



Fraunhofer

TESTED[®] DEVICE

OCTANORM-Vertriebs-GmbH

TPH 2 und DPH 1

Report No. OC 1312-679

DUPLICATE

Statement of
Qualification

GMP

Statement of Qualification

Customer: OCTANORM-Vertriebs-GmbH für Bauelemente
Raiffeisenstraße 39
70794 Filderstadt
Germany

Test results / classification:
(according to EU GMP Annex 1)

Both the wall as well as the ceiling system are principally recommended for use in hygienic environments up to max. GMP Cleanliness Class A. However, this only applies for the tested operating utility when in a resting state and an overall reassessment would need to be made after installation in a manufacturing environment.

Component tested:

Category: Cleanroom Facilities
Subcategory: Wall/Ceiling/Floor
Type: Wall system TPH 2 and ceiling system DPH 1

Assessment of conformity with GMP regulations and EHEDG conception and design recommendations

Standards/guidelines: EU GMP Annex 1; EHEDG Doc. 8; DIN EN 1672-2; ISO 14159
Each standard stated refers to the version valid at the time of testing.

Assessment criteria:

- Materials used
- Material pairings
- Installed components
- Geometries of materials implemented
- Joining techniques
- Constructional details
- Manufacturing processes
- Surface coatings/coating systems

By assessing these criteria, the expertises are able to determine the suitability of the operating utility for use in GMP-conform manufacturing environments, focusing especially on contamination avoidance and on the ability to clean and disinfect the operating utility.

The measuring equipment used for the qualification is regularly calibrated and is based on national and international standards. In the case where no national standards exist, the measuring procedure used corresponds with technical regulations and norms valid at the time of the measurement. The documents drawn up for this procedure are available for viewing.

Please find detailed information about test environment and parameters in the report of Fraunhofer IPA.

Fraunhofer Institute for Manufacturing
Engineering and Automation IPA

Department Ultraclean Technology
and Micromanufacturing

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70569 Stuttgart
Germany

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i. A. Frank Bürger, Project manager Fraunhofer IPA

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