Testing principle for Corona SARS-CoV-2 pandemic respiratory masks

Content

1 Preface

This testing principle has been commissioned by the German ZLS (Central Body of the Federal States for Safety Technology) and issued in collaboration of the following bodies:

Institute for Occupational Health and Safety (IFA) of the German Social Accident Insurance (DGUV)
DEKRA Testing and Certification GmbH
TÜV NORD CERT GmbH
Textile research institute TITV Greiz
ift Rosenheim GmbH (testing institute for fitness for use of construction products)
TÜV Rheinland LGA Products GmbH

1.1 General information and scope

This document specifies the minimum requirements and testing procedures to be applied to respiratory masks (CPA) for the corona SARS-CoV-2 virus pandemic. The CPA specified in this testing principle do not classify as personal protective equipment according to the PPE Regulation (EU) 2016/425 and thus cannot be marked as CE equipment. These CPA are not to be regarded as equivalent to respiratory protective devices which have passed an examination according to EN 149:2001+A1:2009 and are approved on the basis of PPE Regulation (EU) 2016/425.

This principle is only intended for use as part of controlling the marketability of the CPA according to Art. 9(2) of the German MedBVSV (regulation to ensure the supply of medical demand). According to Art. 24(1) of the German ProdSG (product safety act), the marketability of the CPA in the Federal Republic of Germany can only be decided by the market control authority in charge (authority approval). CPA whose marketability has been approved this way can be supplied on the German market solely for the purpose of infection protection. Every packing unit has to be provided with this authority approval by the responsible economic operator (cf. Art. 9(3) MedBVSV).

An assessment letter on the overall result of the tests according to this testing principle will be supplied to the Central Body of the German Federal States for Safety Technology (ZLS).

This assessment letter is intended to be submitted to the market surveillance authorities in order to gain approval according to Art. 9(3) MedBVSV throughout the period in which the Federal Government is taking decisions on the epidemic situation. If the overall test result is positive, the pertinent test report will also be made available to the ZLS.

2 Requirements and tests

For the test, the economic operator has to submit and make available at least three packing units so that the testing body can take the necessary number of samples. These samples have to be taken from at least three different packing units which previously have been submitted to a comparing visual inspection. If this visual inspection already identifies discrepancies, the test is assessed as ‘not passed’.

The tests can only be conducted on the condition that the economic operator supplies a health clearance certificate for the product to the testing body.

2.1 Overview of tests

Table 1 – overview of tests

Title	Number of samples	Conditioning	Test clause of EN 149	Comment
Temperature conditioning	5	--	8.3.2 only a)	24 h 70 °C, dry air
Simulation of wearing	5	--	8.3.1	1 x 20 min
Visual inspection	3	--	--	see section 2.2
Putting-on test	3	--	--	see section 2.3
Breathing resistance (valveless devices)	2	T.C. + S.W. (2)	8.9.2 8.9.3	see section 2.6
Exhalation valve flow rate	2	--	8.3.4	test during measurement of breathing resistance
Breathing resistance (valved devices)	2	T.C. + S.W. + F.C. (2)	8.9.2 8.9.3	see section 2.6
Flow rate through the filter medium	3	T.C. + S.W. (3)	8.11	see section 2.4.1 as per EN 13274-7:2008 sections 5.1, 5.2, 5.3 and 7.3 (paraffin oil)
	3	T.C. + S.W. (3)	8.11	see section 2.4.2 as per EN 13274-7:2008 sections 5.1, 5.2, 5.3 and 6.3 (NaCl)
Marking and manufacturer's information *	--	--	--	see section 2.7

* Definition of manufacturer and other economic operators (see art. 2 ProdSG)

2.2 Visual inspection

When supplied for purchase, the CPA must be packed in such a way that they are protected against mechanical damage and impurity prior to their use.

In order to qualify for a compliance with the requirements of health protection and safety for personal protective equipment, the materials used for the CPA and their processing have to be configured in such a way that they do not provide a hazard or disturbance for the user, see below:

- CPA shall not issue a strong own smell.
- After a mechanical stress of the inside of the CPA (ten brush strokes using a brush with natural hair of 40 mm width and 8 mm thickness) no particles or fibres shall come loose on two of the three masks tested.
- After a mechanical stress of the inside of the CPA (ten brush strokes using a brush with natural hair of 40 mm width and 8 mm thickness) and subsequent flow of 300 l/min through the mask (1 minute, inhalation side) no particles or fibres shall be carried away on two of the two masks tested.
- If statements such as ‘kills germs/bacteria’ or ‘kills viruses’ are printed on the packaging of the CPA, the testing body reserves the right to refuse any subsequent tests.

2.3 Putting-on test

Putting on and removing the CPA must be done easily. The head straps must be strong enough to keep the CPA in place. The CPA must ensure a close fit at the face of the test person. Likewise, the nose clip has to be tested for suitability and fastening (e.g. close fit even after putting on and removing the mask multiple times or permanent adhesion if nose clips are fitted on the outside).
When carrying the mask in a test, which has to be conducted with three persons, no obvious leakage along the sealing line of the mask shall be recognisable. When the test persons use the masks for breathing, no air flow shall be noticeable during the inhalation stage which is caused by leakage in the sealing line (poor facial fit). The number of test persons can be extended to a maximum of seven. The test is deemed as ‘passed’ if it is either passed by all (3 of 3) or by the majority of the test persons (3 of 5 or 4 of 7 persons).

2.4 Flow rate through the filter medium

Either one of the two or both procedures can be applied. At least one of the applied procedures must meet the requirements.

2.4.1 Paraffin oil

The flow rate through the filter of the CPA is tested using paraffin oil at 95 l/min. In total, three samples of the CPA have to be tested.

The three samples are to be conditioned as follows: temperature conditioning only at high temperature, and simulation of wearing with moist breathing for 20 minutes.

The test is carried out in accordance with section 8.11 of EN 149:2001+A1:2009, and the flow rate is tested according to sections 5.1, 5.2, 5.3 and 7.3 of EN 13274-7.

The flow rate through the CPA of all three samples must be ≤ 6.0 %.

2.4.2 Sodium chloride (NaCl)

The flow rate through the filter of the CPA is tested using NaCl at 95 l/min. In total, three samples of the CPA have to be tested.
The three samples will be conditioned as follows: temperature conditioning only at high temperature, and simulation of wearing with moist breathing for 20 minutes.

The test is carried out in accordance with section 8.11 of EN 149:2001+A1:2009, and the flow rate is tested according to sections 5.1, 5.2, 5.3 and 6.3 of EN 13274-7.

The flow rate through the CPA of all three samples must be ≤ 6.0 %.

2.5 Exhalation valve(s)

The CPA may have one or more exhalation valves; these must work properly in any situation. The test has to be carried out in accordance with section 8.9.1 of EN 149:2001+A1:2009.

If one or more exhalation valves are in place, then they must continue to work properly for a period of 30 s after a continuous exhalation flow of 300 l/min. The test is carried out during the measurement of the breathing resistance.

Once the casing of the exhalation valve has been fastened to the mask body, the exhalation valve or its casing is manually pulled with a felt force of 10 N. If the valve comes loose, the test is deemed as ‘not passed’.

2.6 Breathing resistance

The breathing resistance requirements apply to valved and valveless CPA.

2.6.1 Valveless CPA

2 CPA are tested after the temperature conditioning and the simulation of wearing with moist breathing for 20 minutes. The test is carried out following section 8.9 of EN 149:2001+A1:2009. The exhalation resistance is tested in the position ‘looking straight ahead’.

The breathing resistance for inhalation at 95 l/min must be ≤ 3.0 mbar at all samples.
The breathing resistance for exhalation at 160 l/min must be ≤ 3.0 mbar at all samples.

2.6.2 Valved CPA

2 masks are tested after the temperature conditioning, the simulation of wearing with moist breathing for 20 minutes and the flow rate conditioning. The test is carried out following section 8.9 of EN 149:2001+A1:2009. The exhalation resistance is tested in all five positions.

The breathing resistance for inhalation at 95 l/min must be ≤ 3.0 mbar at all samples.
The breathing resistance for exhalation at 160 l/min must be ≤ 3.0 mbar at all samples.

2.7 Marking and manufacturer’s information

The marking of the CPA or the smallest packing unit must contain the following information:

a) name, trademark and/or other details identifying the manufacturer
b) marking identifying the type (number, model or similar, if needed the batch)

Information in German must be supplied with each CPA or smallest packing unit. This information can be displayed either as text or as pictograms, for example. The information must also provide at least details on:

a) fit and correct putting on and removing of the mask
b) instruction on its use for infection protection only

Neither on the product itself nor on its packaging the following marking components shall be permitted:

a) CE marking
b) reference to EN 149
c) product names with or without classification or other addendums from pertinent European standards applying to PPE or law for medical products (e.g. FFP“X”, IIR etc.).

Neither the information on the masks shall display such marking components as properties of the CPA.

2.8 Requirements for the test report and the assessment letter

All test results are to be fully documented in the test report. For each section it needs to be stated whether this section has been ‘passed’ or ‘not passed’.

The marking and labelling of the CPA and the smallest packing unit must be documented so that it becomes unmistakeably clear which CPA was submitted to the test.

The comparing visual inspection must be supplemented by photographic documentation which clearly shows the fastening of the head straps, the labelling, the nose clip and the seam welding. The number of filter layers must be stated in the report.

The assessment letter shall contain a final statement on the compliance of the CPA with the requirements of this testing principle.
Photographs which will allow for a visual recognition of the product shall be included in the assessment letter.