

Information on implementation of Regulation no. (EU) 2016/425 on personal protection

Introduction

As previously communicated, the Directive on personal protection no. 89/686 will be replaced by Regulation no. (EU) 2016/425 on personal protection throughout 2018 and 2019.

Will there be new performance and functional requirements for the personal protection equipment?

As a point of reference, the requirements for the performance and function of the personal protection equipment is somewhat similar for the Directive 89/686 and Regulation (EU) 2016/425. Personal protection equipment that already complies with the newest harmonised standard, will usually not require renewed test to be in accordance with the Regulation. However, there is a sharpened requirement that personal protection equipment must continue to comply with any additional requirements which may have occurred together with the new and recognised knowledge on health and safety, even if it is not yet part of the latest harmonised standard; the so called "State-of-the-art". Manufacturers must observe that certified personal protection equipment which is placed on the market can always be regarded as "State-of-the-art".

Dates and validity of new and existing certificates

Regulation no. (EU) 2016/425 will come into force on 21 April 2018. From this date, new and existing protection equipment may be marketed with referral to accordance with the Regulation.

There will be a transition period until 20 April 2019, until when existing protection equipment, certified according to Directive no. 89/686 can still be marketed, with reference to accordance with the Directive.

On 21 April 2019 Directive no. 89/686 shall be repealed, after which date all marketed personal protection equipment must be in accordance with Regulation no. (EU) 2016/425 in one of the following ways:

- 1) The protection equipment must be certified by a notified body as per the Regulation. All new certifications and all re-certifications of existing protection equipment must be as per the Regulation after 21 April 2019.
- 2) Protection equipment with a valid certificate as per the Directive, with an expiration date, later than 21 April 2019 may under certain conditions still be marketed with referral to the Regulation. Therefore, it is not paramount to possess a certificate issued as per the Regulation, as long as the protection equipment still meets the latest "State-of-the-art" technical requirements, and the manufacturer adjusts the file of the protection equipment, including up-dating of references in the declaration of conformity, the user manual etc. However, all certificates issued as per the Directive will expire on 21 April 2023, unless an earlier expiration date is stated. If the protection equipment is still requested marketed after the expiration of the certificate, possibility 1, as described above, applies.

Please observe:

Apart from requiring that protection equipment must always be "State-of-the-art", manufacturers should also appreciate that the Regulation specifies in extensive detail, which technical documentation must form the basis of a type-examination; of which it is worth mentioning:

- Sharpened requirements as to how the manufacturer describes the protection equipment and its intended use, and as to which of the essential health and safety requirements that are relevant.
- Sharpened requirements to the manufacturer to form an assessment of the risks against which the equipment is to protect, including measures to hinder incorrect or improper use. *
- Updated requirements as to the information to be stated in the instruction manual.
- Update of, to which references the Declaration of Conformity should refer.
- Clarification as to which responsibilities should be handled by: the manufacturer, the importer and the distributor.

*) Interpretation of the level of detail in the risk assessment has not been conclusively decided yet. For the time being, it will be satisfactory if the product meets the requirements of the latest harmonised standard.

Extension of Category III

For the protection equipment pertaining to category III, i.e. protection equipment that will protect against dangers which might result in casualties or irreversible damages to the health, requirements for a notified body to conduct annual production control shall remain. In the Regulation, the list of selected types of protection equipment placed in category III has been extended and now includes:

- Equipment for protection against chemical compounds and mixes hereof, which form a health risk
- Equipment for protection against oxygen deficiency
- Equipment for protection against harmful biological compounds/matter (New)
- Equipment for protection against ionising radiation
- Equipment for protection against temperatures corresponding to 100°C or higher
- Equipment for protection against temperatures corresponding to -50°C or lower
- Equipment for protection against fall from heights
- Equipment for protection against electricity
- Equipment for protection against drowning (New)*
- Equipment for protection against damages inflicted by handheld chain saws (New)
- Equipment for protection against damages inflicted by liquids under pressure (New)
- Equipment for protection against damages inflicted by firearms or stabs (New)
- Equipment for protection against harmful noise (New)

*) only applies to lifejackets level 100 N, 150 N, and 275 N. Not 50 N buoyancy aids.

1) In general, for new protection equipment, not previously certified:

If, as a manufacturer, you produce a new type of protection equipment, you will have to declare accordance with the Directive or Regulation (or both at the same time) by:

- Carrying out a type-examination as per the Directive with a notified body.
- or*
- Carrying out a type-examination as per the Regulation with a notified body.

It is only possible to perform a type-examination as per the Directive until 20 April 2019.

2) In general, for existing protection equipment, already certified as per the Directive:

If, as a manufacturer, you produce a certified type of protection equipment as per the Directive, and meet the design and technical requirements for "state-of-the-art", manufacturers, themselves, may *declare accordance with* the Regulation by 2018-04-21 by:

- Updating the technical file, including marking and instruction

This Declaration of Conformity is valid for protection equipment, category II, as long as the existing certificate, issued as per the Directive, is valid (However, only until 2023-04-21, at the latest), and that the protection equipment continuously is considered "state-of-the-art".

If as a manufacturer, you produce a certified type of protection equipment as per the Directive, and meet the other design and technical requirements for "state-of-the-art", you may *be granted certification* as per the Regulation by:

- Updating the technical file, including marking and user manual
- Carrying out a type-examination as per the Regulation with a notified body.
- If the type-examination is entirely or partly based on test reports, older than 10 years, the notified body may require entirely or partly renewed tests.

If a piece of protection equipment changes from category II to category III, the manufacturer must apply for renewed type-examination as per the Regulation with a notified body.

3) Generally, for old protection equipment, already certified as per the Directive

If as a manufacturer you produce a certified protection equipment as per the Directive, which does not meet the design and technical requirements for "state-of-the-art", you cannot by yourself declare accordance with the Regulation. It is possible to market the protection equipment as being in accordance with the Directive until 21 April 2019, if all other requirements have been met.

If, as a manufacturer, you produce a piece of certified protection equipment as per the Directive, which does not comply with the design and technical requirements for "state-of-the-art", you may obtain certification as per the Regulation by:

- Testing the protection equipment as a "state-of-the-art", usually the present harmonised standard
- Updating the technical file, including marking and the user manual
- Request a type-examination as per the Regulation with a notified body.
- If the type-examination is entirely or partly based on test reports, older than 10 years, the notified body may require entirely or partly renewed testing.

The next step

No matter what you may think of the implementation of the new Regulation, replacing the previous Directive, it will affect everyone who works with personal protection equipment. FORCE Certification A/S offers to assist you with the transformation from Directive to Regulation. It is one of our key competence areas, which is why we can ensure, quickly and efficiently that you may continue to launch your products in the market. Contact us for a non-binding conversation and/or re-certification of your products. We look forward to hearing from you.

Faithfully yours
FORCE Certification A/S

Niels Ovesen
Director

FORCE Certification A/S - Almindelige betingelser

I nedennævnte omfatter certificering også verifikation og inspektion.

1. Aftale om løsning af opgaver

For arbejdet påbegyndes, skal der være truffet skriftlig aftale vedrørende opgavens art og omfang, tidsplan og økonomi.

2. Ejendomsret og ophavsret

FORCE Certification A/S's certifikater, attester m.v. må kun offentliggøres i deres helhed og med kildeangivelse. Anvendelse af uddrag og i citatform må kun ske efter skriftlig aftale herom.

3. Manglende opfyldelse af aftale

FORCE Certification A/S kan ikke gøres ansvarlig for ikke at opfylde aftaler, helt eller delvist, såfremt dette skyldes begivenheder uden for FORCE Certification A/S's indflydelse.

4. Garanti

4.1. FORCE Certification A/S påtager sig at foretage en revideret certificering, hvis der viser sig fejl, der skyldes mangel ved certificeringsprocessen.

4.2. Denne garanti begrænses til fejl, som viser sig inden 12 måneder fra certificeringsdatoen.

4.3. Ved en fornyet certificering skal FORCE Certification A/S have adgang til alt relevant materiale, faciliteter, registreringer m.v. samt til nødvendigt samarbejde med rekvirenten.

5. Ansvar

5.1. FORCE Certification A/S er ikke erstatningsansvarlig for tab eller skade, medmindre det kan dokumenteres, at tabet eller skaden er opstået på grund af fejl eller forsømmelse begået af FORCE Certification A/S i forbindelse med certificeringsprocessen.

5.2. FORCE Certification A/S hæfter ikke for driftstab, tidstab, avancetab eller lignende indirekte tab.

5.3. FORCE Certification A/S løser sine certificeringsaktiviteter på grundlag af gældende standarder og den viden og teknik, FORCE Certification A/S råder over. FORCE Certification A/S påtager sig ikke erstatningsansvar, medmindre det kan bevises, at denne viden eller teknik var mangelfuld på tidspunktet for certificeringen.

5.4. FORCE Certification A/S fralægger sig erstatningsansvar for skader, som måtte indtræffe i forbindelse med en anvendelse af afgivne data og prøvningsresultater, som ligger uden for den opgave og uden for det formål, i forbindelse med hvilke FORCE Certification A/S's har udstedt certifikat/attest.

5.5. FORCE Certification A/S har intet erstatningsansvar for indtrufne skader, såfremt en skade skyldes en egenskab ved et produkt eller en anvendelse af et produkt, som enten ikke er afprøvet eller undersøgt og beskrevet i certificeringsgrundlaget og prøvnings- eller undersøgelsesrapporten, eller som afviger fra FORCE Certification A/S's beskrivelse i certificeringsgrundlaget og prøvnings- eller undersøgelsesrapporten af produktens egenskab eller af en mulig produktanvendelse.

5.6. Hvis andre end rekvirenten rejser krav om erstatning mod FORCE Certification A/S begrundet i forhold, der ligger ud over det erstatningsansvar, som FORCE Certification A/S i henhold til punkt 5.1. - 5.5. har påtaget sig, er rekvirenten pligtig til at overtage sagens førelse og skadesløsholde FORCE Certification A/S for alle omkostninger, herunder sagsomkostninger og erstatningsbeløb.

6. Tvister

Såfremt der opstår tvist mellem rekvirenten og FORCE Certification A/S i forbindelse med udførelsen af en opgave eller fortolkning af aftalen, skal tvisten, såfremt den ikke kan løses ved forhandling mellem parterne, afgøres af Det Danske Voldgiftsinstitut på grundlag af dansk ret.

FORCE Certification A/S - General conditions

The word certification below also includes verification and inspection

1. Agreement

Prior to commencing work, agreement on type and scope as well as timetable and economy shall be made in writing.

2. Ownership and copyright

FORCE Certification A/S's certificates, documents etc. shall only be published in full and with source reference. Extracts shall only be quoted upon prior permission in writing.

3. Non-fulfilment of agreement

FORCE Certification A/S shall neither in whole nor in part be liable for any non-fulfilled agreements owing to events beyond the influence of FORCE Certification A/S

4. Warranty

4.1. Subject as hereinafter set out FORCE Certification A/S shall undertake to perform a revised certification in case of errors owing to a defective certification process.

4.2. This liability is limited to defects which occur or are discovered within 12 months from the date of certification.

4.3. When a certification is under renewal FORCE Certification A/S shall have access to all relevant material, facilities, registrations etc. and to necessary co-operation with the client.

5. Liability

5.1. FORCE Certification A/S shall only be liable for loss or damage if it is proved that the loss or damage is due to errors or negligence by FORCE Certification A/S in connection with the certification process.

5.2. FORCE Certification A/S shall not be liable for any consequential loss, such as but not limited to loss of time or loss of profits.

5.3. FORCE Certification A/S solves its certification activities based on current standards and the knowledge and technology available to FORCE Certification A/S. FORCE Certification A/S shall only be liable if it is proved that this knowledge or technology was faulty at the time of the certification.

5.4. FORCE Certification A/S shall not accept liability for loss or damage that may occur in connection with the client's use of provided data or test results, which lie outside the scope of the task and purpose in connection with which FORCE Certification A/S has issued certificate/document

5.5. FORCE Certification A/S shall not accept liability for damage occurring if such damage is due to a property of a product or an application of a product, which has either not been tested or examined and described in the certification basis and the testing or examination report, or which differs from FORCE Certification A/S's description in the certification basis or the testing or examination report of the property of the product or of a possible application of the product.

5.6. If a third party claims damages from FORCE Certification A/S on grounds, which lie beyond the liability to pay damages undertaken by FORCE Certification A/S in accordance with clauses 5.1 to 5.5, the client shall be under an obligation to take over the conducting of the case and indemnify and hold harmless FORCE Certification A/S for all costs and damages.

6. Disputes

Any dispute between the client and FORCE Certification A/S arising out of or in connection with the performance of a task or the interpretation of the agreement shall if such dispute cannot be solved through negotiation between the parties be settled by Danish Arbitration in accordance with Danish law.