing in order to ensure conformity to EU-type. A notified body assesses the quality system. The idea behind module E is similar to the one under module D: both are based on a quality system and follow module B. Their difference is that the quality system under module E aims to ensure the quality of the final product, while the quality system under module D (and D1 too) aims to ensure the quality of the whole production process (that includes

		the manufacturing part and the test of final product). E is thus similar to module D without the provisions relating to the manufacturing process.
E1 Quality assurance of final product inspection and testing	Design & production	The manufacturer operates a product quality (=' production' quality without the manufacturing part) assurance system for final product inspection and testing in order to ensure conformity to the legislative requirements (no module B (EU-type), used like E without module B). The notified body assesses the quality system. The idea behind module E1 is similar to the one under module D1: both are based on a quality system. Their difference is that the quality system under module E1 aims to ensure the quality of the final product, while the quality system under module D1 aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E1 is thus similar to module D1 without the provisions relating to the manufacturing process.
F Conformity to EU-type based on product verification	Production and follows module B	The manufacturer ensures compliance of the manufactured products to approved EU-type. The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to EU-type. Module F is like C2 but the notified body carries out more systematic product checks.
F1 Conformity based on product verification	Design & production	The manufacturer ensures compliance of the manufactured products to the legislative requirements. The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to the legislative requirements (no EU-type, used like F without module B) Module F1 is like A2 but the notified body carries out more detailed product checks.
G Conformity based on unit verification	Design & production	The manufacturer ensures compliance of the manufactured products to the legislative requirements. The notified

		body verifies every individual product in order to ensure conformity to legislative requirements (no EU-type).
H Conformity based on full quality assurance	Design & production	The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements (no EU-type). The notified body assesses the quality system.
H1 Conformity based on full quality assurance plus design examination	Design & production	The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements (no EU-type). The notified body assesses the quality system and the product design and issues an EU design examination certificate. Module H1 in comparison to module H provides in addition that the notified body carries out a more detailed examination of the product design. The EU-design examination certificate must not be confused with the EU-type examination certificate of module B that attests the conformity of a specimen 'representative of the production envisaged', so that the conformity of the products may be checked against this specimen. Under EU design examination certificate of module H1, there is no such specimen. EU design examination certificate attests that the conformity of the design of the product has been checked and certified by a notified body.

Each product directive will list the possible combinations of conformity modules for a specific product group.

For fuel dispensers dispensing liquid fuel, this is modules B+D, B+F, G and H1.

It is the free choice of the manufacturer to chose from the possible combinations of modules.

Step 5 Choose a Notified Body

Notified bodies operate within the EU inner market (EEA). You may chose a German or French notified body at your convenience. Language, track record and tradition may influence on which Notified Body to choose. Some are more flexible than others and some are more expensive than others.

qa-tech advise is to always ask for a quotation based on the documentation is step 1 + step 2 + step 3.

Be aware: Once you have committed yourself to a Notified Body, you are stuck with it. You cannot change Notified Body once the conformity process is initiated. In most contracts with Notified Bodies, you need to declare that you do not seek the aid of another Notified Body.

BREXIT was a chock to some manufacturers, which had used NMO in Teddington as Notified Body. When Brexit was a reality, there were no Notified Bodies in the UK and updates or expansions of certificates were impossible.

Remember that the Notified Body is meant to assist the manufacturer. There may well be as specific form or layotu the Notified Body sticks to, but mostly it is possible to imclude information relevant to the manufacturer in the module B certificate.

References

Reference	Title	Available here
2014/32/EU	Measuring instrument directive	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0032
Blue Guide	OIML Recommendation R117	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2022.247.01.0001.01.ENG&toc=OJ%3AC%3A2022%3A247%3ATOC
WELMEC WG 7.2	Software Guide (Measuring Instruments Directive 2014/32/EU)	https://www.welmec.org/welmec/documents/guides/7.2/2023/WELMEC_Guide_7.2_2023.pdf
OIML R117:2019	Dynamic measuring systems for liquids other than water	https://www.oiml.org/en/publications/recommendations/en/files/pdf_r/r117-p-e19.pdf

More information

“Trin for trin teknisk dossier” an article (in Danish language) elaborates on the process from product idea to CE-marked product. Available here http://qa-tech.dk/download/step2.pdf.

“Step by step Technical Dossier” same article in English language. Available here http://qa-tech.dk/download/stepbystep.pdf.