

# **DECLARATION OF CONFORMITY**

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OFFICIAL JOURNAL OF PERSONAL  
PROTECTIVE EQUIPMENT REGULATION  
((EU) 2016/425)

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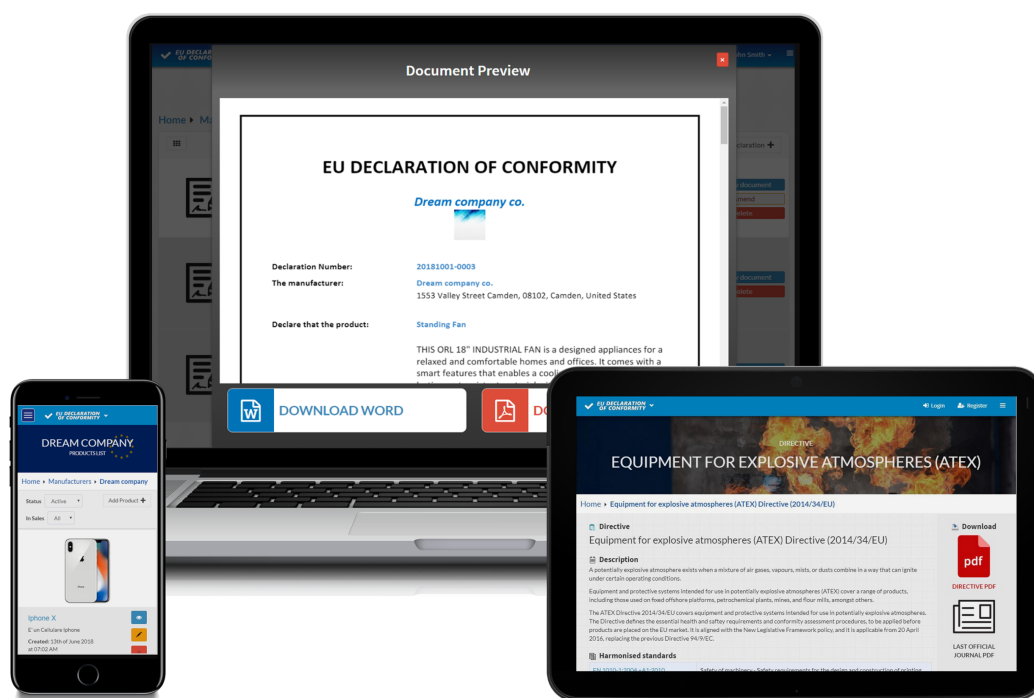
# **DECLARATION OF CONFORMITY**

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**COMMISSION IMPLEMENTING DECISION (EU) 2022/1914****of 6 October 2022****amending Implementing Decision (EU) 2020/668 as regards harmonised standards on personal flotation devices – buoyancy aids, lifejackets and accessories****(Text with EEA relevance)**

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 <sup>(1)</sup>, and in particular Article 10(6) and Article 11(1), point (a), thereof,

After consulting the committee established by Article 22 of Regulation (EU) No 1025/2012,

Whereas:

- (1) In accordance with Article 14 of Regulation (EU) 2016/425 of the European Parliament and of the Council <sup>(2)</sup>, personal protective equipment (PPE) which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* is to be presumed to be in conformity with the essential health and safety requirements set out in Annex II to that Regulation covered by those standards or parts thereof.
- (2) By letter M/031, with the title ‘Standardisation mandate to CEN/Cenelec concerning standards for personal protective equipment’, the Commission made a request to the European Committee for Standardization (‘CEN’) and the European Committee for Electrotechnical Standardization (‘Cenelec’) to develop and draw up harmonised standards in support of Council Directive 89/686/EEC <sup>(3)</sup>. On the basis of the standardisation request M/031, CEN drafted several new standards and revised a number of existing harmonised standards, including those on personal flotation devices.
- (3) On 19 November 2020 the standardisation request M/031 expired and was replaced by a new standardisation request as set out in Commission Implementing Decision C(2020)7924 <sup>(4)</sup>.
- (4) On the basis of the standardisation request M/031 and the standardisation request set out in Implementing Decision C(2020)7924, CEN and Cenelec drafted the new harmonised standards EN ISO 12402-2:2020, EN ISO 12402-3:2020 and EN ISO 12402-4:2020 on lifejackets, EN ISO 12402-5:2020 on buoyancy aids, EN ISO 12402-6:2020 on special application lifejackets and buoyancy aids and EN ISO 12402-8:2020 on accessories of personal flotation devices.
- (5) In November 2020, Sweden raised a formal objection against harmonised standards EN ISO 12402-2:2020, EN ISO 12402-3:2020 and EN ISO 12402-4:2020, the references of which had not yet been published in the *Official Journal of the European Union*.

<sup>(1)</sup> OJ L 316, 14.11.2012, p. 12.

<sup>(2)</sup> 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 (OJ L 81, 31.3.2016, p. 51).

<sup>(3)</sup> 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).

<sup>(4)</sup> Commission Implementing Decision C(2020)7924 of 19 November 2020 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards personal protective equipment in support of Regulation (EU) 2016/425 of the European Parliament and of the Council.

- (6) Standards EN ISO 12402-5:2020, EN ISO 12402-6:2020 and EN ISO 12402-8:2020 are intended to be used in conjunction with standards EN ISO 12402-2:2020, EN ISO 12402-3:2020 and EN ISO 12402-4:2020 in such a way that some or all of the content of standards EN ISO 12402-2:2020, EN ISO 12402-3:2020 and EN ISO 12402-4:2020 constitutes requirements of standards EN ISO 12402-5:2020, EN ISO 12402-6:2020 and EN ISO 12402-8:2020. Therefore, the references of standards EN ISO 12402-5:2020, EN ISO 12402-6:2020 and EN ISO 12402-8:2020 have not been published in the *Official Journal of the European Union*, as EN ISO 12402-2:2020, EN ISO 12402-3:2020 and EN ISO 12402-4:2020 were subject of a formal objection issued by Sweden.
- (7) In the notification under Article 12 of Regulation (EU) No 1025/2012, Sweden makes reference to the previous formal objection, which it lodged in September 2014, in respect of standards EN ISO 12402-2:2006, EN ISO 12402-3:2006 and EN ISO 12402-4:2006 on lifejackets drafted in support of Directive 89/686/EEC.
- (8) The Commission decided to publish references of the harmonised standards EN ISO 12402-2:2006, EN ISO 12402-3:2006 and EN ISO 12402-4:2006 with restriction by Commission Implementing Decision (EU) 2019/1217 <sup>(9)</sup>.
- (9) According to Sweden, the shortcoming indicated in its formal objection from 2014 still exist in the standards EN ISO 12402-2:2020, EN ISO 12402-3:2020 and EN ISO 12402-4:2020 under Regulation (EU) 2016/425. In its evaluation, the Swedish Work Environment Authority concludes that those standards for lifejackets do not provide presumption of conformity for inflatable lifejackets in relation to points 1.1.1, 1.2.1 and 3.4 of Annex II to Regulation (EU) 2016/425, and that those standards do not provide presumption of conformity with item 5 of the preliminary remarks in Annex II to Regulation (EU) 2016/425 concerning the manufacturer's risk assessment and requirements concerning intended use in foreseeable areas of use.
- (10) The Technical Committee 162 – Working Group 6 of CEN replied to the points raised by Sweden, indicating that the Swedish proposals included design-restrictive content, that the experts concluded that the standards in question do include requirements to ensure that the Essential Health and Safety Requirements are covered and met, and therefore the objection could not be considered justified.
- (11) In its statement of December 2020, the International Lifesaving Appliance Manufacturers' Association stated that they would conform to all revised recommendations made during discussion with the ISO Personal Safety Equipment technical committee (TC188 SC1) and the Swedish Authorities, and expressed concerns regarding the potential rejection of the revised standards EN ISO 12402-2:2020, EN ISO 12402-3:2020 and EN ISO 12402-4:2020.
- (12) Having examined the harmonised standards EN ISO 12402-2:2020, EN ISO 12402-3:2020 and EN ISO 12402-4:2020, together with the representatives of Member States and stakeholders in the Personal Protective Equipment Expert Group, 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 inherent risks and other nuisance factors and point 3.4. on Protection in liquids of Annex II to Regulation (EU) 2016/425, do not adequately address the related risks, in particular the risk of drowning for inflatable lifejackets. In fact, 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, the Commission found that products designed and manufactured according to those standards could still cause accidents and incidents involving professional users and consumers.
- (13) Nevertheless, the Commission considers that the other clauses of harmonised standards EN ISO 12402-5:2020, EN ISO 12402-6:2020 and EN ISO 12402-8:2020, which are not subject of the formal objection, remain valid to confer presumption of conformity with the basic health and safety requirements of Regulation (EU) 2016/425 they aim to cover.

<sup>(9)</sup> 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, (OJ L 192, 18.7.2019, p. 32).

- (14) The references of the harmonised standards EN ISO 12402-2:2020, EN ISO 12402-3:2020 and EN ISO 12402-4:2020, should therefore be published 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 Protection in liquids of Annex II to Regulation (EU) 2016/425.
- (15) The harmonised standards EN ISO 12402-5:2020, EN ISO 12402-6:2020 and EN ISO 12402-8:2020 satisfy the requirements which they aim to cover and which are set out in Regulation (EU) 2016/425. It is therefore appropriate to publish the references of those harmonised standards in the *Official Journal of the European Union*.
- (16) It is necessary to withdraw the references of harmonised standards EN ISO 12402-5:2006, EN ISO 12402-6:2006 and EN ISO 12402-8:2006 the *Official Journal of the European Union*, given that those standards have been revised.
- (17) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the day of its publication in the *Official Journal of the European Union*.
- (18) The committee established by Article 22 of Regulation (EU) No 1025/2012 was consulted as regards publication of harmonised standards EN ISO 12402-2:2020, EN ISO 12402-3:2020 and EN ISO 12402-4:2020 in the *Official Journal of the European Union*,

HAS ADOPTED THIS DECISION:

*Article 1*

Implementing Decision (EU) 2020/668 is amended as follows:

- (1) Annex I is amended in accordance with Annex I to this Decision;
- (2) Annex II is amended in accordance with Annex II to this Decision;
- (3) Annex III is amended in accordance with Annex III to this Decision.

*Article 2*

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 6 October 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX I

In Annex I to Implementing Decision (EU) 2020/668, the following entries are added:

| No   | Reference of the standard   |
|------|---|
| '39. | EN ISO 12402-5:2020<br>Personal flotation devices – Part 5: Buoyancy aids (level 50)- Safety requirements (ISO 12402-5:2020)  |
| 40.  | EN ISO 12402-6:2020<br>Personal flotation devices – Part 6: Special purpose lifejackets and buoyancy aids- Safety requirements and additional test methods (ISO 12402-6:2020) |
| 41.  | EN ISO 12402-8:2020<br>Personal flotation devices – Part 8: Accessories – Safety requirements and test methods (ISO 12402-8:2020)'.   |

## ANNEX II

In Annex II, the following entries are added:

| No   | Reference of the standard   | Date of withdrawal |
|------|---|--------------------|
| '30. | EN ISO 12402-5:2006<br>Personal flotation devices – Part 5: Buoyancy aids (level 50)- Safety requirements (ISO 12402-5:2006)  | 7 October 2022     |
| 31.  | EN ISO 12402-6:2006<br>Personal flotation devices – Part 6: Special purpose lifejackets and buoyancy aids- Safety requirements and additional test methods (ISO 12402-6:2006) | 7 October 2022     |
| 32.  | EN ISO 12402-8:2006<br>Personal flotation devices – Part 8: Accessories – Safety requirements and test methods (ISO 12402-8:2006)   | 7 October 2022'.   |

## ANNEX III

In Annex III to Implementing Decision (EU) 2020/668, the following entries are added:

| No  | Reference of the standard   |
|-----|---|
| '4. | <p>EN ISO 12402-2:2020</p> <p>Personal flotation devices – Part 2: Lifejackets, performance level 275 – Safety requirements (ISO 12402-2:2020)</p> <p>Notice:</p> <p>Application of clause 5.6 of this standard does not confer a presumption of conformity with the basic health and safety requirement set out in point 1.1.1. of Annex II to Regulation (EU) 2016/425.</p> <p>Application of clauses 5.1.2, 5.1.3, 5.1.5, 5.1.7, 5.2, 5.3.1.1, 5.3.1.2, 5.3.2.2, 5.3.2.3, 5.3.4.3, 5.3.4.4, 5.6.1.4, 5.6.1.7, 5.6.1.8, 5.6.1.9, 5.6.1.10 and 5.6.1.11 of this standard does not confer a presumption of conformity with the basic health and safety requirement set out in point 1.2.1. of Annex II to Regulation (EU) 2016/425.</p> <p>Application of clauses 5.1.2, 5.2, 5.3.1.1, 5.3.2.2, 5.3.4.2, 5.3.4.4, 5.6.3 and 5.7 of this standard does not confer a presumption of conformity with the basic health and safety requirement set out in point 3.4 of Annex II to Regulation (EU) 2016/425.</p>   |
| 5.  | <p>EN ISO 12402-3:2020</p> <p>Personal flotation devices – Part 3: Lifejackets, performance level 150 – Safety requirements (ISO 12402-3:2020)</p> <p>Notice:</p> <p>Application of clause 5.6 of this standard does not confer a presumption of conformity with the basic health and safety requirement set out in point 1.1.1. of Annex II to Regulation (EU) 2016/425.</p> <p>Application of clauses 5.1.2, 5.1.3, 5.1.5, 5.1.7, 5.2, 5.3.1.1, 5.3.1.2, 5.3.2.2, 5.3.2.3, 5.3.4.3, 5.3.4.4, 5.6.1.4, 5.6.1.7, 5.6.1.8, 5.6.1.9, 5.6.1.10 and 5.6.1.11 of this standard does not confer a presumption of conformity with the basic health and safety requirement set out in point 1.2.1. of Annex II to Regulation (EU) 2016/425.</p> <p>Application of clauses 5.1.2, 5.2, 5.3.1.1, 5.3.2.2, 5.3.4.2, 5.3.4.4, 5.6.3 and 5.7 of this standard does not confer a presumption of conformity with the basic health and safety requirement set out in point 3.4 of Annex II to Regulation (EU) 2016/425.</p>   |
| 6.  | <p>EN ISO 12402-4:2020</p> <p>Personal flotation devices – Part 4: Lifejackets, performance level 100 – Safety requirements (ISO 12402-4:2020)</p> <p>Notice:</p> <p>Application of clause 5.6 of this standard does not confer a presumption of conformity with the basic health and safety requirement set out in point 1.1.1. of Annex II to Regulation (EU) 2016/425.</p> <p>Application of clauses 5.1.2, 5.1.3, 5.1.5, 5.1.7, 5.2, 5.3.1.1, 5.3.1.2, 5.3.2.2, 5.3.2.3, 5.3.4.3, 5.3.4.4, 5.6.1.4, 5.6.1.7, 5.6.1.8, 5.6.1.9, 5.6.1.10 and 5.6.1.11 of this standard does not confer a presumption of conformity with the basic health and safety requirement set out in point 1.2.1. of Annex II to Regulation (EU) 2016/425.</p> <p>Application of clauses 5.1.2, 5.2, 5.3.1.1, 5.3.2.2, 5.3.4.2, 5.3.4.4, 5.6.3 and 5.7 of this standard does not confer a presumption of conformity with the basic health and safety requirement set out in point 3.4 of Annex II to Regulation (EU) 2016/425.’.</p> |