

CTIA banned MOLAXISI respirator which fails FFP2 requirements

(Prague, 9 February 2023) The Czech Trade Inspection Authority found that a respirator in the domestic market does not meet the requirements of the EU regulation on personal protective equipment and does not comply with the requirements for FFP2 type respirators. This respirator is sold as Filter half mask MOLAXISI.

The Czech Trade Inspection Authority found that a model of personal respiratory protective equipment is offered on the Czech market for consumers that does not meet the requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC. This is a respirator that was offered on the internet at the time of the inspection under the name Respirator FFP2 MOLAXISI 20 pcs. The filtering respirator is red and has white elastic bands, with an elastic clasp sewn into the nose section to allow a tight fit on the face. CE-02, FFP2 NR, CE 0370, EN 149:2001+A1:2009. The product was sold in packs of 20 in a carton box printed with the following information: MOLAXISI, PROTECTIVE MASK, MODEL: 1901TX, FFP2, CE0370, MADE IN CHINA, 20 PCS, the inscription on the side: "Read instructions for use", prod. 02/2021, exp. 02/2023, red colour. On the back of the box the instructions for use were in the form of pictograms and text in English only. Inside the box there were 20 items of products, which were individually wrapped in transparent plastic packaging without printing, and a leaflet with product information in English and Chinese. There is no EAN on the product or on the packaging. Instructions for use in the Czech language are missing in the box (they are supposed to be included with each smallest commercially available package), only one was included for all ordered packages in the box.

Laboratory tests were carried out in an accredited laboratory to verify the penetration of the filter material according to the requirements of Article 7.9.2 of EN 149:2001+A1:2009. The tests carried out showed that the product did not meet the requirements for penetration of the filter material (paraffin oil test). The product therefore does not comply with the requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment. Due to the fact that the filtering half mask has a higher penetration through the filtering material, it does not meet the requirements for FFP2 type respirators. Thus, it cannot effectively protect the wearer from solid particles or liquid aerosols. The product also does not meet the requirements for marking, instructions and consumer information. In addition, the EU declaration of conformity confirming that the product has followed the conformity assessment procedure in accordance with the requirements of the above mentioned Regulation has not been attached, nor has it been linked to a website where it can be found.

The Czech Trade Inspection Authority has imposed a protective measure on the distributor of the product, which is a ban on the supply of the MOLAXISI respirator on the market and on the use for own

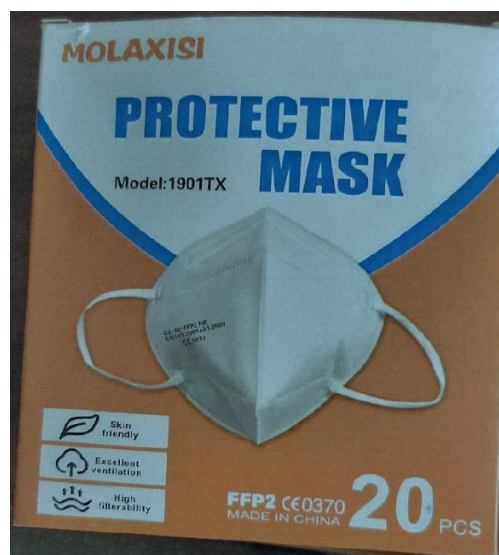
consumption and the withdrawal of the product from the market and circulation. Information on the product has been reported to the MIT contact point and has been published in the Safety Gate system.

Product information:

Product name:	Filtrační polomaska MOLAXISI
Trademark:	MOLAXISI
Model type / number:	1901TX
Production serie number:	02/2021
Identification data of importer:	not displayed
Identification data of manufacturer:	Molasses (JILIN) biotechnology Co., Ltd, 1/f, Workshop 1 No. 188 Yinfu Road, Jingyue Development Zone, Changchun, Jilin, China



Picture of the product



Picture of the product packaging

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Picture of the product leaflet