|  |  |
| --- | --- |
|  | **PRESS RELEASE** |

**CTIA response to current talks on respirators**

***(Prague, 14 March, 2021)* The Czech Trade Inspection Authority responds to various claims about respirators in the media, which can be confusing for consumers. The dramatic reports on the N95 and KN95 respirators, which are spreading in the context of a competitive struggle, are ultimately not only confusing for consumers, but also give the impression that these products are practically ineffective. A functional respirator with filtration of 94% or higher is useful for consumers and performs its purpose when properly deployed.**

**Media claim:** *"In the last two months, the government has even forgiven the sellers of illegal respirators KN95 and N95 for paying the added value tax. While Czech respirator manufacturers have to meet strict certification conditions to reach the protection classes FFP1 to FFP3, importers of illegal respirators KN95 and N95 only need to bring structurally simpler and thus cheaper products that do not meet the safety and efficiency requirements set by the standard EN 149," says Jana Vykoukalová, Chairman of the Board of Directors of the Association of Manufacturers and Suppliers of Medical Devices.*

Source: <https://www.seznamzpravy.cz/clanek/vyrobci-kritizuji-stat-ze-umoznuje-prodej-nelegalnich-respiratoru-z-ciny-146937>

**CTIA response:** Marking N95 or KN95 on a respirator does not mean anything reprehensible. On the contrary, the manufacturer declares in this way that it is a respirator that meets the criteria according to the American or Chinese technical standard on the classification of quality level N95 or KN95 respectively. The same product can be tested and classified according to multiple standards and can also bear multiple designations of the relevant classification (e.g. "FFP2/KN95").

It can be added that technical standards are not generally binding in Czech legislature, and even in the field of respirators, there is not a single technical standard (e.g. EN 149) "strictly ordered" in the legal regulations, which would be permissible to use to declare the quality level of the respirator.

Therefore, not the technical standard applied, which regulates in detail the criteria for the relevant quality classification (e.g. FFP2, N95, CN95), but only the compliance of the product with law is decisive for the legality of the placing of a personal protective device ('PPE') on the market. In the present case, this is a condition for compliance with the more generally defined elementary requirements in Annex II to Regulation 2016/425 on PPE, which is verified before the respirator is placed on the market by the conformity assessment procedure defined in the Regulation, with the participation of one of the European test rooms (so called notified body). The satisfactory result of the conformity assessment procedure with the essential requirements of Regulation 2016/425 is then expressed on the respirator by the CE conformity marking together with the identification number of the competent test room.

In practice, in the vast majority of cases, these test rooms, together with manufacturers, use European standards harmonised to the Regulation to comply with the essential requirements of Regulation 2016/425. This is also the case with EN 149 standard for respirators (i.e. filter semi-face masks), which may give a false impression of a binding nature of this technical standard. In reality, however, Regulation 2016/425 explicitly works with a legally equivalent variant of the conformity assessment with the essential requirements, within which a 'different technical specification' is used.

Typically, therefore, a respirator on the market bears the designation of classification according to the European technical standard (e.g. "FFP2") accompanied with a mark of conformity with Regulation 2016/425 ("CE"), or it is indicated on the product by several classifications according to the various standards used (e.g. "FFP2/KN95" or "FFP2/N95"), again supplemented by the CE conformity marking. – However, as explained above, even a variant, where a product with the CE marking of conformity is further marked on its surface only with the classification according to a „world“ standard other than a European one (e.g. only 'N95' or 'KN95'), cannot automatically be considered illegal on the EU market, since the application of European technical standards is not binding in this respect.

Another thing is that, of course, it can never be completely ruled out that the declaration of level FFP2, KN95 or N95 on a particular item, production batch or even product type does not for some reason correspond with reality (and in this respect, random inspections need to be carried out to an increased extent in order to ensure that similar cases are found at most). However, this is an issue of a completely different level, which does not justify the current attempts to claim a quality declaration according to the technical standard as "illegal" on our market within a competitive fight.

--

**Claim:** Importers of Chinese respirators, as well as other respirators, had three months last spring during which they were to obtain European certificates, point out both domestic companies and jakub Král, a lawyer from the consulting firm Porta Medica. *"I have personally seen several such exceptions, and none of them was declared to be valid until stocks are sold out, either by an applicant forthe exemption or by other articles of the distribution chain,"* says lawyer Jakub Král.

Source: <https://www.seznamzpravy.cz/clanek/vyrobci-kritizuji-stat-ze-umoznuje-prodej-nelegalnich-respiratoru-z-ciny-146937>

**CTIA response:** This claim, unlike the classic procedure described above for the placing on the market of personal protective equipment ('PPE'), relates to the exceptional authorisation scheme of last year, when the Czech Republic took advantage of the possibility of simplified marketing following Recommendation 2020/403 of the European Commission in the event of an acute shortage of PPE on the market. At that time, a sufficient protective function in accordance with the basic requirements of Regulation 2016/425 was evaluated in a procedurally different way by the surveillance authority (CTIA), which also used cooperation with the Czech test room (Occupational Safety Research Institute). Products authorised under this different legal regime for placing products on the market did not bear the CE marking – i.e. such respirators only bore the designation of one of the quality classifications according to the world standards used by the manufacturer.

In addition to our own claim, we state that the possibility of resale of legally marketed products is not governed by the fact whether or not this was expressly stated in the text of the authorisation. Products legally placed on the market — as is the case of respirators meeting the conditions of the authorisation in question (i.e. exemptions provided from the normal marketing regime) — may, by their very nature, remain there. (Provided, of course, that, for example, no specific risk associated with its use, etc. is subsequently found for the product type concerned.)

--

**Claim:** "If inspectors showed up at shopping centres, supermarkets, drugstores, newsagents or looked at online price comparators, they would find hundreds of offers of illegal KN95 and N95 respirators. Most of these products have never even had an exception. We have already recorded cases of classic counterfeits of properly certified products," says Jakub Král.

Source: <https://www.seznamzpravy.cz/clanek/vyrobci-kritizuji-stat-ze-umoznuje-prodej-nelegalnich-respiratoru-z-ciny-146937>

**CTIA response:** The Czech Trade Inspection Authority does not tolerate the sale of illegal respirators and currently pays special attention to the supervision of the supply of personal respiratory protective equipment to the market. About 300 inspections are currently being carried out to verify, for example, the correctness of the markings as well as the legitimacy of the placing of respirators on the market. At the same time, CTIA is actively cooperating with the Customs Administration of the Czech Republic in this area. As part of this cooperation, it has issued more than 50 binding opinions on letting respirators into free circulation since the beginning of the year. A negative opinion was issued in 39 cases on products with a total number of over 11 million items.

--

**Claim:** *"This is not a respirator, this is a kind of respiratory protection according to the KN95 standard, which is unacceptable in the European Union. In fact, from a legislative point of view, you cannot sell this in the Czech Republic, in the European Union, even to a carpenter. This thing (note: meaning KN95) will be at the same level as a tissue,"* says entrepreneur Aaron Günsberger.

Source: <https://www.info.cz/video/tema/ve-zdravi-3>

**CTIA response:** At a time when disinformation is spreading in the Czech Republic in the sense that KN95 is as effective as a tissue, and this information keeps spreading on social media networks, we would like to tell consumers that, on the contrary, it is the mass use of a well deployed functional respirator, with filtration of 94% or higher (FFP2, N95, KN95, etc.), is very important. It is a great pity that dramatic news about KN95 respirators is spreading in the media, which ultimately confuses consumers and gives the impression that these products are practically ineffective. A functional respirator with filtration of 94% or higher is useful for consumers and performs its function when properly deployed.

Regulation 2016/425 also explicitly uses a legally equivalent variant of the assessment of compliance with essential requirements, within which a 'different technical specification' is applied. According to the European Commission's materials, these can mainly be comparable world standards (technical standards) according to the assessment of the World Health Organization ("WHO"). According to the World Health Organisation, the classifications in question (e.g. KN95 or N95) are comparable to the classification of the FFP2 respirator according to a European technical standard in the context of population protection in the Covid-19 pandemic.