Commission Implementing Decision (EU) 2019/1217 of 17 July 2019 on the harmonised standards for personal flotation devices — lifejackets drafted in support of Council Directive 89/686/EEC (Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council[(1)], and in particular point (b) of Article 11(1) thereof,

Whereas:

(1) In accordance with Article 5(2) of Council Directive 89/686/EEC[(2)] Member States are to presume that the personal protective equipment (PPE) referred to in Article 8(2) satisfies the basic requirements referred to in Article 3 if it bears the CE marking with respect to which the manufacturer is able to produce, on demand, not only the declaration referred to in Article 12 but also the certificate issued by the body of which notification has been given in accordance with Article 9 attesting to their conformity to the relevant national standards, transposing the harmonized standards, assessed at the EC type examination level in accordance with the first indent of Article 10(4)(a) and (b).

(2) In September 2014, Sweden lodged a formal objection in respect of standards EN ISO 12402-2:2006 'Personal flotation devices — Part 2: Lifejackets, performance level 275 — Safety requirements (ISO 12402-2:2006)' amended by EN ISO 12402-2:2006/A1:2010, EN ISO 12402-3:2006 'Personal flotation devices — Part 3: Lifejackets, performance level 150 — Safety requirements (ISO 12402-3:2006)' amended by EN ISO 12402-3:2006/A1:2010 and EN ISO 12402-4:2006 'Personal flotation devices — Part 4: Lifejackets, performance level 100 — Safety requirements (ISO 12402-4:2006)' amended by EN ISO 12402-4:2006/A1:2010. At the time of the objection the references of the standards were published in Commission communication in the framework of the implementation of the Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment[(3)] on 11 April 2014. The standards were last published in Commission communication in the framework of the implementation of the Council Directive 89/686/EEC on the approximation of the laws

of the Member States relating to personal protective equipment[4] on 27 March 2018. In accordance with that Communication the harmonised standards concerned continue to confer presumption of conformity only with Directive 89/686/EEC and only until 20 April 2019. Such presumption of conformity under Directive 89/686/EEC will cease as from 21 April 2019. Further, in accordance with Article 47(1) of Regulation (EU) 2016/425 of the European Parliament and of the Council[5], 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.

(3) The ground of the formal objection was based on the alleged failure of the referenced standards to comply with the basic health and safety requirements of Annex II to Directive 89/686/EEC, in particular point 1.1.1 on Design principles — Ergonomics, point 1.2.1 on Innocuousness of PPE — Absence of risks and other 'inherent' nuisance factors and point 3.4 on Prevention of drowning (lifejackets, armbands and lifesaving suits) with respect to inflatable lifejackets.

(4) The formal objection lodged by Sweden refers to a workplace accident, when an inflatable lifejacket equipped with an automatic inflation device, worn by an employee who fell into cold water, did not inflate. Investigations carried out by the Swedish Work Environment Authority came to the conclusion that the lifejacket did not inflate because the gas cartridge was partially detached and thread out, due to body movements, environmental factors and operations carried out during use. If the gas cylinder detaches, the inflatable lifejacket is no longer safe and does not maintain its protective properties throughout use, therefore the product no longer protects against the risk of drowning. Other accidents or incidents have been reported to the Swedish Work Environment Authority, involving professional users and consumers, and loose or detached gas cylinders were also found in several other inflatable lifejackets. Furthermore, some brands of inflatable lifejackets have been found having no indicator window, so that during use there is no indication whether the product is safe for use or not or, where the inflatable lifejacket is equipped with an indicator window, the window is not visible to the user during use, due to its position on the lifejacket.

(5) As a consequence, Sweden identified a shortcoming of the abovementioned harmonised standards. The shortcoming consists in the absence of requirements to ensure that the gas cartridge of the inflatable lifejacket does not detach and thread out during use, making the lifejacket losing its protective function, in particular when the user is exposed to the risk of drowning. In the absence of such requirements, it cannot be ensured that the protective function of the inflatable lifejacket is maintained under all reasonable circumstances of use and foreseeable user behaviour, regardless whether this is for private or professional use.

(6) The Technical Committee 162 of the European Committee for Standardisation (CEN) ('CEN/TC 162') reacted to the formal objection lodged by Sweden, stating that the referred accident was not due to a shortcoming in the concerned harmonised standards. According to their assessment, the detachment of the gas cartridge was due to a defective design of the inflatable lifejacket which was not detected before placing

the product on the market. If an adequate risk assessment with training and maintenance sequences for the user would have been carried out, this would have led to provide the lifejacket with a different and improved inflation device, to prevent accidents.

(7) Sweden replied to the information provided by CEN/TC 162 stating that the problem was not due to a defective design of the inflatable lifejacket, as it was designed according to the relevant clauses of the referred harmonised standards. They reaffirmed that the problem arises because those standards do not contain specific requirements for a locking function to prevent the gas cartridge from becoming detached or loose during use, which prevented the inflatable lifejacket to provide protection against drowning.

(8) Having examined the harmonised standards EN ISO 12402-2:2006 amended by EN ISO 12402-2:2006/A1:2010, EN ISO 12402-3:2006 amended by EN ISO 12402-3:2006/A1:2010 and EN ISO 12402-4:2006 amended by EN ISO 12402-4:2006/A1:2010, together with the representatives of Member States and stakeholders in the Personal Protective Equipment Working Party, the Commission concluded that the clauses of those harmonised standards aimed at covering the basic health and safety requirements set out in point 1.1.1. on Design principles — Ergonomics, point 1.2.1. on Innocuousness of PPE — Absence of risks and other 'inherent' nuisance factors and point 3.4. on Prevention of drowning (lifejackets, armbands and lifesaving suits) of Annex II to Directive 89/686/EEC, do not adequately address the related risks, in particular the risk of drowning for inflatable lifejackets. Actually, the relevant harmonised standards do not contain specific requirements to ensure that the inflation device would correctly work under all reasonable circumstances of use and foreseeable user behaviour, in order to provide the adequate protection against the risk of drowning. Consequently, it has been found that products designed and manufactured according to those standards still caused accidents and incidents involving professional users and consumers.

(9) Nevertheless, the Commission considers that the other clauses of the relevant harmonised standards, which are not the object of the formal objection, remain valid to confer presumption of conformity with the basic health and safety requirements of Directive 89/686/EEC they aim to cover.

(10) Taking into account the abovementioned considerations, the references of the harmonised standards EN ISO 12402-2:2006 amended by EN ISO 12402-2:2006/A1:2010, EN ISO 12402-3:2006 amended by EN ISO 12402-3:2006/A1:2010 and EN ISO 12402-4:2006 amended EN ISO 12402-4:2006/A1:2010, published in Commission communication in the framework of the implementation of the Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment on 27 March 2018, should be maintained with restriction in the *Official Journal of the European Union*. The restriction should exclude the specific clauses of those standards aimed to cover the basic health and safety requirements set out in point 1.1.1 on Design principles — Ergonomics, point 1.2.1 on Innocuousness of PPE — Absence of risks and other 'inherent' nuisance factors and point 3.4 on Prevention of drowning (lifejackets, armbands and lifesaving suits) of Annex II to Directive 89/686/EEC.