

Ministry of Health, Youth, Sport and Voluntary Organisations

**Order of on the homologation of devices for detecting
alcoholic impregnation by exhaled air (or breathalysers)
used by the police force and the gendarmerie and on the approval of laboratories
authorised to perform tests, examinations and inspections on such devices**

The Minister for Health, Youth and Sport,

Having regard to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services and, in particular, Notification No sent to the European Commission;

Having regard to the Highway Code, in particular Articles L. 234-9 and R. 234-2;

Having regard to the opinion of the permanent interministerial group for road safety dated
;

Hereby orders:

Article 1: The following may be approved with a view to their use by the police force and the gendarmerie in operations to detect alcoholic impregnation by exhaled air:

1. Breathalysers having been subjected to approval tests and examinations attesting to their conformity to the requirements established by the standards NF X20702 of July 2007 and NF X20703 of October 2000;
2. Breathalysers which comply with a model covered by a certificate of conformity to the standards, technical specifications and manufacturing and inspection processes guaranteeing a level of reliability equivalent to the standards NF X20702 or NF X20703 cited in 1., issued by an approved laboratory under the terms and conditions of Article 2 of this Order.

Article 2: The approval tests and examinations of breathalysers shall be performed by French bodies or bodies from another Member State of the European Community or from a State party to the Agreement on the European Economic Area or from Turkey duly accredited pursuant to the standard EN / ISO 17025 by the French Accreditation Committee (COFRAC) or by an accreditation body signatory to the multilateral agreement concluded within the framework of the European coordination of accreditation bodies for the inspection of the products cited in Article 1.

Article 3: Homologation shall be requested of the Minister responsible for health, for each type of detection device, by the party responsible for its manufacture, by registered mail with request for confirmation of receipt.

If the letter requesting homologation and, where applicable, the attached documents are not written in French, they shall be accompanied by a translation.

The homologation request dossier shall comprise, as the case may require:

1. For the devices to which it refers, the certificate of entitlement to affix the French Standards BREATHALYSER [NF-ETHYLOTEST] mark;
2. For other devices, the document, where applicable, drawn up by an approved laboratory certifying that the device satisfies the standards, technical specifications and manufacturing processes which guarantee an equivalent level of reliability accompanied by the technical dossier on the detection device.

The dossier shall include a detailed description of the device, the user instructions, the documents explaining the principles and conditions of operation, the duration of use and conservation, and the documents describing any care and maintenance operations necessary.

When the request concerns an electronic breathalyser, it shall be further accompanied by ten devices from the same batch of manufacture free of charge. Such ten devices shall be subjected to the accuracy tests set out in the standard NF X20703 of October 2000. Two of them shall further undergo the series of other tests set out by the standard. Such devices shall be returned to the party responsible for their manufacture upon completion of the tests.

When the request concerns a chemical breathalyser, the party responsible for its manufacture shall provide the products and consumables in quantities sufficient to perform 3,500 analyses.

Article 4: Homologation requests may be examined only if they are accompanied by a complete dossier.

The dossier is considered complete if, in the two-month period subsequent to its receipt, the Minister responsible for health has not made known to the requesting party, by registered mail with request for confirmation of receipt, the list of missing or incomplete items.

Article 5: The tests required for homologation shall be performed at the charge of the party responsible for manufacture. The approved laboratory shall submit a certificate to the party responsible for manufacture, which shall forward it to the Minister responsible for health.

Article 6: For each type of detection device, homologation is issued to the party responsible for manufacture by Order of the Minister responsible for health.

Homologation shall be granted by right when the device is covered by a certificate attesting to the entitlement to affix the French Standards BREATHALYSER mark.

When the user instructions initially provided by the manufacturing laboratory in its homologation request dossier do not meet the minimum requirements mentioned in the certification referential of the French Standards BREATHALYSER mark, the Minister responsible for health shall inform the party responsible for manufacture of any modifications which must be applied to it. The homologation decision shall be granted only after modification of the instructions by the party responsible for manufacture.

If the manufacturer is not a national of one of the Member States of the European Community or party to the Agreement on the European Economic Area or of Turkey, the homologation decision shall be granted to its representative in one of such Member States or parties or in Turkey.

Article 7: All approved products shall bear visible, indelible markings on their outer packaging attesting to their conformity. Such marking shall, in addition to the homologation number, include the following details:

- The model of the device;
- Its serial number;
- The expiry date (month / year);
- Identification of the manufacturer;
- The manufacturing code;
- The condensed user instructions.

The marking and the details included shall also appear on the device.

Article 8: The granting of homologation shall include, as far as the manufacturer and his representative are concerned, the obligation to accede, at their initiative, to annual inspections, at which time samples may be taken.

Such inspections shall be carried out by any approved laboratory under the terms and conditions of Article 2 of this Order.

The laboratory which performed the approval tests and examinations on a device shall of necessity also carry out their inspection.

Article 9: The approval tests and examinations and the inspections referred to in Article 8 shall be performed at the charge of the holder of the homologation, who shall make direct payment to the approved laboratory charged with such operations. The price applicable shall be set under the terms and conditions set out by the French Standards BREATHALYSER mark for the devices concerned which are entitled to affix such mark. For other devices, prices shall be established according to quotations drawn up by the laboratories approached to perform the tests, examinations or inspections.

Devices covered by the certificate of entitlement to affix the French Standards BREATHALYSER mark shall be inspected under the terms and conditions laid down by the mark.

Article 10: Any modification to the device other than a modification to its packaging and any modification to the conditions under which it is manufactured or distributed shall be signalled to the Minister responsible for health. The party responsible for manufacture shall send the

Minister a dossier detailing the technical elements relating to the modifications applied, by registered mail with request for confirmation of receipt.

If the letter and the attached dossier are not written in French, they shall be accompanied by a translation.

Article 11: Homologation may be suspended or withdrawn when the certificate of entitlement to affix the French Standards BREATHALYSER mark is suspended or rescinded, or when it has been established that the detection device does not meet the standards, technical specifications and manufacturing processes referred to in Article 1 of this Order, or that the standards, technical specifications and manufacturing processes which they meet no longer guarantee an equivalent level of reliability.

Likewise when the party responsible for manufacture or its representative does not accede to the inspections laid down in Article 8.

The approved laboratory shall signal the shortfalls observed to the Minister responsible for health under the terms and conditions of Article 2 of this Order.

Suspension or withdrawal of homologation may occur only when the Minister responsible for health has informed the party responsible for manufacture or its representative of the nature of the shortfalls observed and has served upon it official notice to stop them within a specific period of time.

Article 12: The Minister responsible for health may request up to twenty free samples of the approved devices to be submitted to him. Such samples may be used to establish the conformity of devices placed on the market to the approved model at a later date.

Article 13: The Order of 21 March 1983 on the homologation of devices for detecting alcoholic impregnation by exhaled air and the Orders of 6 August 1984 and 10 April 1995 amending it are hereby repealed.

Article 14: The Minister responsible for health is charged with the implementation of this Order, which shall be published in the *Official Journal* of the French Republic.

Done at Paris, on

The Minister of Ecology, Energy, Sustainable Development
and Town and Country Planning

The Minister of the Interior, Overseas
France and Territorial Communities

The Minister of Defence

The Minister for Health, Youth,
Sport and Voluntary Organisations

CONTEXTUAL INFORMATION

Article R. 234-2 of the Highway Code provides that operations to detect alcoholic impregnation by exhaled air, set out in particular in Article L. 234-3 of the same Code, shall be performed by means of a device in conformance with a type approved pursuant to the terms and conditions defined by Order of the Minister responsible for health, after the opinion of the Ministers responsible for transport, the interior and defence.

An Order of 21 March 1983, amended by Orders of 6 August 1984 and 10 April 1995, sets the current terms and conditions of homologation of such devices, referred to as breathalysers, which, for each new model, is translated into an Order of the Minister responsible for health, enacted after the opinion of the interministerial commission for the homologation of breathalysers.

Such commission comprises, pursuant to Article 6 of the aforementioned Order, representatives of the Ministries concerned (health, interior, justice, defence and transport). It gives its opinion based on reports on the tests performed in the laboratory by the national metrology and testing laboratory, and, at the side of the road, by the police force and the gendarmerie, pursuant to a range of specifications defined by the aforementioned Orders, detailing specifications on the design and performance of the devices.

When they set out their calls for tender, the police force and the gendarmerie may choose only devices approved by the aforementioned Order.

Since 1998, there has been a French Standards BREATHALYSER mark for breathalysers that may be used by the general public, the specifications of which are more demanding than those currently imposed for the homologation of breathalysers used by the police force and the gendarmerie.

Therefore, the general health directorate wishes to simplify the current homologation procedure to include technological developments in this field and to simplify the procedure, in particular by doing away with the compulsory examination of requests by the homologation commission. Such amendments imply the drafting of the attached Order.

The Order provides that the French Standards BREATHALYSER mark become the technical standard of reference for the quality control of such devices.

Eligible for homologation are chemical and electronic breathalysers which have been subjected to approval tests and examinations attesting to their conformity to the requirements set out in the standards NF 20702 of July 2007 and NF 20703 of October 2000. Devices which comply with a model covered by a certificate of conformity to the standards, technical specifications and manufacturing and inspection processes guaranteeing a level of reliability equivalent to the standards NF 20702 or 20 703 aforementioned are also eligible.

It is further provided that breathalysers certified pursuant to the French Standards BREATHALYSER mark shall be approved by right by the Minister responsible for health.

Finally, complementary approval tests and examinations shall be performed by French bodies or bodies from another Member State of the European Community or from a State party to the Agreement on the European Economic Area or from Turkey duly accredited

pursuant to the standard NF EN ISO 17025 by the French Accreditation Committee (COFRAC) or by an accreditation body signatory to the multilateral agreement concluded within the framework of the European coordination of accreditation bodies for the inspection of the devices in question.