

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

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1 Preface

This testing principle has been issued by DEKRA Testing and Certification GmbH and the Institute for Occupational Health and Safety (IFA) of the German Social Accident Insurance (DGUV).

Any publication in excerpts of this testing principle requires the written consent of both above-mentioned parties.

This English version is a translation from German. In the case of arbitration only the German wording shall be valid and binding.

1.1 General information and scope

This document specifies the minimum requirements and testing procedures to be applied to respiratory masks (CPA) intended for use related to the corona SARS-CoV-2 virus pandemic. The CPA tested according to this testing principle do not classify as personal protective equipment according to the PPE Regulation (EU) 2016/425. 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.

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This principle is only intended for use as part of the authorities' recommendations on actions to be taken in order to contain the effect of the Corona SARS-CoV-2 outbreak. It refers to the "Commission Recommendation (EU) 2020/403 of 13 March 2020 on the conformity assessment and market surveillance procedures within the context of the COVID-19 threat".

An assessment letter on the overall result, which will be issued once the test result is positive, will be supplied to the Central Body of the German Federal States for Safety Technology (ZLS).

2 Requirements and tests

2.1 Overview of tests

Table 1 – overview of tests

Title	Number of samples	Conditioning	Test clause of EN 149	Comment
Temperature conditioning	10	--	8.3.2 only a)	24 h 70 °C, dry air
Simulation of wearing	5	--	8.3.1	1 x 20 min
Visual inspection	1	T.C. + S.W. (1)	--	see section 2.2
Putting-on test	1	T.C. + S.W. (1)	8.4.1	see section 2.3
Breathing resistance (valveless devices)	2	T.C. + S.W. (2)	8.9.2 8.9.3	wearer looking straight ahead, at 95 l/min
Exhalation valve flow	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	at 95 l/min
Flow rate through the filter medium	3	T.C. + S.W. (3)	8.11	--

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 contamination prior to their use.

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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. When carrying the mask in a test, no obvious leakage along the sealing line of the mask shall be recognisable. When the test person uses the mask for breathing, no air flow shall be noticeable which is caused by leakage in the sealing line (poor facial fit).

2.4 Filter penetration

The penetration through the filter of the CPA is tested using either paraffin oil or sodium chloride (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 respiration for 20 minutes.

The test is carried out in accordance with section 8.11 of EN 149:2001+A1:2009 with the filter penetration according to EN 13274-7.

The penetration of the CPA of all three samples must be $\leq 6.0\%$.

2.5 Exhalation valve(s)

The CPA may have one or more exhalation valves; these must work properly in any position. 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, they must continue to work properly after a continuous exhalation flow of 300 l/min for 30 s. 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.

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2.6.1 Valveless CPA

2 CPA are tested after the temperature conditioning and the simulation of wearing with moist respiration 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 respiration for 20 minutes and the flow 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 be documented so that it becomes unmistakably clear which CPA is provided.

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)

Information 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