



Fraunhofer

**TESTED[®]
DEVICE**

Brecon Group
Brecon Cassette Panel System
Report No. BR 1804-1024

DUPLICATE

Statement of
Qualification

Hygienic Design

Statement of Qualification

Customer

Brecon Cleanroom Systems B.V.
Droogdokkeneiland 7
5026 SP Tilburg
The Netherlands

Component tested

Category: Cleanroom Facilities

Subcategory: Wall / Ceiling / Floor / Door

Product name: Brecon Cassette Panel System (manufacturing date: 4/2018; color panels: RAL 9010); composed of the following objects:

- BM-W-SHC-101/Wall Panel Steel Standard Coated HC
- BM-W-SRW-102/Wall Panel Steel Standard Coated RW
- BM-W-HRW-101/Wall Panel HPL Standard RW
- BM-W-H-air-101/Wall Panel HPL Airduct 500 m³
- BM-D-131/Steel Door with Window and Dropseal
- BM-D-117 + BM-D-118/Built-in Doorcloser
- BM-K-101/Aluminum doorframe
- BM-G-101/Window Standard 120x100x70 Safety glass
- BM-P-104/Ceiling Panel Steel Standard Coated RW
- BM-W-SH-108/PRO 3 Sealant
- BM-W-SH-106/Aluminum Corner Profile
- BM-W-SH-102/Aluminum Floor Profile
- BM-W-SH-109/Round Corner Profile 65 mm (massiv)
- BM-D-139/Inter Lock Control Panel

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 Brecon Cassette Panel System 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 A

However, this recommendation only pertains to the operating utility when in a resting state. An overall assessment of the Brecon Cassette Panel System can only be made after its installation.

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.

Detailed information and parameters of the test environment can be found in the Fraunhofer IPA test report.

Fraunhofer Institute for Manufacturing
Engineering and Automation IPA

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Department of Ultraclean Technology
and Micromanufacturing

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Report No. current document

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Place, current date

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on behalf of 
Dr.-Ing. Frank Bürger, Project Manager Fraunhofer IPA