



**Fraunhofer**

**TESTED<sup>®</sup>  
DEVICE**

OCTANORM-Vertriebs-GmbH  
OCV-SM60

**Report No. OC 1706-924**

DUPLICATE

Statement of  
Qualification

Hygienic Design

# Statement of Qualification

## Customer

OCTANORM-Vertriebs-GmbH  
Raiffeisenstrasse 39  
70794 Filderstadt  
Germany

## Component tested

Category: Cleanroom Facilities  
Subcategory: Wall, Ceiling, Floor  
Product name: Metal facing wall system 60mm OCV-SM60  
(Consisting of the wall element TDA SM60 PE, wall element TDA SI60 PE, ceiling element DDA SM60 PE, ceiling element DDA SI60 PE, door element TDAZDT and silicon sealant)

## Assessment of conformity to GMP regulations as well as to EHEDG conception and design recommendations

Standards/Guidelines: EU GMP Annex 1; EHEDG Doc. 8; DIN EN 1672-2; ISO 14159  
The norms stated generally refer to the version valid at the time of the tests.

Assessment criteria:

- Materials utilized
- Material pairings
- Installed components
- Geometries of components used
- Joining methods
- Detailed constructional solutions
- Manufacturing processes
- Surface coatings/coating systems

The suitability of the operating utility for use in a GMP-conform manufacturing environment is ascertained on the basis of the assessment of these criteria with the aid of expert knowledge. The assessment focuses mainly on the avoidance of contamination as well as on the ability to clean and disinfect the operating utility.

## Test result / Classification

The metal facing wall system 60mm OCV-SM60 is principally suitable for use in hygienic areas up to the following GMP Class according to EU GMP Annex 1:

Suitability
up to GMP Class B

However, this recommendation only pertains to the operating utility when in a resting state. An overall assessment of the metal facing wall system 60mm OCV-SM60 can only be made after its installation in the production line.

The measuring devices used for the qualification tests are calibrated at regular intervals; their results can be traced back to national and international standards. In cases where no national standards exist, the test procedure implemented complies with the technical regulations and norms applicable at the time of the test. The relevant documentation can be viewed on request at any time.

For further information about the test environment and parameters, please refer to the Fraunhofer IPA test report.

Fraunhofer Institute for Manufacturing Engineering and Automation IPA

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on behalf of   
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