

## **Comment of the participating test institutes on the handling of ongoing tests which are affected by the amendments of the testing principle**

The revision no. 2 of the testing principle for Corona SARS-CoV-2 pandemic respiratory masks has been published by the Central Body of the German Federal States for Safety Technology (ZLS) as of 2 June 2020. There is no transition period, the testing principle rev. 2 is valid at once. In order to cope with the new situation, the test institutes which carry out the respective tests have agreed on the following in consent with the ZLS:

1. Tests which were started before this publishing date will be carried out according to rev. 1 of the testing principle. If so, an additional assessment letter will be issued in relation to this testing principle.
2. For tests which were ordered before this date but have not been started, the institutes will address the clients in written form and ask in every single case if the test shall be carried out according to rev. 1 or according to rev. 2. If the client chooses rev. 2 he has to inform the testing institute if he wants
  - a) the testing with paraffin oil
  - b) the testing with sodium chloride (NaCl-test) steam or even
  - c) both tests, paraffin oil and NaClas written in the testing principle rev. 2.

Furthermore, the testing institutes involved point out that corona pandemic respiratory masks (CPA) which have been tested according to rev. 2 of the testing principle may only be marked as such. Masks which are marked with CE or FFP 2 or FFP 3 do not fulfill the requirements of this new testing principle. We ask the clients to take this into account when switching to rev. 2.

Of course, all orders which are placed after the publishing date will be carried out only according to the testing principle rev. 2 that is valid then.

This is due to a modification of the legal basis which we would like to explain:

The testing principle rev. 1 was intended for use as part of the authorities' actions against the effect of the Corona SARS-Cov-2 outbreak in the context of the "Commission Recommendation (EU) 2020/403 of 13 March 2020 on the conformity assessment and market surveillance procedures". However, an assessment letter of conformity with rev. 1 of the testing principle issued by one of the listed testing institutes was not sufficient to launch the masks on the German market. A launch on the market was allowed only, if your CPA was approved by the market surveillance authorities. The authorities did not decide with regard to the letter of conformity alone.

The testing principle revision 2 is intended for use in the context of marketability control acc. to § 9 Regulation for the security of supply with medical requirements (MedBVSV). Here, too, only the market surveillance authorities may approve the marketability of CPA. Each delivery unit needs this consent of the authorities.

Please address any questions on these amendments to the Central Body of the German Federal States for Safety Technology (ZLS).