FORCE Certification A/S

ABC-EU Directives

General Terms for Conformity Assessment of Products, Processes and Services

11th. edition – March 2023

(Supersedes ABC-EU Directives, 10th. Edition January 2023)

Content

1. Introduction and Basis for Product Certificates

The terms in this ABC-EU Directives, shall be complied with to obtain and maintain a conformity assessment of a product according to international and national standards, EU-Directives/Regulations, accreditation requirements and guidelines.

The General Conditions of FORCE Certification A/S cannot be deviated, and they have priority to all other provisions. Additionally, the requirements in this ABC cannot be dispensed and overrules all other terms, which may have been applied.

On our homepage www.forcecertification.com we have published an informative guide describing the conformity assessment procedures. This guide gives a broader understanding of the certification process and a guide to the information which shall be available. We recommend you to read this guide.

The informative guide cannot replace the requirements described in this ABC.

Definitions:

- ***manufacturer*** is used as collective term for manufacturer, his authorized representative in EU, importer, owner and the installation contractor;
- ***certificate*** is used as collective term for e.g. EC-type examination certificate, conformity assessment certificate, inspection reports;
- ***certification*** is used as collective term for the conformity assessment process of a certification, verification or inspection;

This ABC applies to conformity assessment according to the conditions in:

Table 1:

Acronym	Directive No.	Directives and Regulations
EMC	2014/30/EU	DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility
LIFT Annex V	2014/33/EU	DIRECTIVE 2014/33/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts
MarED	2014/90/EU	DIRECTIVE 2014/90/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC
MID	2014/32/EU	SIK 544 dated 28/05/18: Act regarding making available on the market of measuring instruments
NAWI	2014/31/EU	SIK 1381/16: DIRECTIVE 2014/31/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments
PED Excl. Module A2	2014/68/EU	AT 190/2015: DIRECTIVE 2014/68/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment
PPE	89/686/EØF (EU)2016/425	AT 683/13: DWEA Act No. 683 of 10th June 2013 regarding arrangement etc. of personnel protective equipment REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC[1]
RED	2014/53/EU	DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC
SPVD	2014/29/EU	Act 1304/15: DWEA* Act No. 1304/15 of 23rd November 2015 regarding arrangement etc. of simple pressure vessels
TPED	2010/35/EU	Act 685/13: DIRECTIVE 2010/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC,

1. Accreditation and notification in progress
AT: Danish Working Environment Authority
SIK: Danish Safety Technology Authority

The Quality modules D, D1, E, E1, H, H1 are performed according to ABC-SYS, General terms for management systems.

2. General

Issued and valid certificates are the property of FORCE Certification A/S (FC).

It is not permitted to apply for an EC-Type Examination from more than one Notified Body.

The manufacturer shall:

- forward an application stating the manufacturer's choice of module(s) or section(s) including a declaration that a similar application has not been forwarded to another Notified Body
- give our examiners and inspectors from FC access to the products and the production, including (if relevant) access to equipment, facilities, personnel and subcontractors
- forwarding all technical documentation (technical file) regarding the product as described in the directive/regulation
- maintain and file all necessary documentation concerning the product

3. Changes in current Standards, Accreditation Requirements and Guidelines

If, within the period of validity of the contract the requirements to achieve and maintain a conformity assessment according to the international and national standards, accreditation requirements and guidelines change, the manufacturer shall implement these requirements before the date of commencement. The conformity assessment contract shall be changed accordingly.

4. Recording of Complaints (This paragraph is not applicable for PED, TPED and SPVD Directives)

The manufacturer is obliged to set up a registration of complaints relevant to certified products in accordance with this ABC. This registration shall:

- record all complaints, which the manufacturer learns about the product's compliance with the requirements in the relevant standards
- be made available to FC

The manufacturer shall take appropriate action with respect to such complaints and recorded defects which might influence the fulfilment of the certification requirements.

The manufacturer shall document the actions taken.

5. Modification of the Product or the Production Conditions

It is the obligation of the manufacturer to immediately notify FC of any modification to the design of the product that may affect compliance with a FC issued EC-Type Examination Certificate.

Modifications to design include modifications such as:

- legal, commercial, organisational status or ownership
- organisation and management, for instance changes of quality management, decision making or technical key personnel
- any modification to the product or the production method
- changing of production places/sites
- essential modification of the management system (quality)

Concerning modifications FC decides whether the product can continue to be marketed under the current certificate or whether it must be suspended while a revised/new certificate can be worked out. This again might mean that further examination/testing may be necessary.

6. Rules for Communication concerning the Certification

The customer must ensure that all communication referencing the certification of the product comply with the following requirements:

- FC's requirements shall be observed when the customer refers to his certification status in the media such as the Internet, brochures or advertisements or in other documents
- there is made no misleading declaration about the certification
- the impression will not be given that the certification is valid for products or activities beyond the scope of the certification
- the certification will not be used in a way that could bring discredit to FC and/or the certification system and reduce the trust of the public
- certificates are published only in their entirety and extracts of certificates can only be published with FC's permission in writing
- all communication, which refers to the certification is to be stopped immediately if the certification is suspended, withdrawn cancelled or the scope is reduced

7. Rules for use of the Certification Mark

DANAK's accreditation mark must not be used by the customer, manufacturer or legal representatives. This includes any use of the mark on certified products, documents, or any kind of material (including electronic and digital use).

The manufacturer's use of FC's certification mark (our logo incl. certification scope) requires an agreement in writing with FC. The use of certification marks must comply with the following minimum rules:

- the mark must be reproduced in its entirety in a reasonable size and uniform colour and must be accompanied by the number of the standard, which the certificate covers
- the mark may only be used in a manner, which promotes the manufacturer's certified product
- the mark must not discredit the certification attained
- all use of the certification mark must stop immediately at the expiry of the period of validity of the certificate
- all use of the certification mark referring to the certificate is ceased immediately, if the certification is suspended, withdrawn or cancelled

8. Use of FORCE Certification A/S's Identification Number "0200"

The Notification Body identification number for FC is 0200.

The identification number shall only be affixed on the product, if the product is under surveillance of FC, which means that FC has issued one of the modules A1, A2, C, C1, C2, D, D1, E, E1, H or H1 certificates covering the applicable type of product and production. In this case the identification number shall be affixed after the mark of conformity (e.g. "CE 0200") according to the requirements given in the relevant Directive or Regulation. The manufacturer signs an agreement with FC on continuous surveillance prior to affixing the identification number on the products.

If FC assesses that the product cannot fulfil the requirements of the Directive or Regulation, FC may suspend or terminate the agreement - please see chapter 9.

The identification number cannot be affixed to products, where FC does not perform continuous surveillance under one of the mentioned modules.

The identification number is also placed on products when conformity assessment is performed under module F or G. In this case FC place the identification number on the product(s) or appoints a representative of the manufacturer to do so.

9. Withdrawal, suspension and cancelling of certificates or agreements

Should the manufacturer decide, that they no longer can or will maintain the certificate, FC will cancel the certificate after having given written notification according to the conformity assessment agreement.

FC has the right and obligation at any time during its term of validity to:

- withdraw or suspend a certificate,
- cancel or suspend an agreement to use of our Notified Body identification number 0200

under the following circumstances:

- if the manufacturer has given misinformation
- if the test results do not fulfil the specified requirements after retesting
- if the manufacturer does not take corrective action within the time limits agreed upon
- if the manufacturer refers incorrectly to the certification and its conditions
- if the manufacturer misuses the certificate, the agreement or the mark
- if the manufacturer does not comply with the financial terms and conditions of the certification agreement
- if the manufacturer in any way brings discredit to FC or violates the certification agreement

A manufacturer shall be notified of withdrawals in writing, and the letter must include information about appeal procedures.

FC will make public any such certificate suspension, withdrawal, or cancellation in the manner, that FC finds most relevant in the specific case. In all cases FC is obliged to inform other Notified Bodies and or Notification Authorities where certification is refused, suspended, withdrawn or reduced.

Immediately after the announcement of suspension, withdrawal or cancellation, the certificate is no longer valid.

Immediately after the announcement to cancelling or suspension of the agreement to use of our identification number, the manufacturer shall suspend all marketing (sale) of the product(s) with our Notified Body identification number affixed.

10. Confidentiality

FC treats all information gained by its representatives, including any sub-suppliers during the certification process or in any other manner as strictly confidential and will not pass on such information to unauthorised persons without the written consent of the manufacturer in question. FC has taken measures to ensure that confidential information is not accessible to unauthorised persons.

FC is under an obligation upon request to supply responsible authorities – including Danish or European Market Surveillance Authorities – and the accreditation body DANAK with all necessary information for use with its surveillance of our notification or accreditation. FC is under an obligation to receive surveillance visits by Market Surveillance Authorities or DANAK, and the manufacturer must accept that such a surveillance visit can include the conformity assessments activities at the manufacturer's premises.

Provisions related to GDPR

FC does not require general access to manufacturer's registrations including registered personal data, and access to sensitive personal data must be cut off. FC will not select or extract personal data from the manufacturer's registrations.

FC must have the opportunity to evaluate a representative number of employees in order to assess the competence of the staff within the applied certification scheme. This review will mainly take place when visiting the manufacturer's premises. If, in case of applications or documentation of corrective actions, the manufacturer sends evidence of employee competence to FC. This documentation shall not contain any personally sensitive information including Danish CPR numbers, special categories of personal data, union membership or health information. FC deletes documents containing personal data after the assessment.

11. Appeals and complaints

An appeal against a decision made by FC shall be addressed in writing to FC within 4 weeks after the manufacturer has received the decision.

A complaint against FC's activities in connection with the certification shall be addressed in writing and be received by FC within 4 weeks after the issue date of the certificate.

A complaint against FC as a Notified Body can always be submitted directly to the Notifying Authority.

Information on contact and procedure for appeals and complaints appears on www.forcecertification.com.

12. Publication

FC undertakes to publish an up-to-date list with the following information about the registered certificates:

- number of certificate, date of issue and date of expire
- full identification about manufacturers and suppliers (name, address(es))
- identification of the product type
- relevant standards and type testing reports
- special limitations with respect to the scope
- status concerning validation, suspension or withdrawal

13. Cancellation

The conformity assessment agreement can be cancelled by both parties with 90 days written notice.

In the notice period the certificate remains valid, if the product certification is maintained according to the conformity assessment requirements.

14. Special module requirements

14.1 Module A & C and unannounced surveillance

For product certification after module A1 and C1 or surveillance according to SPVD or PED FC shall witness the final verification through unannounced visits, and take samples of the product for further testing, if necessary. On request from FC the manufacturer shall give at least a 2 weeks' notice of production plans.

For conformity assessment in accordance with module A2 or C2 FC shall during onsite visits survey the final verification of the product or take sample of the product for inspection. A conformity assessment according to module C2 is based on an agreement on control between the manufacturer and FC.

14.2 Module B

EC-Type Examination Certificates (module B) may have a limited validity according to the relevant Directive or Regulation, and may be prolonged in the event that not changes is made to the product specifications or design.

14.3 Module F & G

To verify conformity with requirements FC shall witness the test of each product[i] or each production unit for the following modules:

- product verification /final inspection (module F), or
- unit verification (module G)

15. Safety and Access

The manufacturer must ensure that the necessary examinations performed during audits or inspections according to modules A2, Bp, C2, F or G can be carried out in a fully safe manner in accordance with the rules of the working environment legislation, - including the necessary protection against unintentional start-up and special safety measures during internal inspections of equipment.

If FC assesses that it is not possible to carry out the audit or inspection properly in accordance with the rules of the working environment legislation, the audit or inspection will be postponed until the conditions are safe.

In case of inspection of equipment the manufacturer must ensure that the equipment is prepared for the inspection prior to the visit including cleaning, so that the inspection can be carried out in a safe manner. If the manufacturer has special guidelines that must be followed - e.g. the use of special clothing, safety equipment or requires special training, this should be notice to FC and must be agreed prior to inspection.

[i] *Depending on actual Directive or Regulation this can be performed according to a statistical approach.*

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Changes from 10th ed.:
- *Certification of lifts according to LD has been implemented in table 1.*
- *Certification of pressure equipment has been revised in table 1.*

Changes from 9th ed.:
- *FORCE Certification A/S general conditions also applies. This is added in par. 1*
- *Provisions for use of accreditation mark has been updated in par. 7*
- *Obligation to inform other notified bodies and/or notification authorities has been added in par. 9*

Changes from 8th ed.:
- *Safety and Access par. 15 added*
- *Obligation to accept visits from Market Surveillance Authorities is added to par. 10*
- *Minor editorial changes*

Changes from 7th ed.:
- *Conformity assessment requirements for modules A2 and C2 are updated in section 14.1*

Changes from 6th ed.:
- *clarification on use of notification number in par. 8*

Changes from 5th ed.:
- *Table 1 updated with new act No. 544 for MID*

Changes from 4th ed.:
- *Provisions implemented in par. 10 regarding GDPR*

Changes from 3rd ed.:
- *SIK 313/16 updated to SIK 1382/16*
- *SIK 312/16 updated to SIK 1381/16*

Changes from 2nd ed.:
- *Dates of implementation for new directives are deleted from table 1*
- *EMD and RED are added*