



Fraunhofer

**TESTED[®]
DEVICE**

Wiedemann GmbH
BE HYG-100 one-part W
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: Floor Drain System BE HYG-100 one-part horizontal (manufacturing date: 6/2017)
Consist of:

- Housing HYG-100-RD-W round inlet (BG1004502)
- Housing HYG-100-E-W square inlet (BG1004503)
- Hygienic silt box (BG1004654)
- Air trap GV-HYG-Combination (BG1004500)
- Bar grate cover SR-DRS-100-RD round (BG1000139)
- Bar grate cover SR-DRS-100-E square (BG1000847)

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 Floor Drain System BE HYG-100 one-part horizontal 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 Floor Drain System BE HYG-100 one-part horizontal, 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 Engineering and Automation IPA

Department of Ultraclean Technology and Micromanufacturing

Nobelstrasse 12
70569 Stuttgart
Germany

WI 1708-939

Report No. first document

Stuttgart, October 23, 2017

Place, date of first document issued

--

Report No. current document

--

Place, current date

on behalf of

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