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NOTE FOR THE ATTENTION OF MARKET SURVEILLANCE AUTHORITIES AND NOTIFYING AUTHORITIES

Subject: Voluntary certification for products subject of EU technical harmonisation legislation

Some market surveillance authorities have brought to the attention of the Commission and other authorities that a practice of 'voluntary certification' exists for some products, which are subject of EU technical harmonisation legislation (namely for PPE, Medical Devices, ATEX, RED and PED), especially during the COVID-19 crisis. However, later the application of this practice has been noticed for a number of other harmonised products, including very dangerous products (such as machines used in explosive environments, civil explosives or pyrotechnic articles) for which participation of a notified body in the conformity assessment is always necessary.

While the websites for such 'voluntary certification' usually indicate that this activity is not performed in the capacity of the certification body as notified body as such, and it is usually presented as something similar to a 'quality marking', the notified body number has been used in some cases on such documents (whereas the body is not notified for the products in question), these documents are called certificates, and very often the CE marking is present on these documents issued[1]. This is not compatible with the Union product legislation as detailed below, as such a practice leads to confusion and misunderstandings on the effective value of such documents, including also uncertainties about the effective safety and compliance of the concerned products.

It is also to be noted that the terms *certification*, *independent third party* and similar have a specific meaning as it comes to harmonised Union product legislation, essentially related to the work carried out by notified bodies in their capacity and according to the relevant conformity assessment procedure(s), and their use for other types of assessments of products falling under this legislation may be misleading. *Certificate* is a document issued by a body that takes responsibilities in areas of public interest. Therefore, if a Union product legislation does not provide for a third-party involvement in the

[1] The European Safety Federation (ESF), which groups national associations of manufacturers, importers and distributors of Personal Protective Equipment in Europe prepared a list of such certificates and published it on its website: https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe

conformity assessment but the economic operator opts for a voluntary involvement of a third party, the document issued by that third party could bear the name 'certificate' only if the body involved on a voluntary basis is a notified body for the specific area. A notified body may carry out activities in areas where it is not notified (for example, in non-harmonised areas or when products are intended for third countries); but it has to clearly mention that these activities are not in the scope of their notification under harmonised Union product legislation, as notified by the competent authorities and listed in the Commission's NANDO information system and these activities cannot be in an area of harmonised Union product legislation which requires assessment by a notified body. The notified body cannot use its notified body number in relation to assessments, tests, certificates or other activities for the legislation it is not notified for. The non-notified activities may not overlap with the notified ones, they must be clearly distinguished from the notified ones, they may not create confusion and they must be clearly mentioned as "non-notified"; otherwise the notifying authority must take appropriate action.

The notified body must have policies and procedures that distinguish between the tasks it carries out as a notified body and any other activity in which it is engaged, and it must make this distinction clear to its customers. Accordingly, marketing material must not give any impression that assessment or other activities carried out by the body are linked with tasks described in the applicable Union harmonisation legislation. Also to be emphasized that CE marking is only to be affixed after testing the product and performing the prescribed conformity assessment procedure or procedures according to the applicable Union harmonisation legislation. For some product legislation[2] and for medium-high risk products[3], involvement of a notified body is mandatory – the manufacturer cannot perform the assessment alone, nor use of a non-notified conformity assessment body is enough either to issue the EC/EU declaration of conformity or to affix the CE marking.

Article 30(2) of Regulation (EC) No 765/2008 states that *the CE marking <...> shall be affixed only to products to which its affixing is provided for by specific Community harmonisation legislation, and shall not be affixed to any other product*. Article R12(1) of Decision 2008/768/EC, which is integrated in most of the pieces of sectoral legislation[4], foresees a possibility to affix the CE marking to the packaging or the accompanying documents only if fixing it to the product or its data plate is not possible and if the product legislation provides for such documents. Therefore, it is not acceptable for such 'voluntary certificates' to bear a CE marking.

Article 30(5) of Regulation (EC) No 765/2008 states that *the affixing to a product of markings, signs or inscriptions, which are likely to mislead third parties regarding the meaning or form of the CE marking, shall be prohibited*. Clearly, this is the case for 'voluntary certificates' bearing CE marking. Such a 'certificate' leads to understanding that the product is in conformity with applicable Union legislation, however the 'voluntary certificate' is issued without any product checks and is not foreseen in any of the legislation. As stated on the concerned websites, it is usually issued following documentation checks only.

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2 Directive 2013/29/EU on pyrotechnic articles, Directive 2014/28/EU on civil explosives

3 Regulation (EU) 2016/425 on personal protective equipment, Regulation (EU) 2017/745 on medical devices, Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices Directive 2013/29/EU on pyrotechnic articles, Directive 2014/28/EU on civil explosives; under Directive 2014/53/EU on radio equipment, it is mandatory for certain requirements, if relevant harmonised standards do not exist or are not applied.

4 Article 20(41) of Directive 2013/29/EU, Article 23(1) of Directive 2014/28/EU, Article 19(1) of Directive 2014/53/EU (CE marking on the packaging is always mandatory)

Article 30(6) of Regulation (EC) No 765/2008 obliges Member States to *take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements.*

Article R34(1)(a) of Decision 2008/768/EC, which is integrated in most of the pieces of sectoral legislation, requires that where a Member State finds that the conformity marking has been affixed in violation of Article [R11] or of Article [R12], it shall require the relevant economic operator to put an end to the non-compliance concerned. Article R34(2) further requires that where such the non-compliance persists, *the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or ensure that it is recalled or withdrawn from the market*.

Taking into account the above:

(1) **Market surveillance authorities** are requested to take notice of the above and check their respective markets for products, which bear incorrect documentation and, subsequently, take appropriate action. Special attention is to be paid to conformity assessment of products. All products falling under harmonised Union product legislation for which conformity assessment procedures foreseen in the respective legislation have not been followed, shall be taken off the market and this shall be considered as a serious infringement by the economic operator.

(2) **Notifying/designating authorities** are requested to also take notice of the above and make sure that the bodies they have notified or designated are not performing any misleading activities using their notification, also that they use their notified body number properly and only for the sectors they are notified for. The activities outside the scope of technical harmonisation legislation of the notified bodies should not compromise or diminish confidence in their competence, objectivity, impartiality or operational integrity. Where the notification is misused, a withdrawal of notification shall be considered.

Commission reserves the right to also take any necessary action to challenge the competence of notified bodies involved in such practices, or to withdraw their notification by using the specific provisions laid down in EU harmonisation legislation[5].

(e-signed)

[redacted]

[redacted]

[5] For instance, Article 31 of Regulation (EU) 2016/425 on personal protective equipment, Article 47 of Regulation (EU) 2017/745 on medical devices, etc.