



Fraunhofer

TESTED<sup>®</sup>  
DEVICE

Wiedemann GmbH  
BE H-HYG-100 two-part S  
**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 two-part adjustable height vertical (manufacturing date: 6/2017) Consist of: <ul style="list-style-type: none"><li>• Cap piece H-HYG-100-RD HV60/80 round inlet (BG1004534)</li><li>• Cap piece H-HYG-100-RD HV80/140 round inlet (BG1004535)</li><li>• Cap piece H-HYG-100-E HV60/80 square inlet (BG1004532)</li><li>• Cap piece H-HYG-100-E HV80/140 square inlet (BG1004533)</li><li>• Housing H-HYG-100-S (BG1000022, BG1000278, BG1000003, BG1000004, BG1001205)</li><li>• Hygienic silt box (BG1004654)</li><li>• Air trap GV-HYG-Combination (BG1004531)</li><li>• Bar grate cover SR-DRS-100-RD round (BG1000139)</li><li>• Bar grate cover SR-DRS-100-E square (BG1000847)</li></ul>
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:	<ul style="list-style-type: none"><li>• Materials utilized</li><li>• Material pairings</li><li>• Installed components</li><li>• Geometries of components used</li><li>• Joining methods</li><li>• Detailed constructional solutions</li><li>• Manufacturing processes</li><li>• Surface coatings/coating systems</li></ul> <p>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.</p>

Test result / Classification	<p>The Floor Drain System BE HYG-100 two-part adjustable height vertical is principally suitable for use in hygienic areas up to the following GMP Class according to EU GMP Annex 1:</p> <table><tr><td>Suitability</td></tr><tr><td>up to GMP Class C</td></tr></table>	Suitability	up to GMP Class C
Suitability			
up to GMP Class C			
	<p>This only applies for the test piece Floor Drain System BE HYG-100 two-part adjustable height vertical, an overall assessment would need to be made after its installation in a manufacturing environment.</p>		

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.