

# **DECLARATION OF CONFORMITY**

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OFFICIAL JOURNAL OF MACHINERY  
(MD) DIRECTIVE (2006/42/EC)

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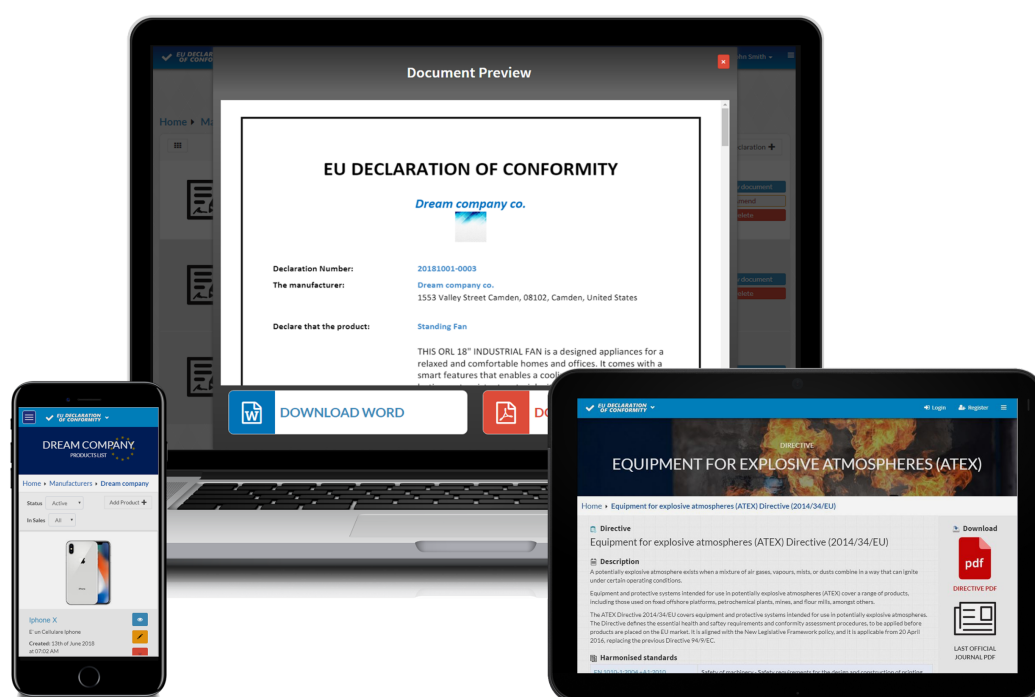
# **DECLARATION OF CONFORMITY**

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**COMMISSION IMPLEMENTING DECISION (EU) 2023/69**  
**of 9 January 2023**  
**amending Implementing Decision (EU) 2019/436 as regards the harmonised standard for electrically**  
**power assisted cycles**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC <sup>(1)</sup>, and in particular Article 10 thereof,

Whereas:

- (1) In accordance with Article 7 of Directive 2006/42/EC machinery manufactured in conformity with a harmonised standard, the reference to which has been published in the *Official Journal of the European Union*, is to be presumed to comply with the essential health and safety requirements covered by such a harmonised standard.
- (2) By letter M/396 of 19 December 2006, the Commission made a request ('request M/396') to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) for the drafting, the revision and the completion of the work on harmonised standards in support of Directive 2006/42/EC to take account of changes introduced by that Directive in comparison with Directive 98/37/EC of the European Parliament and of the Council <sup>(2)</sup>.
- (3) On the basis of the request M/396, CEN and Cenelec drafted the harmonised standard EN 15194:2017 for electrically power assisted cycles. The reference of that standard was published in the *Official Journal of the European Union* by Commission Implementing Decision (EU) 2019/436 <sup>(3)</sup>.
- (4) On 23 August 2019, the Netherlands presented a formal objection in accordance with Article 10 of Directive 2006/42/EC against harmonised standard EN 15194:2017 claiming that it fails to satisfy the essential health and safety requirements set out in points 1.5.5, 1.5.6 and 1.5.7 of Annex I to Directive 2006/42/EC which the standard claims to cover. The Netherlands argued that harmonised standard EN 15194:2017 only informs in its points 4.2.3.1 and 4.2.3.2 on the availability of European standards EN 62133 and EN 50604-1 for testing of batteries, but fails to comprehensively address the safe integration of batteries into battery packs and the incorporation of battery packs into an end-device. The Netherlands claimed that this is insufficient to assess the overall safety levels of the end-device, namely electrically power assisted bicycles, as illustrated by the recurring incidents with those vehicles equipped with lithium-ion cells and/or battery packs.
- (5) The formal objection was discussed in the Committee established by Article 22 of Directive 2006/42/EC, in the meetings of 2 and 3 December 2019 and 19 and 20 February 2020.
- (6) In those meetings, Germany raised an additional objection by expressing the view that harmonised standard EN 15194:2017 also fails to comply with points 1.5.9 and 3.6.3.1 of Annex I to Directive 2006/42/EC with regard to the vibrations transmitted to the cyclist. According to harmonised standard EN 15194:2017 those points are not applicable to electrically power assisted bicycles. However, according to Germany such vibrations may occur when using those bicycles on uneven ground.

<sup>(1)</sup> OJ L 157, 9.6.2006, p. 24.

<sup>(2)</sup> Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (OJ L 207, 23.7.1998, p. 1).

<sup>(3)</sup> Commission Implementing Decision (EU) 2019/436 of 18 March 2019 on the harmonised standards for machinery drafted in support of Directive 2006/42/EC of the European Parliament and of the Council (OJ L 75, 19.3.2019, p. 108).

- (7) The formal objections raised by the Netherlands and Germany were discussed in the Committee established by Article 22 of Regulation (EU) No 1025/2012 of the European Parliament and of the Council <sup>(4)</sup> on 2 July 2021.
- (8) Having examined harmonised standard EN 15194:2017 together with the representatives of the committee established by Article 22 of Directive 2006/42/EC and the representatives of the committee established by Article 22 of Regulation (EU) No 1025/2012, the Commission concluded that the standard fails to meet the essential health and safety requirements set out in points, 1.5.5, 1.5.6, 1.5.7, 1.5.9 and 3.6.3.1 of Annex I to Directive 2006/42/EC.
- (9) Harmonised standard EN 15194:2017 should therefore be maintained in the *Official Journal of the European Union* with a restriction.
- (10) The reference of harmonised standard EN 15194:2017 is included in Annex I to Implementing Decision (EU) 2019/436. Annex II to that Implementing Decision lists the references of harmonised standards drafted in support of Directive 2006/42/EC that are published in the *Official Journal of the European Union* with restrictions. The reference of standard EN 15194:2017 should therefore be deleted from Annex I to Implementing Decision (EU) 2019/436 and it should be included with a restriction in Annex II to that Implementing Decision.
- (11) Implementing Decision (EU) 2019/436 should therefore be amended accordingly.
- (12) 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 date of its publication,

HAS ADOPTED THIS DECISION:

*Article 1*

Annexes I and II to Implementing Decision (EU) 2019/436 are amended in accordance with the Annex 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, 9 January 2023.

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

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<sup>(4)</sup> 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 (OJ L 316, 14.11.2012, p. 12).

## ANNEX

Annexes I and II to Implementing Decision (EU) 2019/436 are amended as follows:

- (1) in Annex I, row 16 is deleted;
- (2) in Annex II, the following row is added:

No	Reference of the standard	Type
'4.	<p>EN 15194:2017</p> <p>Cycles – Electrically power assisted cycles – EPAC Bicycles</p> <p><b>Notice 1:</b> Harmonised standard EN 15194:2017 does not confer a presumption of conformity with the essential health and safety requirements set out in points 1.5.5, 1.5.6 and 1.5.7 of Annex I to Directive 2006/42/EC, which require machinery to be designed and constructed to take into account the risks associated with extreme temperatures, fire and explosion.</p> <p><b>Notice 2:</b> Harmonised standard EN 15194:2017 does not confer a presumption of conformity with the essential health and safety requirements set out in points 1.5.9 and 3.6.3.1 of Annex I to Directive 2006/42/EC, which require machinery to be designed and constructed to take into account the risks resulting from vibrations, and that machinery must be provided with the measurement of vibrations transmitted by the machinery to the operator of the machinery.</p>	C'