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CIVIS d.o.o., Tržaška cesta 65, 2000 Maribor (Work license number: 10200-41/2012/8 issued by the Ministry of Labour, Family, Social Affairs and Equal Opportunities of the Republic of Slovenia):

OPINION
about SHIELD washable hygiene mask

No. 446-20

Company:	**KOVANEC UNLIMITED D.O.O.** **SLOVENSKA CESTA 55 A** **1000 LJUBLJANA**
Place and date of issue of the opinion:	**Maribor, 20.4.2020**
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Civis RADVANJSKA 87 2000 MARIBOR 2 CENTER ZA IZOBRAŽEVANJE, VARNOST, INŽENIRING IN SVETOVANJE

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I. BASIS FOR OPINION

Opinion on the product SHIELD washing hygiene mask (Figure 1) is based on testing performed by the ALBA metrology laboratory on traceably calibrated measuring devices for Civis. Measurement equipment with verified traceability to international etalon standards was used to perform the measurements.

FIGURE 1: SHIELD washable hygiene mask

Testing was performed on 15 samples of personal hygiene masks or the materials of which they are made. The test medium in the permeability and absorption tests was plain water. Testing was performed at a temperature of 21–22 ± 1 °C and a relative humidity of 50 ± 10 %, and at a temperature of 21–23 °C and a relative humidity of 40–60 %.

II. USED METHODS OF MEASUREMENT

The following measuring equipment was used in ALBA's laboratory:

- Stopwatch, code AL 1.13, cert. no.: 19C00506
- Comparator scales, code AL 2.51, cert. no.: 1016-92-1/2019
- Control weight, code AL 2.13, cert. no.: 480-26-1/2019
- Temperature gauge, code AL1.11 T, cert. no.: 25-90-1/2019
- RH gauge, code AL1.11 RH, cert. no.: 25-90-2/2019
- Volumetric gauge 100.1000 µL, cert. no.: 933-26-1/2020

Comparative methods were used for testing.

III. FINDINGS

Based on the test results, ALBA has issued Report no. 554-4-1/2020 on comparative measurements of goods for the permeability and absorption of aqueous particles and Report No. 554-4-2/2020 on measurements of permeability and absorption of aqueous particles. Hygienic face masks are designed to reduce the risk of droplet transmission, meaning that one of the most important parameters is that they do not absorb droplets or humidity.
Testing shows that only two materials are water impermeable; the one that the SHIELD mask is made of (Report No 554-4-1-2020; Sample no. 11), and the one used for the disposable mask certified with EN 149 standard (Report No 554-4-1-2020; sample no. 1). All other masks are permeable to water with only 1 ml of water on the surface of the mask.
Water vapor permeability testing showed that SHIELD hygiene masks allow water vapor to pass from the outside to the inside (Report no. 554-4-2-2020; sample no. 2) within 8-10 min (0.07-0.08). mL / min), and from the inside to the outside (Report No 554-4-2-2020; sample no. 3) in 12-15 min (0.12 mL / min). Disposable protective mask, certified according to EN 149, permeated water vapor from the outside to the inside (report No 554-4-2-2020; sample no. 4) and from the inside to the outside (Report No 554-4-2 - 2020; sample no. 5) in 2.5-3 min (0.04-0.05 mL / min), or at least three times faster.

IV. KEY ITEMS OF LABORATORY TEST COMMENTS

Report no. 554-4-1/2020:

“Materials that are designed to absorb humidity by function, absorb applied water within a short time. Some of the tested materials are multi-layered by visual assessment and absorb the entire amount of applied water - but no water particles were detected on the opposite side of the sample in the case of a smaller amount of applied water.
Note: A person ventilates approximately 100 L of air at 20 °C in 10 minutes, and 50 % of RH contains about 0.9 g of humidity - which is approximately 0.9 mL of water.”

Report no. 554-4-2/2020:

“Testing was performed as a comparison of material properties: 100 % Cotton, Shield Hygiene Masks and Protective Masks certified under EN 149. The material of the outer layer, from which the Shield masks are made, is impermeable to water droplets. Liquid is absorbed from the inside of the mask into the mask, but the outside of the hygiene mask remains dry.
The waterproof mask with EN 149 mark is also impermeable to water droplets. Compared with the material of the Shield mask material, 100 % of cotton in 5 layers got wet in a few seconds and permeated the liquid. Hygienic masks (Shield) and protective masks (EN 149) permeated air (water vapor) in their basic function, which also contains a saturated portion of humidity. But they did not permeated water droplets directly.”

V. CONCLUSION AND OPINION

The SHIELD hygiene mask does not qualify as personal protective equipment in accordance with the requirements of the Rules on personal protective equipment used by employees at work (Official Gazette of the Republic of Slovenia No: 89/99, 39/05), and it is not a medical device in accordance with the requirements of the Medical Devices Act (Official Gazette of the Republic of Slovenia, No: 98/09. It also cannot replace personal protective equipment or medical devices in workplaces where their use is required by law, or in those assessed by risk assessment as sufficiently risky to make such equipment necessary or reasonable.

Nevertheless, we consider that the use of the SHIELD hygiene mask in workplaces that do not fall into the categories, referred to in the previous paragraph, makes sense as a measure to prevent the transmission of the disease.

Results of water and vapor permeability tests have shown that, in some characteristics, it is comparable or even exceeds the properties of a protective mask certified according to the requirements of the EN 149 standard, which is probably also related to the fact that the EN 149 protective mask is intended for single use, and the SHIELD hygienic mask is reusable when instructions for maintenance and washing are in place.

VI. ANNEXES

1. Report on Comparative Measurements of Goods for Water Permeability and Absorption No. 554-4-1/2020 from 17 April 2020
2. Report on Permeability and Absorption Measurements of Water Particles from 17 April 2020