



The Minister for Infrastructure and Transport

HAVING REGARD to Article 17(3) of Law No 400 of 23 August 1988;

HAVING REGARD to Legislative Decree No. 285 of 30 April 1992, containing the 'New Highway Code' and, in particular, Article 125(3c) and Article 75(3b);

HAVING REGARD to law no. 177 of 25 November 2024, and in particular art. 3(1), which amends art. 125 of Legislative Decree no. 285/1992, stipulating that the Minister for Infrastructure and Transport shall establish, by decree, the characteristics of the anti-lock device, the methods of installation and the workshops authorised to carry out the activities referred to in Law no. 122 of 5 February 1992, which are authorised to install *alcohol interlock devices* in accordance with standard EN 50436, and that each device shall be provided with a seal to prevent alteration or tampering after installation;

HAVING REGARD to Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No. 595/2009 and repealing Directive 2007/46/EC;;

HAVING REGARD to Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on the approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles as regards their general safety and the protection of vehicle occupants and other vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 of the Commission;

HAVING REGARD to Commission Delegated Regulation (EU) 2021/1243 of 19 April 2021, supplementing Regulation (EU) 2019/2144 of the European Parliament and of the Council by establishing detailed rules regarding the installation interface of *alcohol interlock devices* in motor vehicles and amending Annex II to that Regulation;

HAVING REGARD to standard EN 50436 '*Alcohol interlocks - Test methods and performance requirements*';

HAVING REGARD to Directive (EU) 2015/1535 of the European Parliament and of the Council, which provides for an information procedure in the field of technical regulations and rules relating to information society services

HAVING IMPLEMENTED the information procedure provided for in Article 5 of the aforementioned Directive (EU) 2015/1535;

HAVING OBTAINED the positive opinion of the European Commission contained in its Communication [...] of [...];

HAVING HEARD the opinion of the Council of State expressed by the advisory section for legislative acts at the meeting of [...];

HAVING REGARD to letter ref. [...] of [...], in which the draft regulation was communicated to the President of the Council of Ministers.

Hereby adopts
the following regulations:

Article 1

(Scope)

1. This Regulation shall apply to the *alcohol interlock devices* referred to in Article 125(3c) of Legislative Decree No 285 of 30 April 1992.
2. This Regulation is without prejudice to European Union harmonisation legislation. Where the devices covered by this Regulation are within the scope of EU harmonisation legislation, they must comply with such legislation.

Article 2

(Definitions)

For the purposes of these regulations

- a) 'vehicle': a vehicle belonging to one of the international categories M1, M2, M3, N1, N2 and N3, as defined in Regulation (EU) 2018/858;
- b) '*alcohol interlock device*': a device which acts as an immobiliser for the vehicle and which, when installed, may only be brought into non-locking condition after presentation and analysis of an accepted breath sample with alcohol concentration not exceeding 0 mg/l;
- c) '*manufacturer*' means the person or organisation responsible for the design, construction and/or production of the *alcohol interlock device* and for ensuring conformity of production;
- d) '*tampering*' means unauthorized changes or interference with the installation or operation of the *alcohol interlock device* in the vehicle;
- e) "*data memory*": record of breath test results and other events with a date and time stored in the internal memory of the *alcohol interlock device*;
- f) '*calibration range*' means the time interval between calibrations during which the *alcohol interlock device* meets the precision requirements for measuring the alcohol concentration in the exhaled breath;
- g) '*installer*': the person or entity responsible for installing the *alcohol interlock device*, including any interface, and authorised to carry out the activities referred to in Law No 122 of 5 February 1992;
- h) '*installation seal*' means an adhesive that self-destructs in the event of an attempt to tamper with the *alcohol interlock device*.

Article 3

(General installation characteristics of the alcohol interlock device)

An *alcohol interlock device* may be installed:

- a) on vehicles of international categories M1, M2, M3, N1, N2 and N3 type-approved in accordance with the provisions of Regulation (EU) 2021/1243 supplementing Regulation (EU) 2019/2144 and for which the manufacturer of the *alcohol interlock device* has provided specific installation instructions for that vehicle type in accordance with standard EN 50436;
- b) on vehicles of international categories M1, M2, M3, N1, N2 and N3 which are not type-approved according to the provisions of EU Regulation 2021/1243, for which the manufacturer of the *alcohol interlock device* has provided specific installation instructions for that type of vehicle in accordance with EN 50436 and for which the installer has access to the relevant information provided by the vehicle manufacturer for the installation of the appropriate interface.

Article 4

(Essential technical, construction and functional characteristics of the alcohol interlock device)

1. The *alcohol interlock device* shall comply with the requirements of EN 50436 '*Alcohol interlocks - Test methods and performance requirements*'.
2. Immobilisation of the vehicle must occur when the *alcohol interlock device* registers an alcohol concentration in the air exhaled by the driver that exceeds 0 mg/l.
3. The *alcohol interlock device* must be approved as an electrical/electronic sub-assembly (ESA) in accordance with UN Regulation No 10 '*Uniform provisions concerning the approval of vehicles with regard to electromagnetic compatibility*' and marked as provided for in Annex I to that Regulation.
4. The device must be CE-marked.

Article 5

(Obligations for the manufacturer of the alcohol interlock device)

1. The manufacturer shall provide the instructions for the installation of the *alcohol interlock device* in accordance with Annex 1.
2. The *alcohol interlock device* shall be legibly marked with the minimum requirements set out in Annex 2.
3. The manufacturer shall provide the instructions for the use of the *alcohol interlock device* in accordance with Annex 3.
4. The manufacturer shall provide the instructions for the maintenance of the *alcohol interlock device* in accordance with Annex 4.
5. The manufacturer shall, from among the workshops authorised to carry out the mechatronics activities referred to in Law No 122 of 5 February 1992, identify the installers authorised to install their devices and communicate them to the Ministry of Infrastructure and Transport — Directorate-General for Motor Vehicles — Division 3.
6. The manufacturer shall forward to the Ministry of Infrastructure and Transport – Directorate-General for Motorisation – Division 3, the type of *alcohol interlock device*, which complies with standard EN 50436, accompanied by the documentation referred to in Annexes 1, 2, 3 and 4 to this Decree, together with a *specimen* of a calibration certificate and a separate list of the vehicle models on which the *alcohol interlock device* may be installed.

7. The manufacturer shall provide the installer with each *alcohol interlock* device with the documentation referred to in Annexes 1, 2, 3, 4 and 5, including a calibration certificate.

Article 6

(Communication obligations)

The Ministry of Infrastructure and Transport – Directorate-General for Motor Vehicles publishes on its website www.ilportaledellautomobilista.it the documentation sent by the manufacturer concerning the authorised installers and the list of vehicle models on which each *alcohol interlock device* may be installed.

Article 7

(Installation and uninstallation of alcohol interlock devices)

1. Installers authorised for installation of the *alcohol interlock devices*, referred to in section 5 of Article 5 above, are responsible for compliance with installation instructions, including the application of a seal that prevents alteration or tampering after installation.
2. The seal, applied by the installer, must be destroyed in case of attempted tampering using self-destructive adhesives.
3. The installers authorised to install the *alcohol interlock devices*, referred to in paragraph 5 of Article 5 above, shall, at the same time as the installation declaration, referred to in Annex 6, provide the calibration certificate for the alcohol interlock device, as provided for in Annex 5, the instructions for use of the *alcohol interlock device*, referred to in Annex 3, and the instructions for the maintenance of the *alcohol interlock device*, referred to in Annex 4.
4. Installers authorised to assemble *alcohol interlock devices*, referred to in paragraph 5 of Article 4 above, are also responsible for any disassembly of the device in accordance with the manufacturer's instructions.
5. The installation and disassembly of the *alcohol interlock device* is not included among the technical operations subject to inspection and testing by the Vehicle Licensing Agency offices pursuant to Articles 75 and 78 of Legislative Decree No 285/1992.

Article 8

(Verification of the correct operation of the alcohol interlock device)

1. In the case of a roadside inspection, the *alcohol interlock device* shall have an intact installation seal and the driver shall be able to produce the original installation declaration according to Appendix 6 and the calibration certificate with the valid calibration interval according to Annex 5.
2. The driver must always check that the calibration certificate has a valid calibration interval according to the manufacturer's instructions in Annex 3.

Article 9

(Final provisions)

1. This decree comes into force on the day following its publication in the Official Gazette.
2. Article 6 '*Reporting obligations*' and the annexes to this Decree may be updated by decree of the

Director-General of the Directorate-General for Motor Vehicles.

This Regulation, bearing the State seal, shall be included in the official collection of legal acts of the Republic of Italy. All interested parties shall be bound to observe and ensure observance of this Decree.

The Minister

Annex 1

Instructions for installation/removal of the *alcohol interlock device*

The installation instructions must contain at least the following information:

- a) list of vehicles and vehicle models for which the device is intended or for which it is known that installation is not possible. This list can be specific or generic, for example 'all cars with petrol engines and 12V batteries with negative pole and ground connection' or 'vehicles for the transport of dangerous goods according to ADR regulations';
- b) installation method illustrated by very clear photographs and/or drawings;
- c) detailed installation instructions which, if correctly followed by a competent installer, do not compromise the safety and reliability of the vehicle and do not affect the electrical characteristics of the vehicle's on-board circuits (conductor cross-sections, contact safety, etc.);
- d) any restrictions on the positioning of any part of the installation in relation to the potential influences of dust, water and temperature;
- e) requirements in relation to possible safety issues, for example, in relation to:
 - airbags;
 - passenger safety;
 - setting the receiver within the reach of the driver;
 - secure mounting of the receiver;
 - software interactions with the vehicle;
 - mouthpiece hygiene;
 - other.
- f) identification of the electrical supply requirements of the *alcohol interlock device* and, where applicable, advice on the appropriate electrical or battery conditions for the installation or removal of the device on the vehicle;
- g) detailed instructions for the installation by the installer of a seal, i.e. a self-destructing adhesive in case of attempted tampering with the *alcohol interlock device*;
- h) post-installation procedures for the control of the alcohol interlock and the operation of the vehicle, including calibration ranges;
- i) instructions for the removal of the alcohol interlock and the restoration of the wiring of the vehicle under safe conditions;
- j) information on the correct disposal of the alcohol interlock at the end of its useful life.

Annex 2

Marking of the *alcohol interlock device*

The device shall be legibly and indelibly marked with the following elements:

- a) the name or trade mark of the manufacturer or of the authorised representative;
- b) type designation;
- c) serial number;
- d) software version;
- e) the identification of the software shall be possible at any time when the device is in operation;
- f) usable interface(s);
- g) version of the protocol used of standard EN 50436-4;
- h) date of validity of the verification;
- i) approval marking in accordance with Annex I to UN Regulation (UN/ECE) No 10 'Uniform provisions concerning the approval of vehicles with regard to electromagnetic compatibility';
- j) CE marking.

Annex 3

Instructions for use of the *alcohol interlock device*

The instructions for use of the *alcohol interlock device* must contain at least the following information:

- a) complete instructions for the correct and safe operation of the *alcohol interlock device*;
- b) mandatory provisions for the regular inspection and calibration of the *alcohol interlock device* and how to identify calibration ranges, including a list of accredited calibration laboratories;
- c) details on the correct functioning and operational limitations, including the following:
 - the actual limit of alcohol concentration in the exhaled air of the *alcohol interlock device* and its significance;
 - operating temperature range and heating time;
 - battery voltage;
 - influence of alcohol in the mouth;
 - influence of substances containing alcohol;
 - the influence of substances other than alcohol;
- d) list of recommended spare parts and accessories;
- e) recommendations for hygiene procedures (e.g. replacement of nozzles);
- f) statements on the nature and meaning of signals, alarms and messages;
- g) details of common sources of malfunction and any corrective procedures (e.g. troubleshooting procedures);
- h) General warning concerning the dangers arising from any modifications or additions to the *alcohol interlock device*;

- i) special instructions for the maintenance of vehicles that have installed an *alcohol interlock device*;
- j) Information on the correct disposal of the *alcohol interlock device* at the end of its service life.

Annex 4

Maintenance instructions for the *alcohol interlock device*

The instructions for maintenance of the *alcohol interlock device* shall contain at least the following information on:

- a) discharge of data from the alcohol interlock memory;
- b) service procedures and general functional tests;
- c) calibration procedures in compliance with the provisions of Annex 5;
- d) list of laboratories where to test the device;
- e) general inspection;
- f) maintenance procedures.

Annex 5

Calibration of the *alcohol interlock device*

An *alcohol interlock device* must be tested in accordance with standard EN 50436-1 by an independent laboratory that meets the following requirements:

- the laboratory is based in the EU (European Union) or the EFTA (European Free Trade Association);
- the laboratory is accredited according to standard EN ISO/IEC 17025 'General requirements for the competence of testing and calibration laboratories';
- the scope of accreditation of the laboratory includes instruments for measuring alcohol in exhaled air;
- the laboratory accreditation certificate is issued by a national accreditation body based in the EU (European Union) or EFTA (European Free Trade Association).

The laboratory shall issue a calibration certificate which shall contain at least the following elements:

- Device manufacturer.....
- Type.....
- Serial number.....
- Calibration interval (Calibration frequency)
- Calibration method.....
- Testing laboratory.....
- EN ISO/IEC 17025 accreditation issued by..... valid until.....

Place.....

Date..... and certificate number.....

Signature.....

Annex 6

Declaration of installation of the *alcohol interlock device*

The undersigned born in
on resident in via in the capacity
of of the company with headquarters in
VAT or tax code

Registered with the CC.II.A. of and identified as an authorized installer by the
manufacturer of the device.....

Aware of the criminal penalties provided for by Article 76 of Presidential Decree No 445/2000 in the event
of false declarations and falsity in documents, within the meaning and for the purposes of Article 47 of the
same Presidential Decree No 445/2000

DECLARES

that he has installed on the vehicle make and type..... bearing the registration plate..... in full
compliance with the *alcohol interlock device* manufacturer's requirements, the vehicle manufacturer's
requirements and the provisions issued by the Ministry of Infrastructure and Transport:

- a) manufacturer of the *alcohol interlock device*:
- b) type designation:
- c) serial number:
- d) interface used:
 - used interface already present on the vehicle: YES/NO (1);
 - interface fitted in accordance with the requirements of the vehicle manufacturer and the
manufacturer of the *alcohol interlock device*: YES/NO (1).

He/she also declares that the *alcohol interlock device* is approved as an electrical/electronic unit (UEE) in
accordance with UN (UNECE) regulation no. 10 with no..... and that he/she has provided,
at the same time, the calibration certificate no.....issued by with calibration valid
untiland that it has been sealed with a tamper-proof seal.

Place and date

signature (in full and legible)

(1) Delete the wording not of interest.