11th October 2017

DGUV Test
Prüf- und Zertifizierungssystem der
Deutschen Gesetzlichen Unfallversicherung

FAQs on changes required as a result of 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

No.	Question	Answer	Reference/note
1	When does Regulation (EU) 2016/425 (the "PPE Regulation") come into effect?	On 21 April 2018; this applies, in particular, to the "Obligations of economic operators" described in Chapter II.	Regulation (EU) 2016/425 Art. 48 (2) and Chapter II; Art. 8 to 13
2	Will the existing certificates (based on Directive 89/686/EEC) automatically cease to apply on that date?	No. According to the Regulation, "Member States shall not impede the making available on the market" of PPE that complies with Directive 89/686/EEC and was placed on the market prior to 21 April 2019.	Regulation (EU) 2016/425, Art. 47 (1)
3	If neither the product nor the state of the art has changed, is it possible to exchange an EC certificate previously issued by a testing and certification body for a new certificate without having to conduct technical testing?	Yes. However, the manufacturer must declare the following: a) that the product has not been modified and b) that the state of the art[1] has not changed. In the case of category III products: c) results of the product monitoring measures conducted in accordance with Annexes VII/VIII. However, the documents must be checked in their entirety as per the Regulation. In particular, this includes the risk assessment to be produced by the manufacturer. If there is good reason to believe that the product *has* been modified, it is advisable to conduct (partial) tests as a precaution, depending on the case in hand.	Regulation (EU)2016/425 Annex V; 7.6 Regulation (EU)2016/425 Annex III; b)
4	What do you have to do if the product has been modified?	Re-assessment with (additional) testing that covers the modification.	Regulation (EU)2016/425 Annex V; 7.2
5	What do you have to do if the state of the art has changed (e.g. new standard)?	Re-assessment with (additional) testing that covers the change.	List of harmonised standards: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/personal-protective-equipment/

[1] The manufacturer is required to provide this declaration irrespective of the review performed by the testing and certification body (Regulation (EU)2016/425 Annex III, f)

No.	Question	Answer	Reference/note
6	What has changed with regard to the technical documentation?	The regulation requires the following additional information to be given in the technical documentation: • "a complete description of the PPE and of its intended use"; • "an assessment of the risks against which the PPE is intended to protect"; and • "the references of the harmonised standards that have been applied for the design and manufacture of the PPE". • testing to verify the conformity of the PPE; • reports on the testing performed to determine the class of protection. The following additional information is required in the "Manufacturer's instructions and information": • manufacturer's name and <u>address</u> and • month and year of manufacture or period of obsolescence of the PPE. <u>Note:</u> Additional descriptions are required for PPE that is adapted to fit an individual user.	Regulation (EU)2016/425 Annex III and Annex V (Module B) 2 and 4 a) Regulation (EU)2016/425 Annex III, a) Regulation (EU)2016/425 Annex III, b) Regulation (EU)2016/425 Annex III, f) Regulation (EU)2016/425 Annex II, 1.4 b) and c) Regulation (EU)2016/425 Annex II, 1.4
7	How old can the referenced test reports be?	A blanket rule is not possible. This aspect must be decided by the certifying person on a case-by-case basis.	
8	Is it possible to exchange certificates issued by other bodies?	Yes. The procedure is the same as the current procedure for accepting a certificate issued by another body, including verification of compliance with the requirements of the regulation. It is beneficial if all the certification and testing bodies concerned are involved in the acceptance process. This is also possible during the period of validity of the original certificate that is to be revoked.	ZEK-GB-2012-01 rev. 1, 28.09.2016
9	Can results from the monitoring process be included for Cat III PPE?	Yes. The certificate and test report for the last monitoring measure in accordance with Art. 11A/11B must be provided.	

10	What happens to the 11A/B certificates?	Upon expiry, they have to be converted as follows: 11A → Module C2 (within one year) or 11B → Module D (depending on period of validity, possibly >1 year)	
11	How long are exchanged certificates valid for?	Max. 5 years	Regulation (EU)2016/425 Annex V; 6.1; 2nd paragraph
12	What does the notified body (NB) do with the manufacturer's risk assessments?	1) Assessment of risks against which the PPE is intended to protect: This is the basis for the categorisation and classification of the PPE according to the relevant PPE standards. The NB checks and assesses the manufacturer's risk assessment. 2) Assessment of risks that can potentially be caused by the PPE: the NB checks the plausibility of the manufacturer's risk assessment. Examples: Health effects on wearer or environment, functional risks, risks from reasonably foreseeable use. 3) The NB ensures that the consequences of the risk assessment (residual risks) have been taken into account in the information provided by the manufacturer.	Regulation (EU)2016/425 Annex I and Annex III b Regulation (EU)2016/425 Annex II, 1.4 Regulation (EU)2016/425 Annex II, preliminary remark 4 Regulation (EU)2016/425 Annex II, preliminary remark 5
13	Does the manufacturer have to put its address on the product?	Yes. The name and postal address of the certificate holder must be legibly marked on the PPE if technically possible or, if not, on the packaging or the instructions. (Optional envelope pictogram; type height at least 5 mm, as with the CE mark)	Regulation (EU)2016/425 Annex II 2.12; Regulation (EU)2016/425 Article 8 (6); Blue Guide, 4.2.2.1; Article 30 of Regulation (EG)765/2008
14	Does the declaration of conformity (DoC) have to be enclosed?	There is no obligation to provide the NB with the EU declaration of conformity (document). The NB checks the DoC (draft) provided in the instructions and/or whether the instructions indicate where the DoC is to be found.	Regulation (EU)2016/425 Annex VII (Module C2), 6.2; Annex VIII (Module D), 5.2; Blue Guide 2016, Annex IV, Module B, "Manufacturer" column

15	What other aspects do the instructions have to include?	The additional aspects required by the regulation, e.g.: • the risk against which the PPE is intended to protect, • references to any applicable harmonised standards (e.g. in the Official Journal of the EU) or the • website on which the DoC can be found.	Regulation (EU) 2016/425, Annex II, 1.4. References to the standards and the website for the DoC are not required if they accompany the PPE.
16	What changes have been made with regard to the evaluation report? (Certification report)	An evaluation report must be produced but it does not have to be part (e.g. annex) of the type-examination certificate.	Regulation (EU)2016/425 Annex V (Module B), 5
17	What is the procedure for "own brand" certificates?	They have to be dealt with at the same time and in accordance with the same rules as the "original certificate".	
18	Own-brand type-examination certificate for licensed manufacture?	Same rules as for original certificate.	
19	What needs to be borne in mind if the product changes from category II to III?	Note on the certificate stating the change to Cat. III with an obligation to perform monitoring measures. (Note: This is only possible with the new type-examination certificate). Supervised product checks in accordance with Module C2 within one year of the Cat. III certificate being issued or surveillance in accordance with Module D after the Cat. III certificate (type-examination certificate) is issued but before production begins.	Regulation (EU) 2016/425 Annex V (Module B), 6.2. k) Regulation (EU) 2016/425 Annex VII (Module C2), 4.2 Regulation (EU) 2016/425, Art. 19 c)
20	Does the change in the monitoring procedure from Art. 11A/B to modules C2 or D have any influence on the transfer of the type-examination certificate?	No	
21	Where can I download the "PPE Regulation"?	One possibility is the following website: http://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32016R0425 where the regulation is available in all of the official languages of the EU.	