

## Information on the EU Regulation on personal protective equipment (PPE)

Requirements for personal protective equipment have been governed by 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 since 21 April 2018. The Regulation is directly applicable. Nevertheless, it must be applied in conjunction with the Act of 13 April 2016 on conformity assessment and market surveillance systems. The Act also covers the provisions of Regulation (EU) 2016/425 common to the harmonised area, especially issues relating to market surveillance and penalties.

Regulation (EU) 2016/425 has replaced Directive 89/686/EEC (PPE) and has been additionally extended to include requirements arising from the New Legislative Framework. The transitional provisions set out in Article 47 of Regulation (EU) 2016/425 state that:

- without prejudice to paragraph 2, Member States shall not impede the making available on the market of products covered by Directive 89/686/EEC which are in conformity with that Directive and which were placed on the market before 21 April 2019,
- EC type-examination certificates and approval decisions issued under Directive 89/686/EEC shall remain valid until 21 April 2023 unless they expire before that date.

The national Regulation that implemented the PPE Directive, issued under the Conformity Assessment System Act of 30 August 2002 (Journal of Laws 2002, No 166, item 1360, as amended), was repealed in 2019 (Journal of Laws, item 966).

The EU provisions arising from Regulation (EU) 2016/425 set out essential requirements for personal protective equipment. It should be noted that these requirements may not be the only requirements to be met before placing personal protective equipment on the market.

The European Commission's websites containing useful information on the application of provisions

- A website on provisions on personal protective equipment, from which guidelines, inter alia, may be downloaded (please note: the guidelines are not legally binding). Link: <https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment/>
- a NANDO database containing information on notified bodies that meet the requirements of EU acts. Link: <https://ec.europa.eu/growth/tools-databases/nando/index.cfm>

Polish notified bodies - product certification bodies - are subject to accreditation by the Polish Centre for Accreditation (Polskie Centrum Akredytacji, PCA). A search engine for product certification bodies accredited by the PCA is available at:

<https://www.pca.gov.pl/akredytowane-podmioty/akredytacje-aktywne/jednostki-certyfikujace-wyroby/>

Harmonised standards are developed in order to help manufacturers demonstrate the conformity of their personal protective equipment with essential requirements and to facilitate access to the market. Their reference numbers are published in the Official Journal of the European Union. In harmonised standards, essential requirements are translated into detailed technical requirements, with, for example, measurement methods and/or figures used for assessing the conformity of products with essential requirements being specified. Harmonised standards provide a presumption of conformity with essential requirements. The national standardisation body in Poland is the Polish Committee for Standardisation (Polski Komitet Normalizacyjny, PKN).

The European Committee for Standardisation is currently preparing standards harmonised with PPE Regulation (EU) 2016/425, while the harmonisation of standards with PPE Directive 89/686/EEC, which was previously in force, expired on 21 April 2018.

Therefore, please note that if manufacturers are unable to carry out a full conformity assessment on the basis of standards, they may have their products or parts thereof that have not been assessed due to deficiencies in the standards examined by a conformity assessment body that will be able to carry out such examinations.

Irrespective of the above, manufacturers may always have such examinations carried out if, for example, there are any doubts as to whether they have correctly carried out conformity assessments.

Search engine for standards

<https://wiedza.pkn.pl/wyszukiwarka-norm>

The market surveillance authorities responsible for the PPE Regulation are:

National Labour Inspectorate (Państwowa Inspekcja Pracy) <https://www.pip.gov.pl/pl/>

Trade Inspectorate (Inspekcja Handlowa) [https://www.uokik.gov.pl/wazne\\_adresy.php#faq595](https://www.uokik.gov.pl/wazne_adresy.php#faq595)