ZG 250-2

of 25 May 2021

OFI CERT Certification Basis (ZG)

Air hygiene test of FILTERS IN PASSENGER COMPARTMENTS OF VEHICLES with regard to reducing the risk of transmission of infectious agents

Erweiterte Anforderungen und Prüfungen zu bioziden Oberflächeneigenschaften für die Zuerkennung des Zeichens OFI CERT

Additional requirements for, and tests of, biocidal surface properties with regard to the right to use the OFI CERT label

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This Certification Basis will continually be adapted according to the requirements of the quality standard. Please do not hesitate to provide written input in this regard.

Note: The original of this text has been drawn up in German. The German version shall be the authentic one and prevail over the English one in all matters of interpretation and construction.
The English version shall be deemed to be only a translation for information purposes.

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1 CURRENT SITUATION – MOTIVATION, OBJECTIVES

Respiratory diseases are not only caused by particulate matter, pollutants or allergens – it is particularly viruses and bacteria that bring about a series of severe diseases of the upper and lower respiratory tracts. Epidemics and pandemics caused by influenza viruses and corona viruses have been recorded since 1918 on a worldwide scale. Notably the Spanish flu (1918), as well as the Asian flu (1957), SARS (2002) and MERS (2012), and currently COVID-19 (2019), have resulted in millions of deaths, with massive consequences for social and economic life worldwide.

However, severe diseases are not always caused by viruses: bacteria also play a relevant role: when viral infections damage the mucous membranes of the respiratory system, this facilitates the entry and reproduction of bacteria. Depending on the type of bacteria, a common cold caused by a virus can thus turn into sinusitis, bronchitis or even pneumonia. In the case of influenza, such an additional bacterial infection (secondary infection) will bring about a more severe development. *Streptococcus pneumoniae is* the most common bacterial cause of pneumonia.

Wherever groups of people are in the same room for longer periods, the risk of infections with influenza or cold viruses and bacteria rises. Whenever an infected person breathes, coughs or sneezes, thousands of infectious droplets – aerosols – are ejected. These aerosols are laden with viruses and bacteria, which are embedded in a watery coat of bronchial mucus, saliva and dissolved salts.

The use of effective air filters in ventilation systems and public/private means of transport can reduce the infection risk considerably.

This Certification Basis, including the tests and assessment criteria described herein, permits a reduction of the infection risk in public/private means of transport.

2 SCOPE OF APPLICATION

This Certification Basis ZG 250-2 applies to filters in ventilation systems that influence the quality of air recirculating in the passenger compartments of vehicles. It describes additional requirements for passenger compartment filters with biocidal surface properties as a specific mode of action (surface disinfecting properties). These passenger compartment filters are subject to additional requirements in order to ensure their effectiveness for reducing the transmission risk of infectious agents under any possible and realistic operating conditions of the filtration system. All requirements given in ZG 250-1 shall nevertheless continue to be binding as basic requirements.

In the context of this Certification Basis, the term ‘vehicle’ shall refer to:

- motor vehicles: passenger cars, lorries and buses
- rail vehicles: underground trains, commuter trains, long-distance trains and locomotives.

3 TESTS

The tests are based on codes of practice such as OECD guidelines, EN, ISO and DIN standards, as well as VDI standards. In addition, OFI’s biologically validated test procedures (SOPs) that are relevant for the case in question are applied.

Tests of passenger compartment filters with biocidal surface properties

In addition to the basic requirements laid down in ZG 250-1 regarding the retention capacity for viruses and bacteria, the suppression of a possible microbial re-

aerosolisation due to functional layers with biocidal surface properties is another significant, provable mode of action to reduce the transmission risk of infectious agents.

Re-aerosolisation (also referred to as virus shedding) means that viruses and bacteria previously captured on surfaces are released, as microbial aerosols, into the ambient air or air flows.

In order to suppress a possible release of already captured viruses and bacteria into the purified air flow under any possible and realistic conditions of operation of the filter system (use of the vehicle in high humidity or if intensive cooling is required, as well as under extreme conditions in which relevant amounts of water enter the air conditioning unit in extreme weather and/or due to insufficient draining of water, or operation of the air conditioning unit in a war wash etc.), it is necessary at first to provide evidence of the bactericidal and virucidal surface properties of the functional layer of the passenger compartment filter, as a provable mode of action.

The following sections thus describe both tests of biocidal surface properties as such, as well as tests regarding the suppression of possible viral re-aerosolisation due to functional layers of passenger compartment filters and the resulting additional requirements for quality assurance.

3.1 Tests of biocidal surface properties

The functional layer to be tested is examined – both in new condition and after ageing – with regard to its bactericidal/virucidal effects as the mode of action of a biocidal suppression of re-aerosolisation (viruses from the surface entering the air flow).

3.1.1 Proof of mode of action: bactericidal/virucidal effect

In order to reduce the re-aerosolisation of bacteria and viruses to a minimum under all operating conditions of the filtration system, proof of the bactericidal and virucidal effects of the filtering system needs to be provided.

The corresponding requirements for the functional layer to be tested are given in Table 1.

Ageing of the functional layer is achieved by the following steps:

1. Store at 80 °C for 24 h.
2. Allow to cool to room temperature.
3. Store at 55 °C with 95 % relative humidity for 48 h.
4. Allow to cool to room temperature.
5. Store at -20 °C for 24 h.
6. Allow to warm to room temperature before testing.

Table 1: Requirements for bactericidal/virucidal effect (proof of mode of action)

Test item	Minimum requirements	Proof
Bactericidal effect		
Functional layer (new/ after ageing)	Bacteriostatic/bactericidal activity value: S ≥ 3.0 L ≥ 1.0	On the basis of JIS L 1902 / ISO 20743 (stricter requirements)
Virucidal effect		
Functional layer (new/ after ageing)	Antiviral value: 3.0 > M_V ≥ 2.0: good effect M_V ≥ 3.0: excellent effect	On the basis of ISO 18184 with viruses (bacteriophages)

3.1.2 Suppression of re-aerosolisation

Regarding additional requirements for passenger compartment filters with biocidal surface properties, special attention is paid to the suppression of a possible viral re-aerosolisation resulting from functional layers with biocidal surface properties compared to the corresponding performance data of a control fabric without biocidal properties.

For this purpose, both fabric samples are at first exposed to a suspension that has been defined in particular with regard to its viral concentration, and moistened during the contact period. Then a virus-free unpurified gas flow is led through the two fabric samples, with regard to the entry of viruses from the fabric samples into the purified gas flow, while the fabric samples continue to be moistened during the period in which gas passes through them.

The suppression of re-aerosolisation resulting from the functional layer is assessed by determining the viral load (infectious titres) in the purified air flow with regard to the viral load (infectious titre) in the purified air flow of a standardised control fabric without biocidal properties:

$$M_R = \log_{10}(V_C/V_F) = \log_{10}(V_C) - \log_{10}(V_F)$$

M_R: Suppression of re-aerosolisation

V_F: Purified gas infectious titre for the functional layer (in pfu*)

V_C: Purified gas infectious titre for the control fabric without biocidal properties (in pfu*)

*pfu… plaque-forming units

The requirements for the functional layers to be tested are given in Table 2.

Table 2: Requirements for suppression of re-aerosolisation in accordance with ZG 250-2

Test item	Minimum requirements	Proof
Suppression of re-aerosolisation (additional requirements ZG 250-2)		
Functional layer (new/ after ageing)	Suppression of re-aerosolisation: $M_R \geq 2$	OFI SOP 350.013 re-aerosolisation additional requirements ZG 250-2

3.1.3 Performance classes

The categories listed in Table 1 can be used for assessing passenger compartment filters with biocidal surface properties; for tests see Table 1.

Table 3: Performance classes of passenger compartment filters with biocidal surface properties

Test item	Established property	Performance class
Virucidal effect		
Functional layer (new/ after ageing)	Suppression of re-aerosolisation:	
	$3.0 > M_R \geq 2.0$: good effect	Good effect
	$M_R \geq 3.0$: excellent effect	Excellent effect

4 LABELLING

The certificate holder shall be responsible for labelling. The manufacturer shall, as a minimum, provide the following information on the product, or at least in the product documentation:

- certificate number (e.g. 0123)
- label of certification body: OFI CERT (referred to as ‘Konformitätszeichen’ / conformity mark in the application for certification)
- number of Certification Basis: ZG 250-2
- optional: OFI logo.

5 QUALITY ASSURANCE

Quality assurance consists of initial testing and quality monitoring, consisting of internal inspection and third-party inspection.

5.1 Scope of initial testing

The scope of initial testing is given in Table 4.

Table 4: Scope of initial testing

Type of test	Test/requirement
Proof of mode of action: Bactericidal/virucidal effect, suppression of re-aerosolisation	Sections 3.1.1 and 3.1.2 / tests of functional layer (new/after ageing)

5.2 Scope of internal inspection

In order to ensure a consistent high quality, components or filter elements shall be tested annually by the manufacturer, in accordance with the scope of testing given below. The test records and test specimens shall be kept for 5 years.

Table 5: Scope of internal inspection

Type of test	Test/requirement
For the scope of the internal inspection see requirements in ZG 250-1.	

5.3 Scope of third-party inspection

In order to ensure third-party inspection, a certification contract shall be concluded with OFI CERT. In order to ensure a consistent high quality, each certified functional layer shall be tested every two years, with the following test scope:

Table 6: Scope of third-party inspection

Type of test	Test/requirement
Suppression of re-aerosolisation	Section 3.1.2 / test of functional layer (new)
Verification of internal inspection check of test reports by OFI CERT	Inspection of test records by OFI CERT

The results will be summarised in a third-party inspection report and made available to the certification body.

6 MODIFICATIONS

This Certification Basis will continually be adapted in accordance with the state of the art. Please do not hesitate to send any requests for modifications, or comments, to the OFI CERT certification body (office@ofi.at), where they will be collected and discussed by the bodies in charge.

OFI CERT shall be notified of any changes relating to the certified product (e.g. changes in raw materials, components etc.). OFI CERT will, in cooperation with the testing body, decide whether a new initial test will be required.

7 DOCUMENTS CITED

The relevant tests are carried out in accordance with (or on the basis of) the following air quality guidelines (German versions whenever available):

DIN 71460-1	Road vehicles – Air filters for motor passenger compartments – Part 1: Test for particulate filtration
DIN EN 481	Size fraction definitions for measurement of airborne particles
EN ISO 18184	Textiles – Determination of antiviral activity of textile products
ISO 20743	Textiles – Determination of antibacterial activity of textile products
JIS L 1902	Testing Antibacterial Activity and Efficacy on Textile Products
SOP 350.013	Re-Aerosolisierung gemäß ZG 250-1 (re-aerosolisation in accordance with ZG 250-1)
USP 87	Biological reactivity tests, in vitro
VDI 3867	Particulate matter measurement – Methods of characterizing and monitoring test aerosols
VDI 3491	Particulate matter measurement – Generation of test aerosols
VDI 6032-1	Ventilation and indoor-air quality in vehicles – Hygiene requirements for ventilation and air-conditioning systems