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Mr. Martin Liedtke
By email martin.liedtke@dguv.de

Dear Mr Liedtke,

We were surprised to read your letter dated 11 March 2024 on behalf of the Horizontal Committee of Notified Bodies Group for Personal Protective Equipment (HCNB), where you question the procedure followed by the Commission to clarify a question on the implementation of the conformity assessment procedure, module C2, laid down in Annex VII of the Personal Protective Equipment (PPE) Regulation ([1]).

The Commission has not introduced any change to the conformity assessment procedures laid down in the PPE Regulation.

As explained in section 3.4. of the explanatory memorandum of the Commission proposal for a Regulation on personal protective equipment ([2]) and recitals 6 and 30 of the PPE Regulation, the PPE Regulation updated the conformity assessment procedures from the PPE Directive ([3]) in line with Decision No 768/2008/EC2 ([4]), and those procedures have been applicable since 21 April 2018. However, market surveillance authorities brought to our attention that notified bodies have not been applying the updated module C2 procedure uniformly throughout the European Union ever since and asked the Commission for a clarification about its implementation.

Point 1 of Annex VII of the PPE Regulation lists the obligations that a manufacturer needs to fulfil under module C2: perform the internal control of production (point 2), lodge an application with a notified body (point 3), have the products checks done (point 4), be in possession of the test report (point 5.2), affix the CE marking, affix the identification number of the notified body and draw up the EU declaration of conformity (point 6). Many notified bodies have allowed manufacturers to affix the identification number of the notified body without having performed the first product check. This is a practice inherited

([1]) 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/EE, OJ L 81, 31.3.2016, p. 51–98

([2]) https://ec.europa.eu/transparency/documents-register/detail?ref=COM(2014)186&lang=en

([3]) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment, OJ L 399, 30.12.1989, p. 18–38

([4]) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ L 218, 13.8.2008, p. 82–128.

from the times of the PPE Directive, but after the update of the conformity assessment procedure in the PPE Regulation it is not possible anymore as it leads to a situation where manufacturers would place their products on the market without having fulfilled the obligations laid down in points 4 and 5.2 of Annex VII of the PPE Regulation.

We have discussed the topic at length since 2021 directly with the HCNB and in other fora where the HCNB participates such as the PPE administrative cooperation group (ADCO) or the PPE Expert Group, and we have had different written exchanges including a detailed position paper from the Commission on the topic, that you will find attached. As a result of those exchanges, in order to clarify the subject and ensure a uniform application, the Commission has updated the PPER guidelines, as it is purely a matter of a correct application of the existing legislation.

Yours sincerely,

E-signed
Mehdi HOCINE
Head of Unit

Enclosure: Commission position paper "Placing on the market after B+C2 conformity assessment procedure"