



**Fraunhofer**

**TESTED<sup>®</sup>  
DEVICE**

Wiedemann GmbH  
Drainage Channel System  
**Report No. WI 1708-939**

DUPLICATE

Statement of  
Qualification

Hygienic Design

# Statement of Qualification

## Customer

Wiedemann GmbH  
Siemensstrasse 16-18  
25813 Husum  
Germany

## Component tested

Category: Cleanroom Facilities

Subcategory: Wall, Ceiling, Floor

Product name: Drainage Channel System  
(manufacturing date: 7/2017)  
Consist of:

- Channel end cap (OKBF, AF/HFLALO, HF), profile (OKBF, AF/HFLALO, HF)
- Channel basin profile (OKBF, AF/HFLALO, HF)
- RBE HYG-100-S (BG1004585), RBE HYG-100-W (BG1004584)
- Cap Outlet HV80/140 (BT106340), HV60/120 (BT106368), HV100/160 (BT106369)
- Housing H-HYG-100-S (BG1000022, BG1000278, BG1000003, BG1000004, BG1001205)
- Hygienic silt box (BG1004654)
- Air trap GV-HYG-Combination (BG1004531)
- Air trap GV-HYG-Combination (BG1004500)
- Bar grate basin welded (BG1004645)
- Cover basin seamless (BT106554)
- Bar grate Channel welded (various width and length)
- Cover Channel seamless (various width and length)

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

Standards/Guidelines: EU GMP Annex 1; EHEDG Doc. 8, 44; 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 Drainage Channel 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 C

This only applies for the test piece Drainage Channel System, an overall assessment would need to be made after its installation in a manufacturing environment.

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  
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on behalf of

  
Dr.-Ing. Frank Bürger, Project Manager Fraunhofer IPA

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